

DESIGN AND DEVELOPMENT OF PATIENT SPECIFIC 3D HEART MODEL FOR PREOPERATIVE SURGICAL PLANNING

Submitted in partial fulfillment of the requirements for the award of
Bachelor of Technology degree in
Biomedical Engineering

By

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**DEPARTMENT OF BIOMEDICAL ENGINEERING SCHOOL OF BIO
AND CHEMICAL ENGINEERING**

SATHYABAMA

**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)**

Accredited with Grade "A" by NAAC

JEPPIAAR NAGAR, RAJIV GANDHI SALAI, CHENNAI - 600 119

MAY 2022



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DEPARTMENT OF BIOMEDICAL ENGINEERING

BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of **E.KAVITHA(Reg. No.38240013)**, **K.KANIMOZHI(Reg. No.38240012)** who carried out the project titled **"DESIGN AND DEVELOPMENT OF PATIENT SPECIFIC 3D HEART MODEL FOR PREOPERATIVE SURGICAL PLANNING"** under our supervision from **September 2021 to March 2022**.

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DECLARATION

We **E.KAVITHA**(Reg. No. 38240013), **K.KANIMOZHI** (Reg. No. 38240012) hereby declare that the Project Report entitled “**DESIGN AND DEVELOPMENT OF PATIENT SPECIFIC 3D HEART MODEL FOR PREOPERATIVE SURGICAL PLANNING**” done under the guidance of **Dr.J.PremKumar, Department of Biomedical Engineering** is submitted in partial fulfillment of the requirements for the award of **Bachelor of Technology** degree in **Biomedical Engineering**.

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ABSTRACT:

As the process of additive manufacturing, or three dimensional (3D) printing, has become more practical and affordable, a number of applications for the technology in the field of pre-operative surgical models have been considered. Pre-operative planning for heart is challenging in open heart surgery with severe heart disease, including those with coronary heart disease or severe defects and in the presence of heart attack or blood vessel damage. We evaluated whether a rapid prototype model, which is a life-sized reproduction based on 3-dimensional CT SCANS can determine the feasibility of treatment and provide information about the size and position of the artificial heart component in severe blood vessel deformities. Our hypothesis was the creation and pre-operative dissection of such a model was possible and would demonstrate potential benefits in case of abnormal condition of heart anatomy.

KEY WORDS: 3d printing, life-sized reproduction, feasibility of treatment

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LIST OF ABBREVIATIONS

CHD	Congenital Heart Disease
DICOM	Digital and Imaging Communication in Medicine
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
TTE	Trans Thoracic Echocardiography
STL	Standard Tessellation Language
FDM	Fused Deposition Modeling
MAPCA	Major Aorto-Pulmonary Collateral Artery
ICU	Intensive Care Unit.
CAB	Coronary artery bypass
CABG	Coronary artery bypass graft
TMLR	Transmyocardial Laser Revascularization (TMLR)
ICD	Implantable cardioverter defibrillators
STEM	Scanning transmission of electronic microscope
CHD	Congenital heart diseases
AHA/ACC	American heart association/American college of cardiology
DELIPRECAS	Delirium Prevention Cardiac Surgery
CAM-ICU	Confusion Assessment Method in Intensive Care Units
PLA	Poly Lactic Acid
AM	Additive manufacturing
STL	Standard Tessellation Language

FFF	Fused filament fabrication
NURBS	Non-uniform Rational B-Splines
VSD	Ventricular spiral defect
GA	Great arteries
IVC	Inferior vena cava
SVC	Superior vena cava
PV	Pulmonary valve
RVLA	Right ventricle long axis
RV	Right ventricle
TOF	Tetralogy of fallot
ROLSA	Retro-oesophagian left sbuclaviar artery
TAPVR	Total anomalous pulmonary veins return
DTGA	D- Transposition of great arteries
PAVSD	Pulmonary atresia with ventricular septal defect
ROSCA	Retro-oesophagiansbuclaviar artery
TGA	Transposition of great arteries
HTX	Heart transplantation
PB	Pulmonary branch
CPB	Cardio pulmonary bypass
DORV	Double outlet right ventricle
UVH	Univentricular heart
LVOTO/CCTGA	Left ventricular outflow tract obstruction/congenitally corrected transposition of great arteries

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CHAPTER-1

INTRODUCTION

Today, there are about 500,000 open heart surgeries performed each year. It is most often used for complicated procedures, such as coronary artery bypass, or complex procedures to the aorta or the heart itself. These procedures usually involve a hospital stay of a week or more and a lengthy recovery time. By restoring blood flow to the heart, CABG can relieve symptoms and potentially prevent a heart attack. Coronary bypass operations are performed half a million times a year with an overall success rate of almost 98 percent. The heart-lung machine is also called a cardiopulmonary bypass machine. It takes over for the heart by replacing the heart's pumping action and by adding oxygen to the blood. This means that the heart will be still for the operation, which is necessary when the heart has to be opened (open heart surgery). When you are connected to the heart-lung machine, it does the same job that your heart and lungs would do. The heart-lung machine carries blood from the upper-right chamber of the heart (the right atrium) to a special reservoir called an oxygenator. Inside the oxygenator, oxygen bubbles up through the blood and enters the red blood cells. This causes the blood to turn from dark (oxygen-poor) to bright red (oxygen-rich). Then, a filter removes the air bubbles from the oxygen-rich blood, and the blood travels through a plastic tube to the body's main blood conduit (the aorta). From the aorta, the blood moves throughout the rest of the body. The heart-lung machine can take over the work of the heart and lungs for hours. Trained technicians called perfusion technologists (blood flow specialists, also called the "pump team") operate the heart-lung machine. Cooling techniques let surgeons stop the heart for long periods without damaging the heart tissue. Cool temperatures avoid damage to the heart tissue by reducing the heart's need for oxygen.

The heart may be cooled in 2 ways:

- Blood is cooled as it passes through the heart-lung machine. In turn, this cooled blood lowers body temperature when it reaches all of the body parts.
- Cold salt-water (saline) is poured over the heart.

After cooling, the heart slows and stops. Injecting a special potassium solution into the heart can speed up this process and stop the heart completely. The heart is then safe from tissue injury for 2 to 4 hours.

During heart surgery, a highly trained group works as a team.

- The cardiovascular surgeon heads up the surgery team and performs the key parts of the surgery.
- The assisting surgeons follow the direction of the cardiovascular surgeon.
- The cardiovascular anesthesiologist gives you the medicines that make you sleep during the surgery (called anesthesia) and monitors the ventilator, which breathes for you during surgery.
- The perfusion technologists run the heart-lung machine.
- The cardiovascular nurses are specially trained to assist in heart surgery. kinds of heart and blood vessel surgeries :

Coronary Artery Bypass:

This is the most common kind of heart surgery, also called coronary artery bypass graft surgery (CABG), coronary artery bypass (CAB), coronary bypass, or bypass surgery. The surgery involves using a healthy section of blood vessel from another part of the body to bypass a part of a diseased or blocked coronary artery. This creates a new route for blood to flow, so that the heart muscle will get the oxygen-rich blood it needs to work properly. During bypass surgery, the breastbone (sternum) is divided, the heart is stopped, and blood is sent through a heart-lung machine. Unlike other kinds of heart surgery, the chambers of the heart are not

opened during bypass surgery. The terms single bypass, double bypass, triple bypass, or quadruple bypass refer to the number of arteries that are bypassed.

Valve repair or replacement

Blood is pumped through your heart in only one direction. Heart valves play key roles in this one-way blood flow, opening and closing with each heartbeat. Pressure changes behind and in front of the valves allow them to open their flap-like “doors” (called cusps or leaflets) at just the right time, then close them tightly to prevent a backflow of blood. Two of the most common kinds of valve problems that require surgery are

- **Stenosis**, which means the leaflets do not open wide enough and only a small amount of blood can flow through the valve. Stenosis (narrowing) occurs when the leaflets thicken, stiffen, or fuse together. Surgery is needed to either open the valve that is there or replace it with a new one.
- **Regurgitation**, which is also called insufficiency or incompetence, means that the valve does not close properly and blood leaks backward instead of moving in the proper forward direction. Surgery is needed to either tighten or replace the valve.

Surgical repair of a valve involves the surgeon rebuilding the valve so that it will work properly. Valve replacement means that the valve is replaced with a biological valve (made of animal or human tissue) or a mechanical valve (made from materials such as plastic, carbon, or metal).

Arrhythmia Surgery

Any irregularity in your heart’s natural rhythm is called an arrhythmia. Arrhythmias are usually treated first with medicines. Other treatments may include

- Electrical cardioversion, where the cardiologist or surgeon uses paddles to “shock” the heart back into a normal rhythm.

- Catheter ablation, where the cardiologist uses a special tool to destroy (ablate) the cells that are causing the arrhythmia. This is done in the cardiac catheterization laboratory (the cath lab).
- Pacing and rhythm-control devices, including pacemakers and implantable cardioverter defibrillators (ICDs). Patients can have these devices implanted while in the operating room or the cath lab. Pacing and rhythm-control devices, including pacemakers and implantable cardioverter defibrillators (ICDs). Patients can have these devices implanted while in the operating room or the cath lab.

When these treatments do not work, surgery may be needed. One type of surgery is called Maze surgery. In Maze surgery, surgeons create a “maze” of new electrical pathways to let electrical impulses travel easily through the heart. Maze surgery is used most often to treat a type of arrhythmia called atrial fibrillation. Atrial fibrillation is the most common type of arrhythmia.

Aneurysm Repair

- An aneurysm is a balloon-like bulge in a blood vessel or in the wall of the heart. An aneurysm occurs when the wall of a blood vessel or the heart becomes weakened. Pressure from the blood forces it to bulge outward, forming what you might think of as a blister. An aneurysm can often be repaired before it bursts. Surgery involves replacing the weakened section of blood vessel or heart with a patch or artificial tube (called a graft). Aneurysms in the wall of the heart occur most often in the lower-left chamber (called the left ventricle). These aneurysms are called left ventricular aneurysms, and they may develop after a heart attack. (A heart attack can weaken the wall of the left ventricle.) If a left ventricular aneurysm leads to an irregular heartbeat or to heart failure, the surgeon may perform open heart surgery to remove the damaged part of the wall.

Transmyocardial Laser Revascularization (TMLR)

Angina is the pain you feel when a diseased vessel in your heart (called a coronary artery) can no longer deliver enough blood to a part of the heart to meet its need for oxygen. The heart's lack of oxygen-rich blood is called ischemia. Angina usually occurs when your heart has an extra need for oxygen-rich blood, such as during exercise. Angina is nearly always caused by coronary artery disease (CAD). Transmyocardial laser revascularization (TMLR) is a procedure that uses lasers to make channels in the heart muscle, in an attempt to allow blood to flow from a heart chamber directly into the heart muscle. If the blood flow is increased, more oxygen can reach the heart. This procedure is only done as a last resort. For example, TMLR may be done in patients who have had many coronary artery bypass operations and cannot have another bypass operation.

Carotid Endarterectomy

Carotid artery disease affects the vessels leading to the head and brain. Like the heart, the brain's cells need a constant supply of oxygen-rich blood. This blood supply is delivered to the brain by the 2 large carotid arteries in the front of your neck and by 2 smaller vertebral arteries at the back of your neck. The right and left vertebral arteries come together at the base of the brain to form what is called the basilar artery. A stroke most often occurs when fatty plaque blocks the carotid arteries and the brain does not get enough oxygen. Carotid endarterectomy is the most common surgical treatment for carotid artery disease. Surgeons make an incision at the location of the blockage in the neck and a tube is inserted above and below the blockage to reroute blood flow. Surgeons can then remove the fatty plaque. A carotid endarterectomy can also be done by a technique that does not require blood flow to be rerouted. In this procedure, the surgeon stops the blood flow just long enough to peel the blockage away from the artery.

Heart Transplantation

The first heart transplants were performed in the late 1960s. But it was not until the use of anti-rejection medicines in the 1980s that the procedure became an accepted operation. Today, heart transplantation gives hope to a select group of patients who would otherwise die of heart failure. The need for a heart transplant can be traced to one of many heart problems, each of which causes damage to the heart muscle. The two most common heart problems are idiopathic cardiomyopathy (disease of the heart muscle without a known cause) and coronary artery disease (the buildup of plaque in the arteries of the heart). As the heart problem gets worse, the heart grows weaker and is less able to pump oxygen-rich blood to the rest of the body. Because the heart must work harder to pump blood through the body, it tries to make up for this extra work by becoming enlarged (hypertrophied). In time, the heart works so hard to pump blood that it may simply wear out, overcome by disease and unable to meet even the smallest pumping demands. Medicines, mechanical devices to assist the heart, and other therapies (including stem cell therapy) can sometimes help and even improve a patient's condition. But when those treatments fail, transplantation becomes the only option.

Benefits of 3D technology in refinement of the anatomic diagnosis of congenital heart diseases

(CHD) are increasingly reported. The different facets of this technology are helpful in the setting

of the large anatomic variation and complexity of CHD. Hitherto, however, the usefulness of 3D

technologies to fine-tune surgical or catheter-based procedures has to be explored. It is now possible

to build a 3D laboratory in a tertiary surgical center, and to manage locally the process from the

treatment of a digital imaging and communication in medicine (DICOM) file to the final obtaining

of a 3D printed model.

The sequential process for obtaining 3D models that can be shared for communication can be summarized in original acquisition, images segmentation, post-processing, and printing (1–3).

Orthopedics and maxillofacial have been pioneers in this field.

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Cardiac surgery has been largely used as a clinical model of reperfusion injury. Major advantages are a controlled onset of ischemia and reperfusion following the completion of cardiac surgery procedure coronary artery bypass grafting ((CABG), aortic valve replacement). However, the extent of myocardial injury observed in this model is (hopefully) very small with hemodynamic conditions dramatically different from that observed in STEMI. Although the effect of a protective intervention may be statistically significant, its clinical relevance is always questionable. This has unfortunately been confirmed by large trials recently published testing the potential protective effect of remote conditioning in cardiac surgery. Cardiac Surgery is the medical discipline dealing with the surgical treatment of congenital and acquired diseases of the heart and great vessels. Among the most common procedures within the specialty are coronary artery bypass grafting; aortic, mitral, and tricuspid valve surgery (replacement and repair); and surgery on the thoracic aorta as well as

various procedures for heart anomalies. Furthermore, the full spectrum of the specialty comprises minimally invasive, endoscopic, endovascular, and robotic procedures. There are not many specialties so tightly linked to technology as cardiac surgery. The extracorporeal circulation machine, one of the highest technologies used, substitutes the pumping action of the heart and the respiratory function of the lungs during the surgical procedure. Hi-tech monitoring devices are employed in order to control perfusion intra operatively. Furthermore, high-resolution cardiac computed tomography and cardiac magnetic resonance are often used for the preoperative planning of cardiac procedures. Pacemakers, prosthetic valves, mechanical assist devices, and artificial hearts are all products of advanced technology related to heart surgery. This reality, along with the fact that the cardiovascular system has a lot of variations, comprises the rationale for the necessity of preoperative study of three-dimensional models and subsequent design of the surgical procedure in such a wide range pathology. Thus, cardiac surgery represents one of the fields where 3D printing is expected to contribute to the progress of the specialty. Cardiac surgery services typically treat several patient groups with typical pathologies and different requirements for intensive care. Each group has a typical pattern of age, gender distribution, and comorbidities.

- Benefits of 3D technology in refinement of the anatomic diagnosis of congenital heart diseases (CHD) are increasingly reported.
- The usefulness of 3D technologies to fine-tune surgical or catheter-based procedures has to be explored.
- It is now possible to build a 3D laboratory in a tertiary surgical center, and to manage locally the process from the treatment of a digital imaging and communication in medicine (DICOM) file to the final obtaining of a 3D printed model.
- Main objective is -To design the Pre-Operative surgical models using CAD, for designing we have to measure the patient specific requirement.
- - To check the feasibility of the treatment according to the patient condition.
- Imaging modalities used for diagnosis and treatment planning are computed tomography (CT), magnetic resonance (MR) imaging, and echocardiography

their 3d valves

- 3D technology support is an emerging technology in the field of congenital heart diseases (CHD). The goals of 3D printings or models is mainly a better analysis of complex anatomies to optimize the surgical repair or intervention planning. Method: We performed a systematic review to evaluate the accuracy and reliability of CHD modelization and 3D printing, as well as the proof of concept of the benefit of 3D printing in planning interventions. Results: Correlation studies showed good results with anatomical measurements. This technique can therefore be considered reliable with the limit of the operator's subjectivity in modelizing the defect. In cases series, the benefits of the 3D technology have been shown for describing the vessels anatomy and guiding the surgical approach. For intra-cardiac complex anatomy, 3D models have been shown helpful for the planification of intracardiac repair. However, there is still lack of evidence based approach for the usefulness of 3D models in CHD in changing outcomes after surgery or interventional procedures due to the difficulty to design a prospective study with comprehensive and clinically meaningful end-points. Conclusion: 3D technology can be used to improve the understanding of anatomy of complex CHD and to guide surgical strategy. However, there is a need to design clinical studies to identify the place of this approach in the current clinical practice.
- Benefits of 3D technology in refinement of the anatomic diagnosis of congenital heart diseases(CHD) are increasingly reported. The different facets of this technology are helpful in the setting of the large anatomic variation and complexity of CHD. Hitherto, however, the usefulness of 3D technologies to fine-tune surgical or catheter-based procedures has to be explored. It is now possible to build a 3D laboratory in a tertiary surgical center, and to manage locally the process from the treatment of a digital imaging and communication in medicine (DICOM) file to the final obtaining of a 3D printed model.
- The sequential process for obtaining 3D models that can be shared for communication can be summarized in original acquisition, images segmentation, post-processing, and printing (1–3).

- Orthopedics and maxillofacial have been pioneers in this field.

PULMONARY STENOSIS:

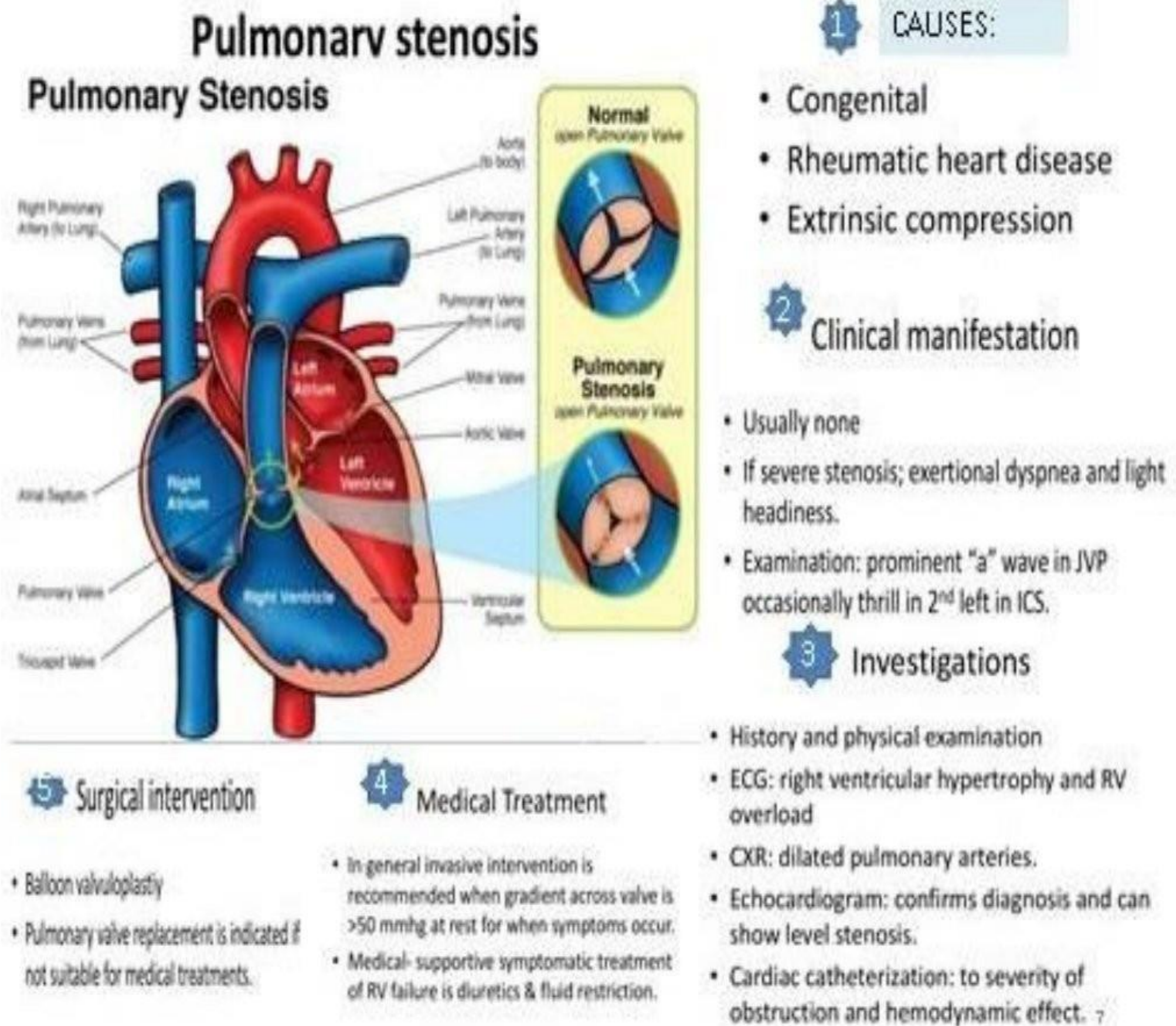


Fig.1.2 Introduction to Pulmonary stenosis

BASED ON SEVERITY: Severity of pulmonary stenosis is classified based on the estimated peak velocity and peak resting gradient calculated using modified Bernoulli equation. It is classified into:

Mild: Peak velocity less than 3m/s and peak gradient is less than 36 mm Hg.

Moderate: Peak velocity is 3m/s to 4m/s and peak gradient is 36 to 64mm Hg.

Severe: Peak velocity is greater than 4m/s and peak gradient is greater than 64mm Hg. According to 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease, stages of severe pulmonic stenosis are defined as follows: This form of aortic stenosis presents later in life, usually after the age of 75

.Tab.1.3 Stages , description & symptoms of pulmonary stenosis

STAGES , DESCRIPTION & SYMPTOMS :

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
C,D	Severe pulmonic stenosis	- Thickened, distorted, possibly calcified leaflets with systolic doming and/or reduced excursion - Other anatomic abnormalities may be present, such as narrowed RVOT.	Vmax >4 m/s; peak instantaneous gradient >64 mm Hg	- Right ventricular hypertrophy - Possible RV, RA enlargement - Poststenotic enlargement of main pulmonary artery	None or variable and dependent on severity of obstruction

• According to 2014 AHA/ACC Guidelines for the Management of Patients With Valvular Heart Disease, progression of valvular heart disease (VHD) are defined as follows⁽⁷³⁾

Stage	Definition	Description
A	At risk	Patients with risk factors for development of valvular heart disease
B	Progressive	Patients with progressive valvular heart disease (mild-to-moderate severity and asymptomatic)
C	Asymptomatic severe	Asymptomatic patients who have the criteria for severe valvular heart disease: - C1 Asymptomatic patients with severe VHD in whom the left or right ventricle remains compensated - C2 Asymptomatic patients with severe VHD with decompensation of the left or right ventricle
D	Symptomatic severe	Patients who have developed symptoms as a result of valvular heart disease

GENETIC DISORDERS:

Syndrome	Genetic Defect	Cardiac features	Other features
Noonan syndrome ⁽¹⁷⁾	• PTPN11, SOS1 • Heterogeneous trait • Aberrant RAS-MAPK signaling	• Dysplastic pulmonary valve stenosis • Supravalvular pulmonary stenosis • Hypertrophic cardiomyopathy	• Short stature • Hypertrichosis • Downward eye slant • Low set ears
Williams Beuren ⁽¹⁸⁾	• 7Q11.23 deletions • Autosomal dominant trait	• Supravalvular aortic or pulmonary stenosis	• Elfin face • Short stature • Impaired cognition and development • Endocrine disorders and genitourinary abnormalities
Leopard syndrome ⁽¹⁹⁾	• PTPN11, RAF-1 • Autosomal dominant trait	• Electrocardiographic abnormalities • Supravalvular or valvular pulmonary stenosis	• Lentiginos⁽²⁰⁾ • Ocular hypertrichosis • Abnormal genitalia • Growth retardation • Deafness
DiGeorge syndrome ⁽²¹⁾	• 22Q11 deletion • Autosomal dominant trait	• Conotruncal defects such as tetralogy of Fallot • Interrupted aortic arch • Truncus arteriosus • Vascular rings • ASD/VSD	• Hypertrichosis • Low set and posteriorly rotated ears • Palatal abnormalities • Micrognathia • Developmental delay • Hypoplastic thymus • Hypocalcaemia • Immunological abnormalities
Alagille ⁽²²⁾	• AG-1, NOTCH-2 • Autosomal dominant trait	• Peripheral pulmonary stenosis⁽²³⁾	• Facial dysmorphias (triangular face, wide nasal bridge, deep set eyes) • Intrahepatic cholestasis

SYMPTOMS:

	Mild valvular PS	Moderate Valvular PS	Severe Valvular PS	Infundibular Pulmonic Stenosis	Supravalvular Pulmonic Stenosis	Right Heart Failure
Clinical Features	Asymptomatic	• Exertional dyspnea • Fatigue	• Exertional dyspnea • Chest pain • Syncope	• Angina • Dyspnea • Dizziness • Syncope	• Dyspnea • Fatigue on exertion	• Exercise intolerance • Fatigue • Shortness of breath • Swelling of the feet or ankles • Abdominal discomfort

PHYSICAL EXAMINATION:

	Mild valvular PS	Severe Valvular PS
Physical Examination Findings	• Normal jugular venous pulse • Absent right ventricle lift • Ejection click in the pulmonary area which decreases with inspiration • Ejection systolic murmur in the pulmonary area heard in the ending of mid systole increasing in intensity during inspiration	• Elevated JVP with a prominent "a" wave • Right ventricular heave • Louder and longer ejection murmur in the left parasternal area in second and third intercostal space • Ejection click is softer and absent with increasing severity • Wide split S2 with reduced or absent P2 component • Right sided S4 can be audible

INTERVENTION OPTIONS & OUTCOMES:

Intervention Options:

Percutaneous balloon pulmonary valvulotomy (BPV) has widely replaced surgical valvulotomy as a treatment option for pulmonary valve stenosis.

Catheter intervention is recommended for patients with doming valves which are not dysplastic.

Surgery is recommended for patients with:

- Subinfundibular or infundibular [pulmonic stenosis](#) and hypoplastic pulmonary annulus
- Dysplastic pulmonary valves

Intervention Outcome:

Surgical outcomes in patients with valvular stenosis is good with [survival rate](#) of 90 to 96% 25 years after the surgery when its done in the childhood.¹

Survival is around 70% at 25 years when the surgery is performed in adulthood.

BPV has shown to have good outcomes in long term follow up with very low rate of re-intervention requirement.¹ BPV has shown to have sub-optimal results in patients with dysplastic valves when compared to doming valves.¹²

Fig.1.4 intervention option and outcomes of pulmonary stenosis

CHAPTER-2

LITERATURE SURVEY

.Multivariable modelling using logistic regression, concordance statistic (c-statistic), and net reclassification index was used to identify factors contributed characteristics to a multivariable model improved discrimination between elderly patients with and without disability at 3 month after cardiac surgery (Lisa Verwijmeren et al 2020)

The impact of preoperative penicillin allergy evaluation on perioperative cefazolin use in patients undergoing cardiac surgery. Integrating penicillin allergy evaluation into routine preoperative care ensured that almost all evaluated patients undergoing cardiac surgery risk reduction. (Jessica et al 2020)

The primary outcome measure was the development of delirium, diagnosed using the Confusion Assessment Method in Intensive Care Units (CAM-ICU), during the stay in the intensive care unit after cardiac surgery. The DELIPRECAS model (Delirium Prevention Cardiac Surgery), consisting of four well-defined clinical risk factors, can predict in the preoperative period the risk of developing postoperative delirium in patients undergoing cardiac surgery. Olgade la Varga-Martinez 2021. (Varga-Martínez et al 2021)

ADD were more likely to be older, of female sex, to have had higher length of hospital stay prior to surgery, and to have undergone emergency surgery. instrument for prediction of loss of the ability to live independently in patients undergoing cardiac surgery. (Andre F. Gosling M Detal 2021)

The variables used for analysis included demographic characteristics, clinical condition, preoperative biochemistry data, preoperative medication, and intraoperative variables such as time-series hemodynamic changes. The efficacy of the single model that most accurately predicted the outcome, RF exhibited the greatest AUC (0.839, 95% confidence interval [CI] 0.772–0.898), whereas the AUC (0.843, 95% CI 0.778–0.899) of ensemble model (RF + XGboost) was even greater than that of the RF model alone. (Po-Yu Tsen et al 2020,)

Impact of preoperative nasopharyngeal cultures on surgical site infection after open heart surgery Author links open overlay panel Yoshiyuki Takami M Detal

2021..Microorganisms isolated from the NCx and SSI pathogens were counted to explore the microbial pattern and associated variables in patients with and without postoperative SSI. Preoperative NCx may be useful to predict SSI after open heartsurgery via median sternotomy, as well as screening for methicillin- resistant Staphylococcus aureus.panel

The intraoperative hase was divided into the following: (1) CPB, (2) outside CPB, and (3) total surgery for quantifying IOH only.XGB machine learning model from IOH outside the CPB phase seemed to offer a better discrimination, sensitivity, specificity, and positive predictive value compared with other models.(BentoFernandes Ph Detal 2021)

Anaesthesia geriatric evaluation to guide patient selection for preoperative multidisciplinary team care in cardiac surgeryAuthor links open overlay panelLisaVerwijmerenetal 2020.Multivariable modelling using logistic regression, concordance statistic (c-statistic), and net reclassification index was used to identify factors contributing to patient selection.The addition of preoperative frailty characteristics to a multivariable model improved discrimination between elderly patients with and without disability at 3 months after cardiac surgery panel.

discrimination and accuracy, with C-statistic of 0.78 (95% confidence interval [CI] 0.76-0.79) and unmodified Brier score of 0.177 (reliability 0.001).prediction of loss of the ability to live independently in patients undergoing cardiac surgery. (AndreF.GoslingMDetal 2021.)

to evaluate the accuracy and reliability of CHD modelization and 3D printing, as well as the proof of concept of the benefit of 3D printing in planning interventions.3D technology can be used to improve the understanding of anatomy of complex CHD and to guide surgical strategy. (ClémentBatteuxetal 2019)

CHAPTER-3

AIM AND SCOPE

AIM:

- This project is to control and reduce the operation time to 4 hours that too my using a formula ,Disease prediction + knowledge of disease = chance of survival is more
- To minimize the risk of surgical complications and offer the best treatment outcomes to the patients.
- Our aim is to design a pre-operative surgical models to understand the patient condition and choose a accurate treatment

SCOPE

3D printing is an ideal manufacturing process for creating patient-matched models (anatomical models) for surgical and interventional planning. Cardiac anatomical models have been described in numerous case studies and journal publications. However, few studies attempt to describe wider impact of the novel planning augmentation tool. The work here presents the evolution of an institution's first 3 full years of 3D prints following consistent integration of the technology into clinical workflow (2012–2014) - a center which produced 79 models for surgical planning (within that time frame). Patient outcomes and technology acceptance following implementation of 3D printing were reviewed.

CHAPTER-4

MATERIALS AND METHODS

MATERIALS:

PLA plastic or polylactic acid is a vegetable-based plastic material, which commonly uses cornstarch as a raw material. The monomer is usually made from fermented plant starch. This material is a thermoplastic aliphatic polyester and it is the primary natural raw material used in 3D printing. PLA filament is a thermoplastic polymer made strictly from renewable resources. Poly Lactic Acid (PLA), is generated from biodegradable material like cornstarch, potato starch, sugarcane and tapioca roots, and has a smooth, shiny appearance.

PROPERTIES:

- DIAMETER: 1.75MM
- COLOR:NATURAL

FACTORS:

- EASY AND GOOD PRINTABILITY
- VERY GOOD STRENGTH
- ECO FRIENDLY AND BIODIGRADABLE
- BETTER STIFFNESS
- NO FUMES AND TOXIC
- DURABILITY 2 HOURS

PLA Technical Specifications & Properties

- Flexural Strength: 88.8 MPa.
- Melting Temperature: >155°C.
- Tensile Strength: 61.5MPa.
- Heat Deflection: n/a.
- Heat Resistance: 110°C.
- Impact Strength: 30.8[kJ/m²]
- Elongation at Break : 6%

- Standard Tolerance: +/-0.05mm.

PLA components are produced:

- **3D printing:** FDM 3D printing is a very common way to produce parts in PLA: The material is very easy to print, and it doesn't need high temperatures, a heated bed, or a direct drive extruder.
- **Injection molding:** Injection molding is the most popular method of manufacturing plastic parts, and it's how most day-to-day plastic parts are made. While injection molding is typically used with ABS plastic to make parts like Lego bricks or internal car parts (like dashboards), this method can also work with PLA. However, PLA isn't as commonly used for injection molding due to its low crystallization rate.
- **Casting and more:** Casting is very similar to injection molding but uses gravity instead of applied pressure to form a part. There are also other similar manufacturing methods for PLA, like thermoforming. Like injection molding, these methods aren't super popular for producing PLA parts, but are used in some industries.

PLA is comparatively easy to work with, usually requiring minimal effort to produce quality parts, especially on an FDM 3D printer. As it's created from natural or recycled materials, PLA is also embraced for its eco-friendliness, biodegradability, and many other characteristics.

METHODOLOGY

We performed a systematic review to evaluate the accuracy and reliability of CHD modelization and 3D printing, as well as the proof of concept of the benefit of 3D printing in planning interventions. Different studies suggested that 3D could improve medical understanding, teaching surgical training and patient information in CHD. Still, there is no clear demonstration of these benefits in well-designed studies. Notwithstanding this lack of data, it is highly probable that the decreasing cost of printed 3D models of CHD will modify the current approach of CHD in a short future. Intuitively, these models will help to share complex information from different imaging

modalities between caregivers. Convenience of these 3D models has to be clearly evaluated, as congenital cardiologists have to be trained to manipulate these information and to understand the limits of the different steps in the process. The next phase is to demonstrate the value of these 3D models in planning surgical procedures in complex CHD. Certainly, there should be a proof of concept step before designing trials aiming to show the efficiency of these models in improving outcomes. Here, we reviewed the available literature on intervention planning in complex CHD with the help of 3D models. Our aim was to set up the bases for a study aiming to demonstrate the benefit of these models in modifying outcomes after surgical or interventional procedures. We performed an extensive literature's search using PubMed and Google Scholar. At least 3 of 4 the following terms were combined in the query: 3D printing, 3D printed model, complex congenital heart disease, and surgery. The terms surgical planning, and measurement correlation were optionally added into the query. Two congenital heart diseases specialists reviewed all retrieved abstracts. Publications describing only medical comprehension of CHD and/or patient information with 3D-models were excluded. All articles describing surgical strategy or measurement's correlation in CHD were included and analyzed.

A retrospective analysis was designed to investigate the anatomical model's impact on time-based surgical metrics. A contemporaneous cohort of standard-of-care pre-procedural planning (no anatomical models) was identified for comparative analysis. A post-surgery technology acceptance assessment was also employed in a smaller subset to measure perceived efficacy of the anatomical models. The data was examined.

HARDWARE USED

FDM:

Fused Deposition Modeling (FDM) Technology works with specialized 3D printers and production-grade thermoplastics to build strong, durable and dimensionally stable parts with the best accuracy and repeatability of any 3D printing technology.

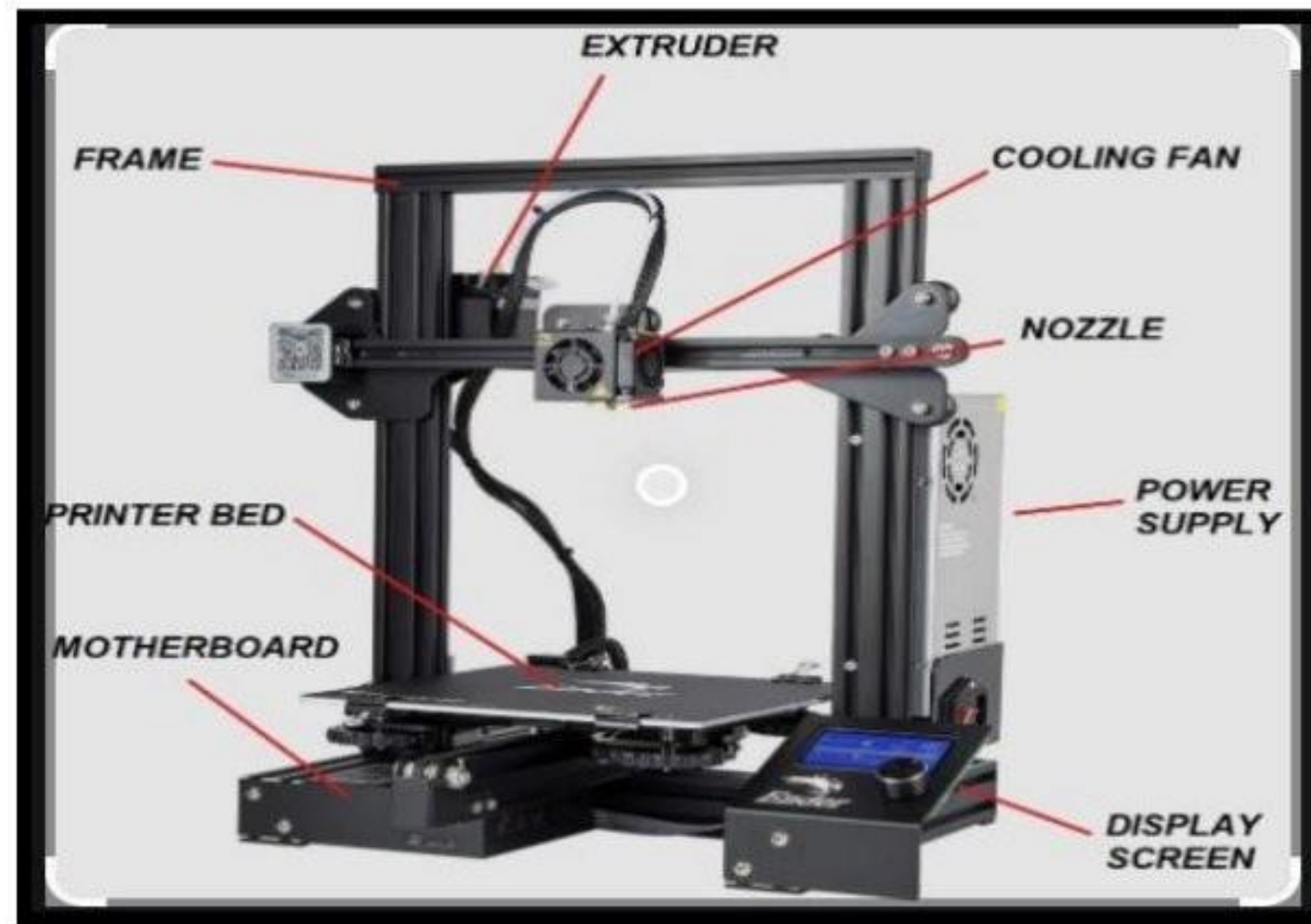


Fig.4.1 FDM machine

3D printing, also referred to as additive manufacturing (AM), involves manufacturing a part by depositing material layer by layer. There is a wide array of different AM technologies that can do this, including material extrusion, binder jetting, material jetting and directed energy deposition. These processes have varied types of extruders and extrude different materials to achieve the final product.

FFF begins with a software process which processes an STL file (STereoLithography file format), mathematically slicing and orienting the model for the build process. If required, support structures may be generated. The nozzle can be moved in both horizontal and vertical directions, and is mounted to a mechanical stage, which can be moved in the xy plane

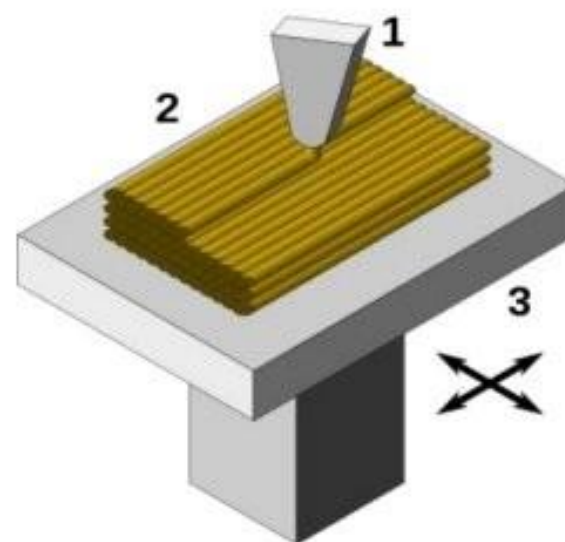


Fig 4.2 FDM nozzle

Process: 1 – 3D Printer Extruder, 2 – deposited material (modeled part), 3 – controlled movable table

As the nozzle is moved over the table in a prescribed geometry, it deposits a thin bead of extruded plastic, called a “road” which solidifies quickly upon contact with the substrate and/or roads deposited earlier. Solid layers are generated by following a rasterizing motion where the roads are deposited side by side within an enveloping domain boundary.

Stepper motors or servo motors are typically employed to move the extrusion head. The mechanism used is often an X-Y-Z rectilinear design, although other mechanical designs such as deltabot have been employed.

Once a layer is completed, the platform is lowered in the **z direction** in order to start the next layer. This process continues until the fabrication of the object is completed.

For successful bonding of the roads in the process, control of the thermal environment is necessary. Therefore, the system is kept inside a chamber, maintained at a temperature just below the melting point of the material being deposited.

Although as a printing technology FFF is very flexible, and it is capable of dealing with small overhangs by the support from lower layers, FFF generally has some restrictions on the slope of the overhang, and cannot produce unsupported stalactites.

Myriad materials are available, such as Acrylonitrile Butadiene Styrene (ABS), Polylactic acid (PLA), Polycarbonate (PC), Polyamide (PA), Polystyrene (PS), lignin, rubber, among many others, with different trade-offs between strength and temperature properties. In addition, even the color of a given thermoplastic material may affect the strength of the printed object. Recently a German company demonstrated for the first time the technical possibility of processing granular PEEK into filament form and 3D printing parts from the filament material using FFF technology. During FFF, the hot molten polymer is exposed to air. Operating the FFF process within an inert gas atmosphere such as nitrogen or argon can significantly increase the layer adhesion and leads to improved mechanical properties of the 3D printed objects. An inert gas is routinely used to prevent oxidation during selective laser sintering.

FILAMENT MANUFACTURING PROCESS:

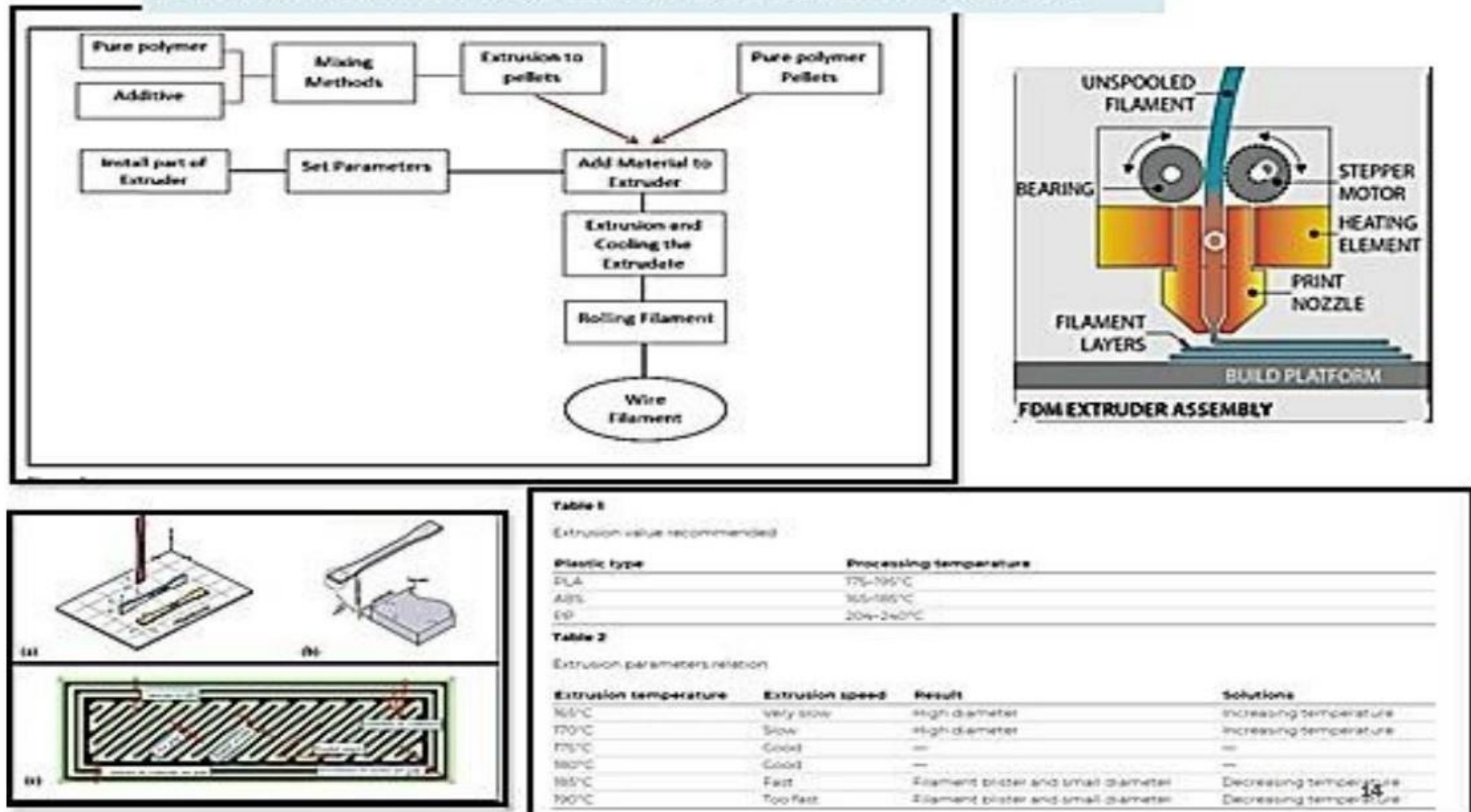


Fig.4.3 FDM filament manufacturing process

SOFTWARE USED RHINOCEROUS

Rhino can create, edit, analyze, document, render, animate, and translate NURBS curves, surfaces and solids, subdivision geometry (SubD), point clouds, and polygon meshes. There are no limits on complexity, degree, or size beyond those of your hardware.

Special features include:

- **Uninhibited** free-form 3D modeling tools like those found only in products costing 20 to 50 times more. Model any shape you can imagine.
- **Accuracy** needed to design, prototype, engineer, analyze, and manufacture anything from an airplane to jewelry.
- **Compatibility** with all your other design, drafting, CAM, engineering, analysis, rendering, animation, and illustration software.
- **Read and repair** meshes and extremely challenging **IGES** files.
- **Accessible**. So easy to learn and use that you can focus on design and visualization without being distracted by the software.
- **Fast**, even on an ordinary laptop computer. No special hardware is needed.
- **Development platform** for hundreds of specialty 3D products.
- **Affordable**. Ordinary hardware. Short learning curve. Affordable purchase price. No maintenance fees.

Model Creation Tools

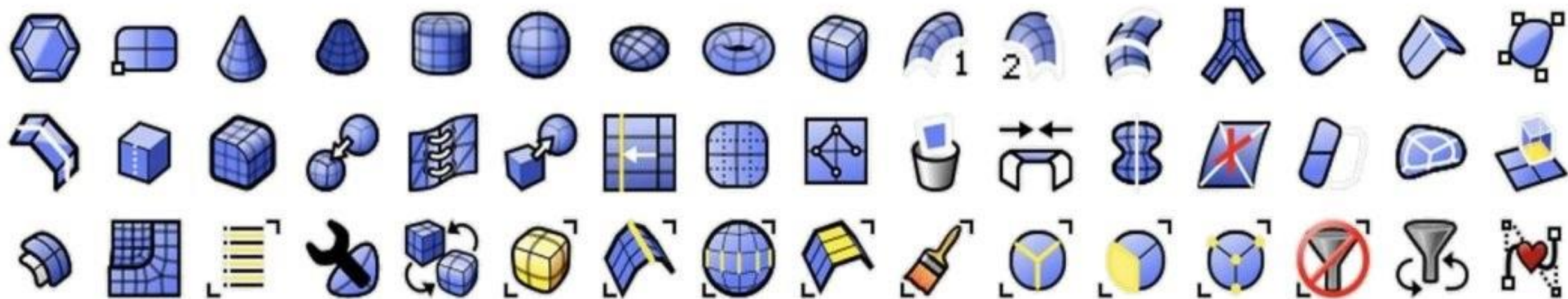


Fig.4.4 Model creation tools of Rhinoceros

Points: Points, point clouds, point grid, extract from objects, mark (intersection, divide, draftangle, ends, closest, foci).

Curves: Line, polyline, polyline on mesh, free-form curve, circle, arc, ellipse, rectangle, polygon, helix, spiral, conic, TrueType text, point interpolation, control points (vertices), sketch.

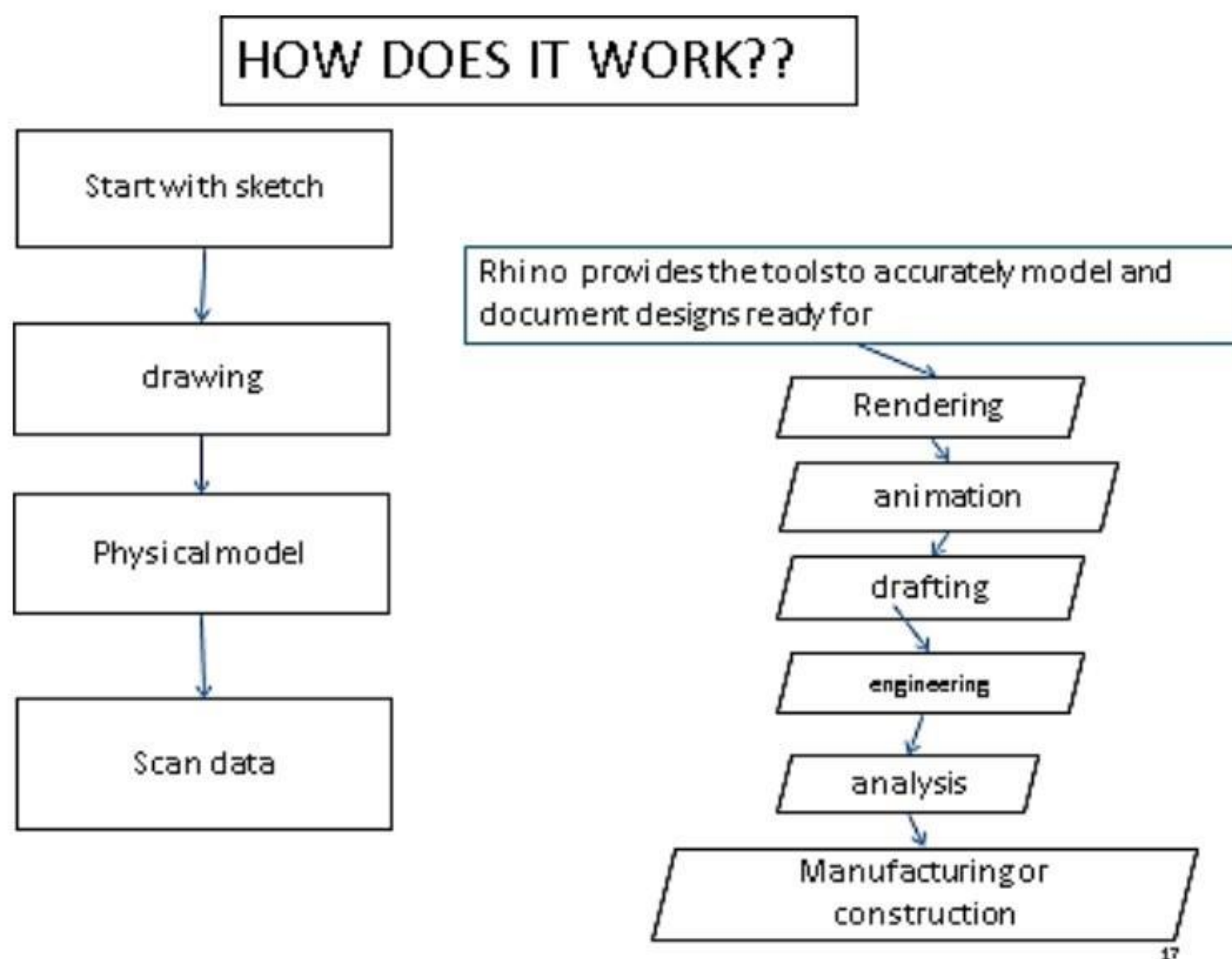
Curves from other objects: Through points, through polyline, extend, continue curve, fillet, chamfer, offset, blend, arc blend, from two views, tween, cross section profiles, intersection, contour on NURBS surface or mesh, section on NURBS surface or mesh, border, silhouette, extract isoparm, extract curvature graph, projection,

pullback, sketch, wireframe, detach trim, 2D drawings with dimensions and text, flatten developable surfaces.

Surfaces: From 3 or 4 points, from 3 or 4 curves, from planar curves, from network of curves, rectangle, deformable plane, extrude, ribbon, rule, loft with tangency matching, developable, sweep along a path with edge matching, sweep along two rail curves with edge continuity, revolve, rail revolve, tween, blend, patch, drape, point grid, height field, fillet, chamfer, offset, plane through points, TrueType text, Unicode (double-byte) text.

Solids: Box, sphere, cylinder, tube, pipe, cone, truncated cone, pyramid, truncated pyramid, ellipsoid, torus, extrude planar curve, extrude surface, cap planar holes, join surfaces, region, no manifold merge, TrueType text, Unicode (double-byte) text.

Meshes: From NURBS surfaces, from closed polyline, mesh face, plane, box, cylinder, cone, and sphere.



Inspection and Analysis

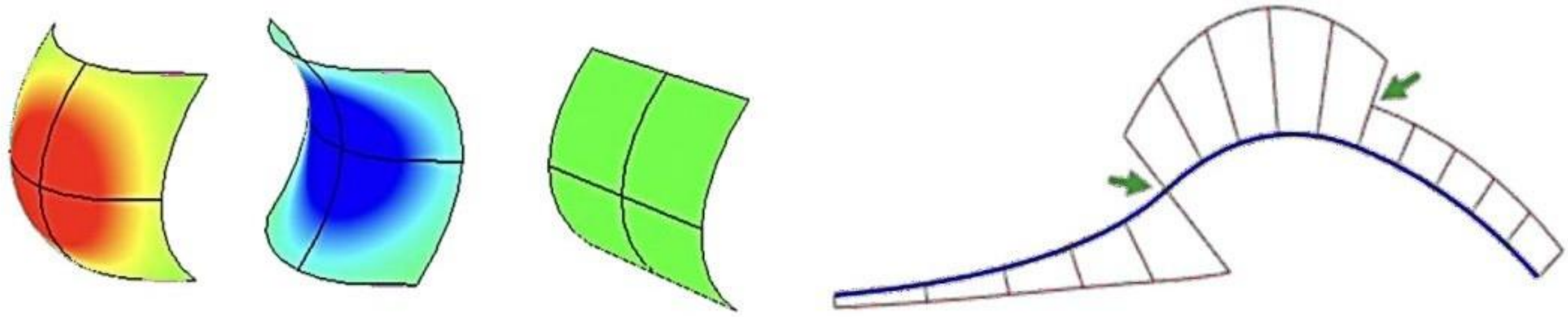


Fig.4.5. Inspection and analysis of Rhinoceros

Design realization requires high-quality 3D models in every phase of design, presentation, analysis, and fabrication. Rhino includes tools to help ensure that the 3D models used throughout your process are the highest possible quality.

Analysis: point, length, distance, angle, radius, bounding box, normal direction, area, area centroid, area moments, volume, volume centroid, volume moments, hydrostatics, surface curvature, geometric continuity, deviation, nearest point, curvature graph on curves and surfaces, naked edges, working surface analysis viewport modes (draft angle, zebra stripe, environment map with surface color blend, show edges, show naked edges, Gaussian curvature, mean curvature, and minimum or maximum radius of curvature).

ULTIMAKER CURA

- 1. Import a Model:** This allows you to import models into the Cura software. You can import also by using the top menu or by drag and dropping the file over the build area. The file will be imported into the centre of the Cura Build area as seen above.
- 2. Printer Select:** This is the current printer selected and if you have more than one printer you can set them up and access them here using a dropdown menu.
- 3. Materials and Nozzle Diameter Settings:** Allows the print core and material choice to be quickly selected which will then load the associated print profile settings.
- 4. Workflow Stages:** Currently selected and displaying the Prepare stage. This stage is to decide all parameters to be made prior to slicing. Preview stage lets you see the slice layers that Cura has created and evaluate them. Monitor stage allows you to observe all the 3D printers on your network, all their properties and print operations.

5. Print Settings Overview: Gives an overview of basic current settings and by clicking anywhere on this section it will open access to print settings.

6. Model Adjustment Panel: If your model is in the wrong place, wrong orientation, need to be mirrored, is not scaled the right way or you want to manually create support structures using multiple models this panel does it all. Make sure to select the model to allow access to the panel.

7. Build Space of your Printer: Everything inside the blue box is printable space that you can fill with components.

8. Print Settings: Allows default profiles to be selected or for new profiles to be created. Difference between profiles of the same material tends to be a trade-off between the speed of print and the quality of the final component. Deeper more advanced settings can be accessed here by clicking on the gear symbol when highlighting a settings section header.

9. Useful Menu: Allows default view orientation to be chosen, gives max dimensions of design, allows the name of the exported file to be chosen and gives a list of all models currently on the build plate.

10. Slice Button: Will slice your CAD file into a stack of layers. You can access the Preview stage and see these layers making up your component. Each time a parameter is changed you will need to re-slice your model.

11. View Type: Layer View lets you see each line on each layer location (great when zoomed in close) or an X-ray view letting you see the internal structure of your print.

12. Marketplace: Gives you access to community and commercially made plugins, material defaults and modify those plugins currently installed.

13. Build View: When your model is sliced by viewing it on the build area all the paths that the 3D printer will take will be displayed, allowing for inspection and analysis.

14. Build Height Slider: By altering this you can see each layer of the sliced model from the first base layer all the way to the top final layer.

15. Print Nozzle Path Preview: By pressing play this will show you the path that the print nozzle will take for the currently viewed print layer. Great for inspecting any potential problems.

16. Print or Export Tab: Will give you a prediction of the time required to print, how much filament will be used and allow you to either export the G-Code file or Print the model directly.

17. Monitor Tab: This is the monitor page where you can observe the printers on your network, their properties and operations. It also links you to Ultimaker Connect. Compatibility knowledge for UltimakerCura Software with other file standards is seen below.

- UltimakerCura works with: STL, OBJ, X3D, 3MF, BMP, GIF, JPG, PNG,
- Printable Format exported by Cura (the recipe!): G-CODE
- Plugin interactions: SolidWorks, Siemens NX, Autodesk Inventor, Fusion 360

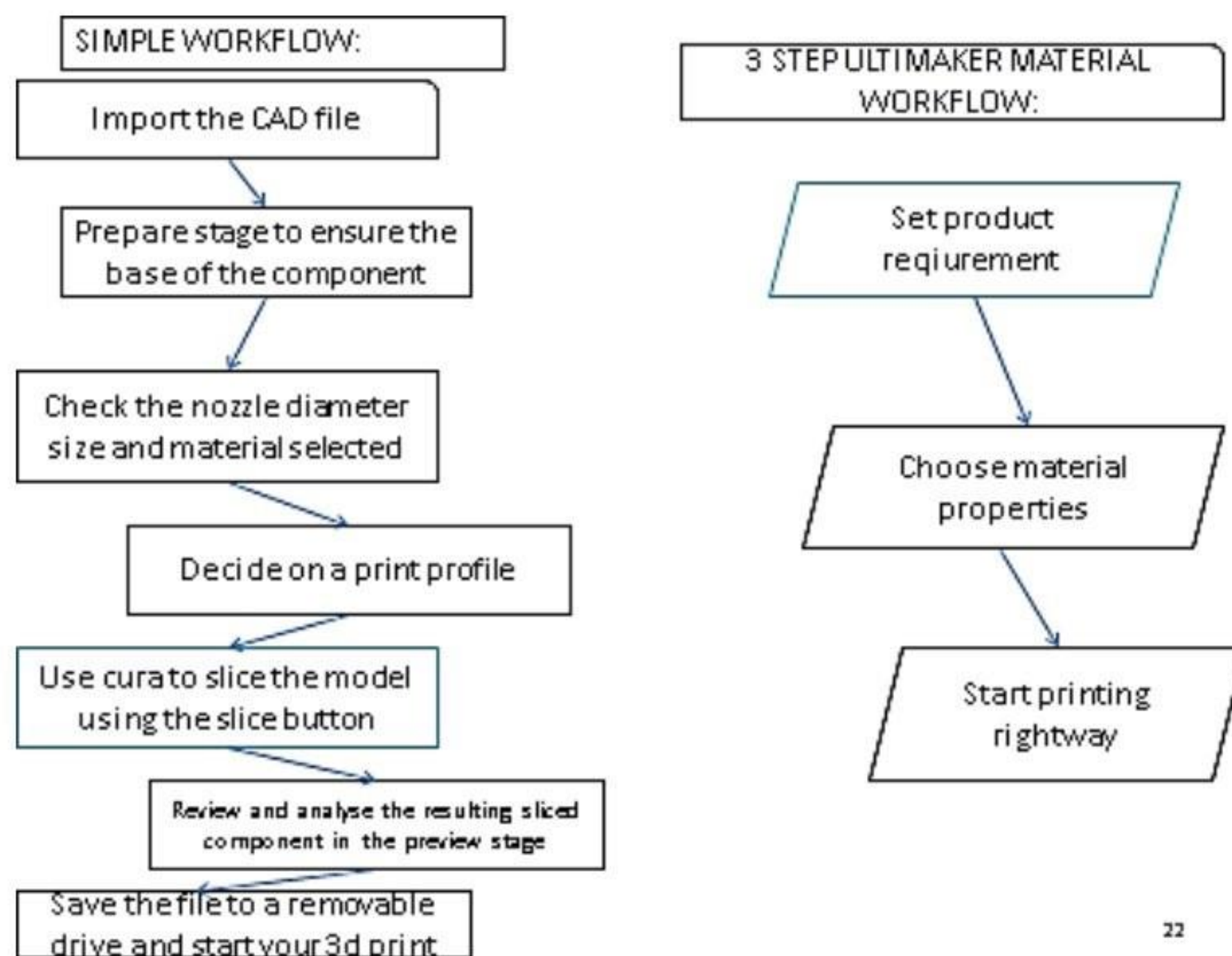


Fig.4.6. Ultimakercurawork flow

CHAPTER – 5

RESULT AND DISCUSSION

RESULT

Within the timeframe of the study, 928 primary-case cardiothoracic surgeries (encompassing both CHD and non-CHD surgeries) took place at the practicing pediatric hospital. One hundred sixty four anatomical models had been generated for various purposes. An inclusion criterion based on lesion type limited those with anatomic models to 33; there were 113 cases matching the same criterion that received no anatomical model. Time-based metrics such as case length-of-time showed a mean reduction in overall time for anatomical models. These reductions were not statistically significant. The technology acceptance survey did demonstrate strong perceived efficacy. Anecdotal vignettes further support the technology acceptance.

Accuracy and Reliability of a 3D Printed Model of Congenital Heart Diseases;

The first step for this new technology was to validate the reproducibility of 3D models with the original source by measurement's accuracy studies.

The analysis of the different processes to obtain a 3D printed model is necessary to understand that 3D segmentation and printing open the way to possible measurement's bias. The potential risk that the final 3D printed model would not be anatomically similar to the original should indeed be carefully estimated.

Pre-segmentation and Segmentation Processes

To create a 3D printed heart, the first step is to proceed to the segmentation of a model from various imaging modalities (cardiothoracic computed tomography CT, Magnetic Resonance Imaging MRI, Transthoracic Echocardiography TEE). Segmentation means treating DICOM's images from a stack of slices to a 3 dimensional scene. To do this, each structure of a scene is isolated as a model and

reported in the 3D field by a segmentation process, as for example: blood pool, myocardium, great arteries, and coronary arteries. Pre-segmentation consists in isolating a chosen structure, by using an algorithmic treatment of pixels: thresholding, edge attraction, clustering, classification, are the four more used pre-segmentation modes.

Then, segmentation consists in filling the isolated structure in the 3-dimensions fields; then the structure is transformed from slices of pixels to a 3 dimensional model with proper X;Y;Z coordinates. To proceed in segmentation, a semi-automatic mode is often used. The presegmentation mode can be modified and the segmentation filling is guided by the operator who defines which structures have to be segmented and then let the algorithm work to complete the process.

Different Segmentation Softwares and Printing Modality

A large variety of segmentation softwares are used. Most of them involve a human intervention to obtain a final 3D model. This is clearly a source of uncertainty. Total 3D-coordinates of a model is called a mesh, and the most frequently used computed-format to save this model is the Standard Tessellation Language (STL), that will be used for the final printing.

This final step of printing adds another source of discordance between the original source and the final printed piece. These discordances are closely dependent on the type of printer and on the modality for printing (FDM: fused deposition modeling, stereolithography, SLS: selective laser sintering, polyjet). The reliability of the final printed model depends on a multistep process in which almost each phase creates additive errors and/or approximations.

Choice of Segmentation Software

The choice of segmentation software depends on the expectations of the user as well as on his confidence in 3D segmentation and modeling.

Two different categories of 3D modellers can be identified. The first categories of users usually work with a turn-key product predefined and automatic segmentation,

and including all processes permitting to obtain the final 3D model within single software. This easy-to-use solution, as proposed by Materialize (Mimics), represents a quick and easy way to perform 3D modeling in medicine. The limits of this type of practice are the cost of the license (more than 10,000\$ per year) and the lack of independence for the user during the 3D modeling, the post-processing, and the pre-printing step.

Conversely, the second group is that of self-taught users. Using opensourcesoftwares (Itk-snap, slicer), they can control each step of the segmentation by manually modifying the primary DICOM contrast or the threshold. They can either easily manage the propagation of the segmentation and the post-processing steps. As these software are open-source, they can be downloaded for free and they are frequently upgraded by the developers. The main limit of this approach is the need for a learning curve and the risk of potential subjective bias in the modeling.

Correlation Studies

Correlation studies evaluate the concordance between a printed model and the original structure (13–23) (see details in Table 1).

Authors	Case	Comparison	Software	Structure	Measure (model × structure × operator)	Pearson correlation	Mean diff (mm)	Analysis
<u>Lau et al. (13)</u>	1	3D vs. CT	Mimics	VSD/Aorta/PB	1 × 3 × 2	0.99	0.23	Pearson
<u>Valverde et al. (14)</u>	20	3D vs. CT	Itk-snap	10 vascular diameters	320	0.99	0.27	Pearson
<u>Greil et al. (15)</u>	1	3D vs. mortem	Visualization toolkit	Distances	unclear		0.27	Interactive closest point
<u>Ma et al. (16)</u>	35	3D vs. vivo	Philips EBW	VSD	35 × 1 × 1		No diff ($t = 0.83$, $P = 0.412 > 0.05$)	t
<u>Olejník et al. (17)</u>	8	3 D vs. vivo	3D slicer	Vascular diameters and distance	8 × 3 × 1		0.13 ± 0.26	Bland-Altman
		3D vs. dicom			8 × 5 × 1		0.19 ± 0.38	
<u>Valverde et al. (18)</u>	1	3D vs. MRI	Ayra	Aorta diameters	2 × 8 × 2		0.18 ± 0.38	Pearson and Bland-Altman
		3D vs. X ray			2 × 8 × 2		0.55 ± 0.46	
		Global					0.36 ± 0.45	
<u>Zhao et al. (19)</u>	8	3D vs. CT	Mimics	VSD/Ao arch/PA	8 × 3 × 1	0.977		Pearson
<u>Olivieri et al. (20)</u>	9	3D vs. echo	Mimics	VSD and perivalvar leak	22	0.988	0.4 ± 0.9; t : NS	Pearson Bland-Altman and t
<u>Ngan et al. (21)</u>	6	3D vs. CT	Mimics	MAPCA diameters	6 × 1 × 1		0.26–0.85	t
							97% accuracy feeling	
<u>Farooqiet al. (22)</u>	19	3DM vs. 3DBP	Mimics	GA/IVC/SVC/PV	19 × 5 × 4 × 2		Blood pool >myocardium	Anova
<u>Farooqi et al. (23)</u>	6	3D vs. MR	Mimics	AA/VSD/RVLA	6 × 3 × 1	0.99		Pearson
						AA 0.88 VSD 0.74 RV 0.99		

Measurement's accuracy with 3D printed models. CT, computed tomography; MRI, Magnetic Resonance Imaging; 3DM, 3D myocardium; 3DBP, 3D bloodpool; VSD, ventricular septal defect; PB, pulmonary branch; Ao Arch, aortic arch; MAPCA, major aortopulmonary collateral artery; SVC, superior vena cava; IVC, inferior vena cava; Ao, Aorta; PA, pulmonary artery; PV, pulmonary valve; AA, aortic annulus; RVLA, right ventricle long axis.

The methods of these 11 studies were variable, using either an original substrate or DICOM sliced usual imaging modalities (TEE, CT, MRI), or angiography,, per-operative or postmortem measurement as controls. The techniques for measuring the 3D printed model measurement were not homogeneous: directly on the printed model or indirectly from a CT of the printed model. The number of operators, the structures, and the number of measurements were highly variable. Despite this methodological heterogeneity, the correlation between the measurements made with the 3D printed model and the original structure was always satisfactory. Therefore, confidence should be given to the process of segmentation and printing at least for the size of the cardiac structures. It seems reasonable to evaluate this technology in surgical planning.

For the segmentation of the myocardium, two methods have been compared by Farooqi et al. the first direct method used a presegmentation algorithm to isolate the myocardium, this region was then filled; the second indirect method identifies the bloodpool, and then create a shell with an arbitrary thickness surrounding the bloodpool surface to represent the myocardium. In this latter method, the inner surface represents the endocardial surface anatomy, whereas the outer surface is a fabricated structure.

Whereas, the different methods used to analyze the accuracy of 3D models are heterogeneous, they show an acceptable correlation between the 3-D printed-model and the "original structure" with differences being always infra-millimetric. These data suggest that 3D-models could be reliable to appreciate the complex anatomy of cardiac structures in CHD and to adequately plan surgical interventions.

Surgical Planning With 3D Printed Models—Proof of Concepts by Cases Reports and Single-Center Experiences

The number of case reports suggesting that the 3D visualization and/or printing of complex CHD are helpful in planning surgery or interventional procedure is increasing every day. To summarize, the 3D printed models have been used with two aims.

The first group of case reports describes the anatomy of extra-pericardial structures (great vessels, their branches, intra-thoracic course and relationship with other organs such as the trachea and esophagus) with the objective to refine the diagnosis and to precise the surgical repair (see Table 2)

Table 2

Cases reports about extra-pericardial benefits of 3D-printed models in congenital heart diseases' surgical planning

References	CHD	Problematic?	Benefit of 3D printed model?
VESSELS VIEWING			
Biglino et al. (24)	Truncus arteriosus	Aorta-RPA relationship?	Better surgical approach, need of CPB
Deferm et al. (25)	TOF	Pulmonary arteries?	Better understanding of distal circulation
			Relationship with bronchal tree
Sodian et al. (26)	Komerell with ROLSCA	Anatomic complexity of aortic arch	Intra-operative view to guide surgery
Ryan et al. (27)	TOF	MAPCA localization	Sustend to cath to isolate a MAPCA
Anwar et al. (28)	Vasc ring, TOF, TAPVR	Vessels disposition and diameters and relationship	Surgical viewing and approach
	Heterotaxy with 1V, DTGA Senning		Direct observation in the operating room
		Pulmonary veins approach	Show anatomy and spatial relationship
Ngan et al. (21)	PAVSD	MAPCA?	Peroperative Visualization number of MAPCA
Schmauss et al. (29)	Heart transplantation	Complex vessels anatomy	Surgical planning by understanding anatomy
	ROSCA	Complex surgical approach	Perioperative orientation by conditionnement
HEART TRANSPLANTATION			
Smith et al. (30)	Situs in vs.-DORV-TGA going to HTx	Complex anatomy	Understanding anatomy
			Upgrade surgical approach
			Reduce CPB time
Sodian et al. (31)	Failing 1V repair going to HTx	Complex vessels disposition	Added understanding in complex vessels disposition
			Peroperative view
SURGICAL GESTURE DECISION			
Kiraly et al. (32)	Aortic arch obstruction	Arch repair modality?	Autologous flap repair without patch
CATHETERIZATION PROCEDURES			
Valverde et al. (18)	Aortic arch hypoplasia		Planning and training for the stenting
Olejnik et al. (17)	Complex CHD	Collateral arteries	Indication for cath embolization, for PB stenting
	(Ambiguous spatial anatomical relationship)	PB morphology	

TOF, Tetralogy of Fallot; ROLSCA, retro-oesophagian left subclavian artery; TAPVR, total anomalous pulmonary veins return; 1V, one ventricle; DTGA, D transposition of great arteries; PAVSD, pulmonary atresia with ventricular septal defect; ROSC, retro-oesophagian subclavian artery; DORV, double outlet right ventricle; HTx, heart transplantation; RPA, right pulmonary artery; MAPCA, major aortopulmonary collateral artery; CPB, cardiopulmonary bypass; PB, pulmonary branch.

For these extracardiac structures, the better understanding of the anatomy and more convenient viewing of the structures facilitated the surgical planning and access to the vessels to be treated. When cardiopulmonary bypass was needed, some authors suggested that using 3D models could reduce the cross clamping time in complex cases but this has yet to be demonstrated Smith et al. (30).

Case Series Using 3D Models for Planning of Surgery: Where Do We Stand?

Three series attempted to demonstrate the benefit of 3D models in planning surgical procedures in congenital heart diseases (Table 3). Ma et al. (16) prospectively analyzed 35 cases of tetralogy of Fallot with 3D printed models. The authors' main objective was to compare printed models with intra-operative findings. They showed that the 3D printed models were reliable to predict intra-operative findings. This study confirmed the reliability of 3D models but focused on a defect in which decision-making is consensually easy.

Table 3

Studies about benefit of 3D printing technology in complex CHD's surgical planning.

References	Cases	CHD	Comparison	Result	
Ma et al. (16)	35	TOF	Prospective monocentric description	Better conditionnement and surgical planning	
			3D printed model vs. peri-operative funding		
Valverde et al. (14)	40	19 DORV, 8 TGA, 4 UVH	Prospective multicentric case - crossover	Surgery decision	Surgical planning
		5 large VSD	Stage 1 strategy with usual exams	3/12 conservative -> surgery	12/28 no change
		1 LVOTO/CCTGA	Stage 2 strategy with 3D printed models	1/28 surgery -> conservative	15/28 change
		1 heterotaxy	Stage 3peri-operative strategy		1/28 no surgery
		3 criss cross heart	<i>Decision-making/strategy/global contribution</i>	Global contribution of 3D	21/40 : no impact of 3D
					19/40 : impact of 3D
Zhao et al. (19)	25	DORV	Measure GA and VSD	0.094 accuracy	
			Prospective comparison : 3D (8) vs. usual (17)		
			Time : <i>CBP (min), ACC (min)</i>	Lower ventilation time 56.43 ± 19.74 ; $96.76 \pm$	
			<i>Ventilation (hours), ICU(days)</i>	Lower ICU 99.04 ± 16.13 ; 166.94 ± 90.30 p =	

TOF, Tetralogy of Fallot; DORV, double outlet right ventricle; TGA, transposition of great arteries; UVH, univentricular heart; VSD, ventricular septal defect; LVOTO, left ventricular outflow tract obstruction; CCTGA, congenitally corrected transposition of great arteries; GA, great arteries; CPB, cardiopulmonary bypass; ACC, aortic cross clamping; ICU, intensive care unit.

Valverde et al. (14) reported a multicentric prospective study using 3D models of complex CHD as double outlet right ventricle, complex transpositions of the great arteries, criss cross heart, and univentricular hearts. The design was a case-crossover method comparing the surgical indication using classical imaging modalities by a multidisciplinary team followed by the same process using 3D printed models, and finally compared to the surgical findings. In this study, the 3D models were considered helpful in optimizing the surgical planning in 50% of the cases. This interesting report does not give indication on the anatomical structures that were key to modify the decision and grouped a large variety of anatomies. It remains therefore difficult to foresee the indications for the use of 3D models for this purpose.

The third study by Zhao et al. (19) evaluated the benefit of the use of 3D models in 25 double outlet right ventricles. The end-point was clinically meaningful as they showed that ventilation time and ICU stay were shorter in the group analyzed with 3D models suggesting a shorter time in the operating room and/or a more appropriate strategy. This study clearly indicates that 3D models could help optimizing surgical planning in complex CHD. The limitation was essentially related to the unclear description of cases selection and randomization.

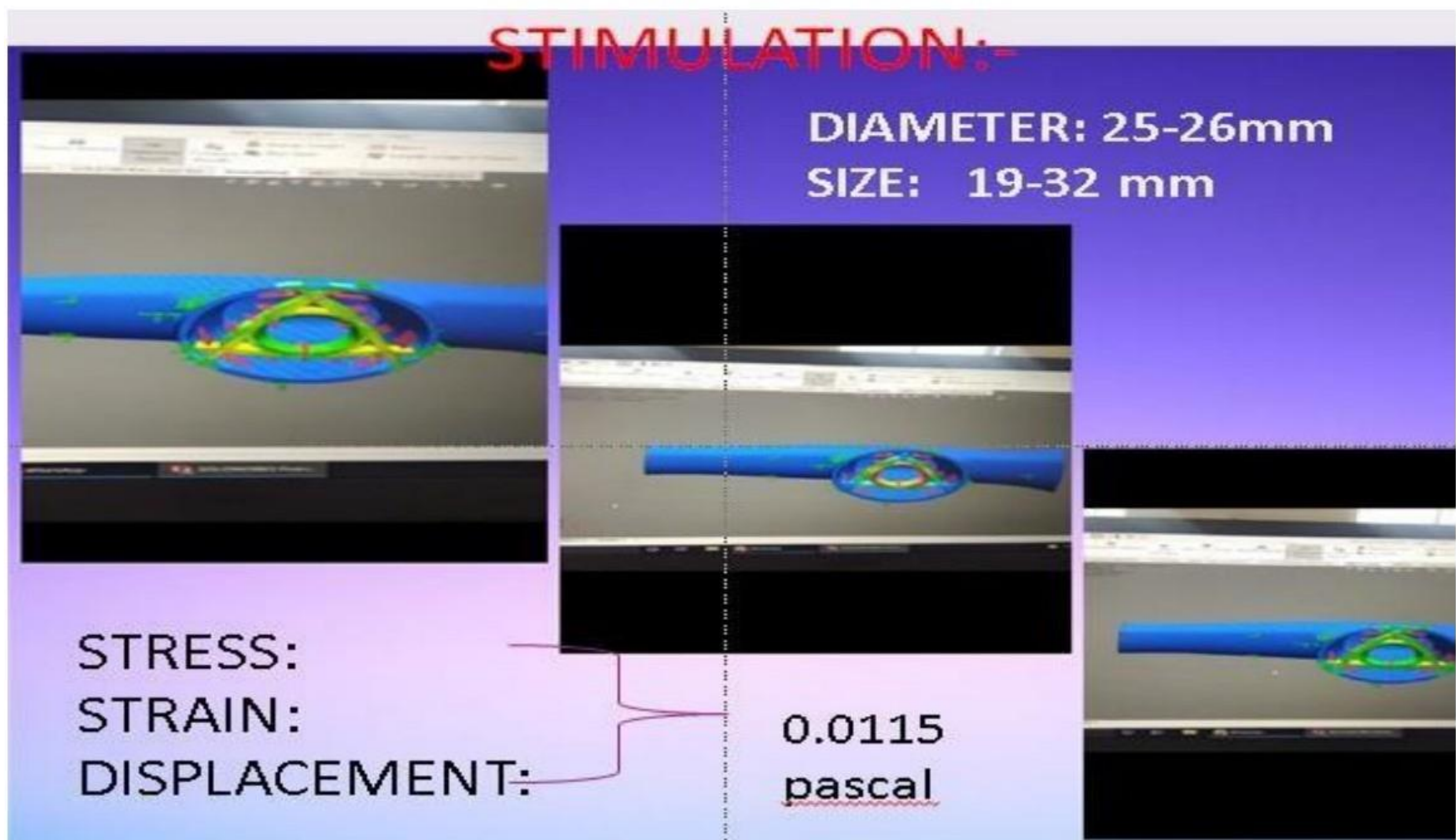


Fig.5.1. Stimulations of 3d pulmonary valve .

Discussion and Conclusion

The anatomical models demonstrate trends for reduced operating room and case length of time when compared with similar surgeries in the same time-period; in turn, these reductions could have significant impact on patient outcomes and operating room economics. While analysis did not yield robust statistical powering, strong Cohen's d values suggest poor powering may be more related to sample size than non-ideal outcomes. The utility of planning with an anatomical model is further supported by the technology acceptance study which demonstrated that surgeons perceive the anatomical models to be an effective tool in surgical planning for a complex CHD repair. A prospective multi-center trial is currently in progress to further validate or reject these findings.

How to Design a Study to Demonstrate the Benefit of 3D Models in the Surgical Approach of Complex CHD?

To be convincing, a clinical study using 3D models should have a clinically meaningful end-point. This type of hard end-point could only be obtained through a prospective study that will compare a homogeneous group of complex CHD. Hard end-points that could be obtained in the operating room (cross-clamping time) are questionable as the variety of procedures and surgical skills are difficult to control. In addition, the surgical strategy can certainly not be completely planned due to the diversity of the defects and associated anomalies. Post-operative end-points such as ICU stay may also be patient dependent and therefore randomization and stratification strategies would lead to an excessive number of patients to be included. We estimate that the first step to demonstrate the convenience and usefulness of 3D models in complex CHD should be a retrospective study aiming to compare the added value of 3D models to usual multimodality imaging to plan surgical repair. Indeed, the group of malposition of the great arteries is the most challenging group of CHD and the different surgical techniques available for biventricular repair require a precise evaluation of intracardiac anatomy. The primary end-point of this type of study

could be the proportion of predicted surgical repair using conventional imaging modalities without or with the 3D model. Secondary or exploratory end-points that would be of interest are the additional information obtained from 3D models and potentially the optimization of surgical strategy. Cardiac surgeons, congenital cardiologists and radiologists should be involved and blinded of the final procedure (Figure 1).

This type of retrospective design might prove the complementary value of 3D models in planning surgical repair in this group of patients. If positive, a prospective design with hard end-points could be built to attempt to show a clinical benefit in a larger population.

An immediate and friendly use of these models would be for teaching purposes. Indeed, organizing hands-on session with specimen is always a complex process and this is possible only in institution who have a collection of specimens. The presence of a trained anatomist is mandatory and the risk is to damage the specimens during this type of teaching session. 3D printing is an elegant way to transmit anatomical knowledge in complex CHD. The 3D models can be obtained from living patients but they can also be obtained from high resolution CT of specimen. We are currently scanning our collection to build a virtual and printed new collection of CHD specimen with the objectives to preserve it and to teach CHD anatomy.

Conclusion and Perspectives

3D modeling and 3D printing technologies are reliable and suitable for the analysis of congenital heart diseases. Hitherto, however, 3D has its own limits and potential bias, related to the part of subjectivity in the process of modelizing CHD. Today, it remains an additional tool in the decision making for complex CHD. There is a need to improve the process for obtaining and manipulating 3D models in the daily clinical practice. The final step would be to use 3D models as a summary of the diagnosis in a given patient and as a reliable tool to decide which treatment has to be applied. This evidence-based information should be obtained through studies with clinically meaningful end-points.

Fig.5.2 Existing system and proposed system

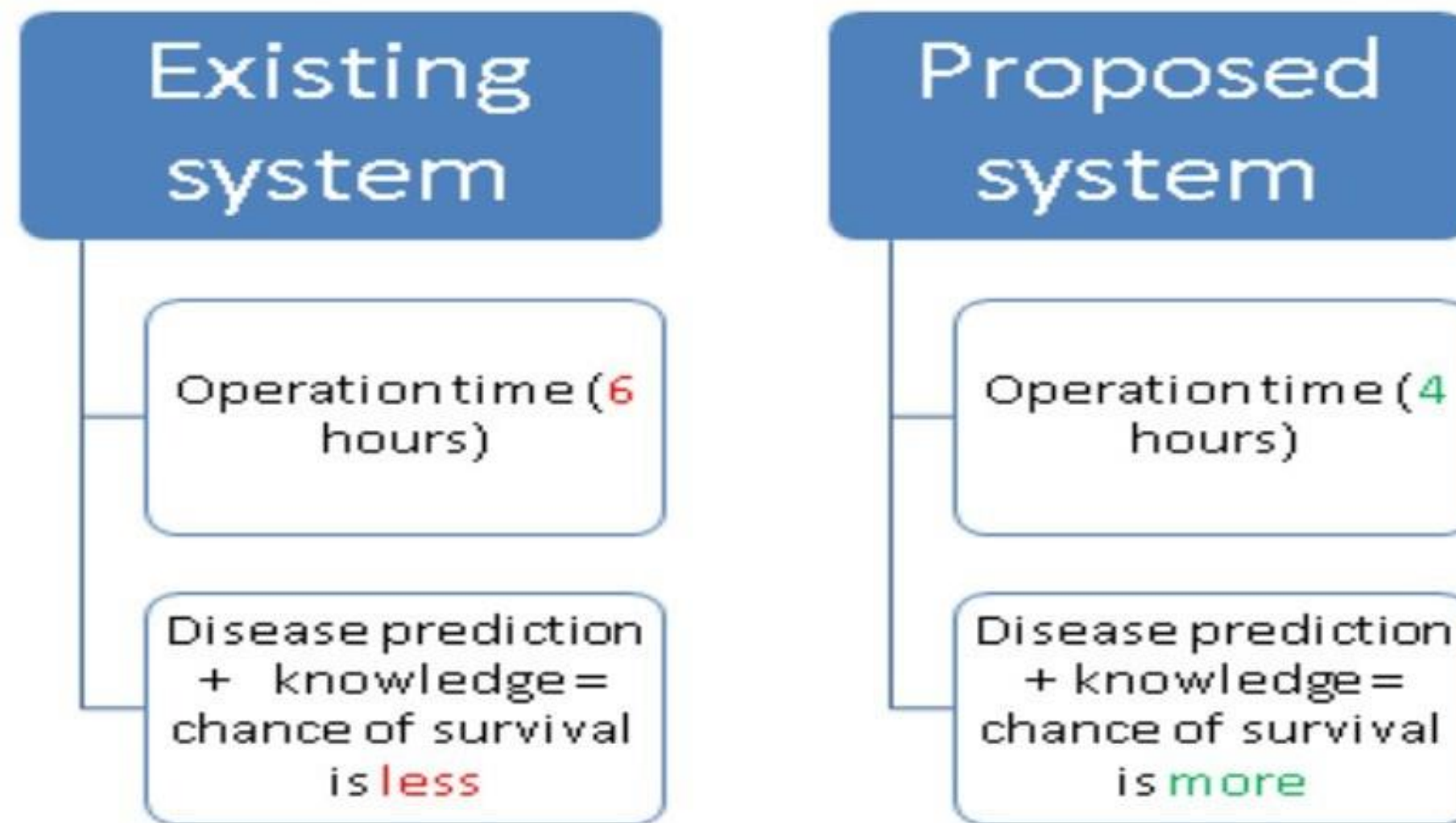


Fig.5.3 Existing and proposed system of prototype

3D technology can be used to improve the understanding of anatomy of complex CHD and to guide surgical strategy. However, there is a need to design clinical studies to identify the place of this approach in the current clinical practice.

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