

# **Impact of Pre-Procedural Planning with 3D Printed Cardiac Models for Ventricular Assist Device Placement in Patients with Congenital Heart Disease**

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## **A. Study Purpose and Rationale:**

Congenital heart disease (CHD) is the most common type of major congenital malformation and the leading cause of mortality from birth defects. Up to twenty five percent of patients with CHD will progress to heart failure (HF) by age 30. Patients with complex CHD include those with lesions such as double outlet right ventricle (DORV), transposition of the great arteries (TGA), and those with single ventricle palliation, among others. This population is at the highest risk for developing HF. Ventricular assist devices (VADs) are mechanical pumps, which are surgically placed in the chest to augment cardiac output in patients with heart failure. Utilization of VADs in patients with CHD and HF remains rare due in part to the highly variable anatomy and complex physiology in this population. Anatomic factors, which play a role in potentially complicating VAD placement, are numerous in patients with CHD. Specifically, ventricular dilation and presence of trabeculations and abnormal vascular anatomy make the delineation of inflow and outflow cannula placement particularly challenging.

While advanced imaging techniques such as cardiac magnetic resonance imaging (CMR) or computed tomography (CT) aid cardiothoracic surgeons in pre-surgical planning for VAD placement in this population, it remains a challenge to adequately depict all of the components of a complex patient's cardiac anatomy in a two dimensional (2D) imaging dataset. Three-dimensional (3D) printing, a technology that is quickly gaining utility in the medical field, enables the creation of patient-specific physical anatomic models from a patient's 3D imaging data. 3D printed models provide a physical guide to understanding the anatomic features that can make VAD and cannula placement challenging in patients with CHD.

The goal of this study is to assess the utility of using 3D models in the planning of VAD placement in patients with complex CHD. We will survey cardiac surgeons regarding the utility of the 3D models in visualizing the anatomy and planning an approach to device implantation before and after the procedure. These results will be compared to controls, in which traditional two-dimensional images are used for pre-surgical planning. It is expected that the use of 3D models will enhance understanding of complex anatomy and ultimately cut down on procedure times. We hypothesize that patient specific 3D printed models will allow more informed preoperative planning with clear demonstration of the best site for inflow cannula, outflow cannula and VAD placement leading to better surgical preparedness, less operating room time and improved patient outcomes.

## **B. Study Aims:**

**AIM 1: To assess if a 3D printed cardiac model improves visualization of VAD and cannula placement sites in CHD-HF patients as compared to 2D imaging.** We will prospectively enroll CHD-HF patients at multiple centers and randomize to group A (3D printed models will be used for pre-VAD planning) or Group B (controls). For patients in Group A, the surgeon performing the procedure will complete a questionnaire 1) after reviewing 2D imaging data and 2) after reviewing a patient specific 3D model. Our primary outcome measure will be an improvement in the clarity of cannula and VAD site demonstration. We hypothesize that the 3D models will more clearly demonstrate the sites of cannula and VAD placement as compared to 2D imaging.

**AIM 2: To determine if perioperative factors and patient outcomes improve in CHD-HF patients with use of 3D printed model versus traditional imaging in VAD placement planning.** Clinical characteristics will be collected at the time of enrollment including primary diagnosis and indication for VAD. After VAD placement, information regarding the intraoperative and postoperative course will be collected including surgical cardiopulmonary bypass time (CPB), need for cannula repositioning and length of stay. Longer CPB increases morbidity and mortality and is associated with intensive care readmission in patients after LVAD placement. Our primary measures of improvement will be CPB and length of stay. We hypothesize that the improved preoperative planning based on the 3D models will lead to a decrease in CPB time and decreased length of stay.

### **C. Location of the Study**

The primary center for this study is New York Presbyterian, Columbia University Medical Center. Nine other centers to date have agreed to serve as collaborating centers.

1. Montefiore Medical Center, Albert Einstein College of Medicine, New York
2. University of Iowa, Iowa
3. Mayo Clinic, Rochester, Minnesota
4. University of Michigan, Ann Arbor, Michigan
5. UT Southwestern, Texas
6. Washington University School of Medicine, St. Louis, MO
7. Harvard University, Boston, MA
8. Heart Institute, Mexico City, Mexico
9. Johns Hopkins, Baltimore, MD
10. Case Western Reserve University, Cleveland, OH
11. Nationwide Children's Hospital, Columbus, OH
12. Montreal Heart Institute, Montreal, Canada

All participating centers will be required to complete their own IRB in order to be part of this study.

### **D. Study Design**

#### **Registry Inclusion**

Patients over age 13 with congenital heart disease and clinical heart failure who are candidates for MCS will be prospectively identified at the participating centers. After identification, informed consent or assent will be obtained and preoperative clinical data will be collected. Exclusion criteria: Any CHD-HF patient unable to tolerate a CMR or CT will be excluded.

#### **Transfer of Images**

The cardiac MRI or CT images will be uploaded to an online secure website, Lifeimage, by the participating institution. Lifeimage is a cloud based, medical image sharing and viewing website, which is HIPAA compliant and secure. The images will then be accessed for post-processing.

#### **Image post-processing**

We will be able to use software, which is licensed by the Division of Pediatric Cardiology, Mimics (Materialise©, Belgium) to post process the cardiac imaging datasets. Post-processing involves isolating the area of interest (AOI) by segmentation. Blood pool segmentation will be used to create the 3D models in all patients. After segmentation, a preliminary 3D virtual model will be created, which will be edited to exclude extra cardiac structures. The 3D object will be cropped to best demonstrate the relevant anatomy of interest for each patient and subsequently stored as a stereolithography file (STL).

**Rapid prototyping/3D printing**

A Stratasys J750 3D printer will be used to create cardiac models with fine resolution and excellent anatomic detail. This printer is able to print in a soft tissue like material, which will mimic the consistency of myocardium. In addition, a hard plastic model will be printed to provide a rigid replica of the cardiac anatomy for each patient. An additional hard plastic model will be created for our center (CUMC) to keep a library of the models created for this study as well as to ease any further communication between our center and other centers regarding anatomic details of a specific patient.

**Aim 1. Preoperative, intraoperative and postoperative assessment**

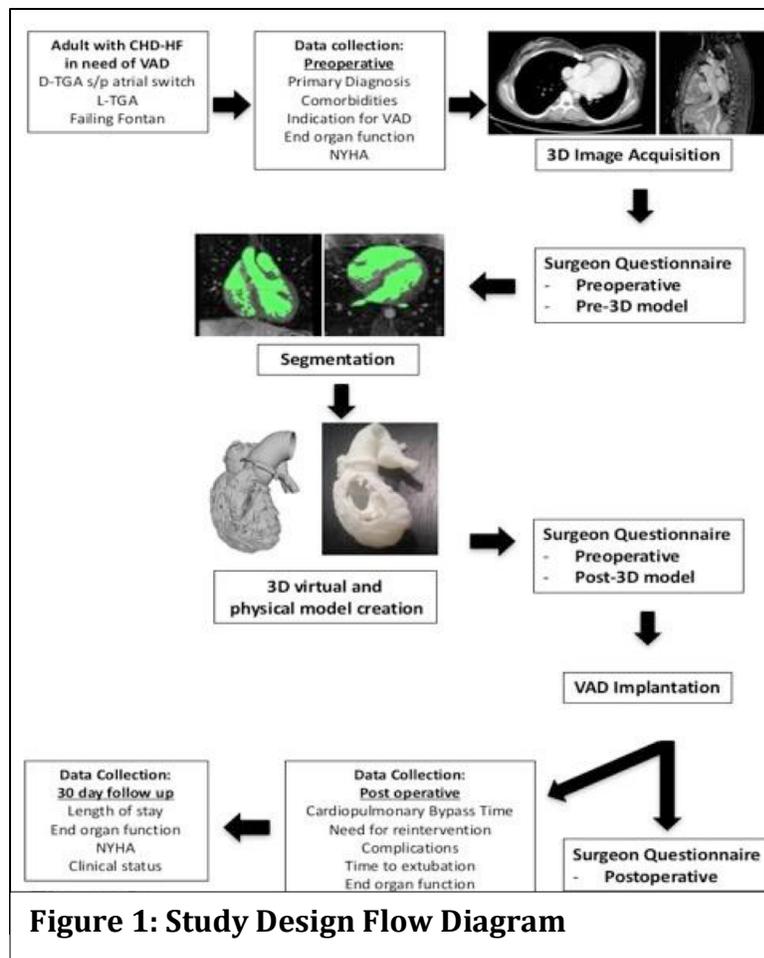
The surgeon will complete a questionnaire once the initial patient data including the 2D imaging data has been presented to him or her, prior to the 3D model being examined. Once the 3D printed model is received, the surgeon will fill a second questionnaire. The final questionnaire will be completed in the postoperative period in to assess the accuracy and utility of the model.

**Aim 2. Clinical variable collection**

The initial clinical variables will be collected at the time of enrollment. After the surgical repair, additional relevant intraoperative variables such as need for cannula repositioning, CPB time and estimated blood loss will be collected. Our primary outcome variable will be cardiopulmonary bypass time. Our secondary analysis will assess for improvement in VAD flows and decrease in the need for revision of VAD or cannula placement.

**30-day postoperative assessment**

Further data will be collected at the 30-day time point, mainly relating to patient postoperative course, recovery and clinical outcome. We will be focusing on identifying improvement in 30-day mortality and decrease in the need for VAD revision with 3D model use preoperatively. Information regarding postoperative course including the need for inotropic or respiratory support, renal and liver function, arrhythmia, bleeding complications or stroke will also be collected.



## E. Statistical Analysis

For Aim 1, improvement in survey responses regarding clarity of VAD or cannula site placement will be analyzed using chi-squared tests. Sample size calculations are based on improving the delineation of any of four anatomical elements (placement of the inflow cannula, placement of the outflow cannula, possible cannula obstruction, and location of the ventricular apex) using the 3D model. We also assume a one-sided test of significance, as it is not expected that the 3D model will worsen the anatomical delineation compared with the usual 2D models. Since there are four possible ways to improve the delineation, we compute sample size effects using an alpha value of 0.0125, based on the Bonferroni criterion (0.05/4) for independent hypothesis tests. Assuming an effect size of 0.25, and 62 subjects, the McNemar test would have 80% power, assuming that the proportion of discordant pairs is 0.4. If recruitment is as little as 29 subjects, then the study will have 80% power to detect an increase of 0.35. Because the Bonferroni criterion is very conservative in general and even more so in the case of dependent tests, we expect the actual power to exceed these nominal powers.

Additionally, for Aim 2, clinical variables will be compared between the control and model groups. Our main analysis of the collected clinical variables will be a comparison of cardiopulmonary bypass time using a t-test. 44 subjects in each arm (3D model and control) will be recruited to achieve 80% power assuming a 20-minute decrease in cardiopulmonary bypass time.

Other outcome continuous variables include VAD placement time, estimated blood loss, days of



**Table 2. Postoperative Surgical Questionnaire-** Fill immediately postoperatively.

1. The 3D model was an accurate representation of the patient's anatomy.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
2. The 3D model gives me additional spatial information of the congenital heart disease as compared to only using standard modes of imaging.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
3. The 3D model helped me in planning the surgical approach I will use for this patient.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
4. The 3D model was able to delineate the site of inflow cannula placement  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
5. The 3D model was able to delineate the site of outflow cannula placement  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
6. The 3D model was able to delineate possibility of inflow cannula obstruction by trabeculae  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
7. The 3D model was able to delineate the location of ventricular apex  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
8. The 3D model helped me in planning the surgical approach I will use for this patient.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
9. I would prefer inclusion of 3D cardiac models for such patients for planning of ventricular assist device placement in the future.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
10. I believe that using the 3D model for presurgical planning decreased the time it took for VAD placement.  
Strongly Disagree      Disagree      Neutral      Agree      Strongly Agree
11. I would estimate the time saved or lost (please specify) during VAD placement to be \_\_\_\_\_minutes due to 3D model use for presurgical planning.

**Table 3. Preoperative Clinical Information**

Initials:	Sex: M/F	Date:	Race:	Ethnicity:	DOB:	Ht:	cm	Wt:	kg
Primary Diagnosis:	DTGA	LTGA	Fontan Dx:	Other					
Secondary Diagnosis:	Chromosomal abnormality:			Syndrome:					
Previous Surgeries:									
Indication for VAD:									
Respiratory Support: None					Mechanical Ventilation				
Inotropic Support: None					Continuous Infusion				
Cardiac Medication: Diuretic			ACE	ARB	Other:				
Arrhythmia: Y/N	Type: A flutter/ Afib/ Vtach				Pacemaker: Y/N				
NYHA: I	II	III	IV						
Labwork - BUN/Creatinine:				Direct Bili			Total Bili		
Albumin	AST	ALT	BNP	PT	PTT	INR	Hct	Fe	
Imaging – Modality: Echo/MRI/CT      Date of study:      /      /									
Ventricular function: LVEF %, LAVVR- qualitative									
RVEF (qualitative by echo, quantitative by CMR), RAVVR- qualitative									
Single V (qualitative by echo, quantitative by CMR), cAVVR - qualitative									
Cath – Cardiac Output: (method) PAp : Sys/Dias      PCWP      CVP									

### G. Confidentiality of Study Data

A REDCAP database will be created for data entry from each of the centers. Each center will be responsible for submitting clinical variables as well as answers to the surgeon surveys at three different time points. All study data will be coded, and a code number should be used for all study subjects. Data will be stored in a secure location, accessible only to the investigators.

## Citations:

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