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PROJECT COMPLETION REPORT

1. **Project Number** : P6236
2. **Title of the Project** : RECONSTRUCTION GEOMETRY OPTIMIZATION AND METHODOLOGY DEVELOPMENT USING COMPUTATIONAL FLUID DYNAMICS EVALUATION FOR PATIENT SPECIFIC VASCULAR MODEL ACQUIRED BY MRI SCANNING
3. **Funding Agency Name** : TDF - SCTIMST
4. **Project Reference Number provided by the Funding Agency:**
P6236
5. **Principal Investigator (Name & Address):**
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7. **Implementing Institution** : SCTIMST
8. **Collaborating Institutions** : Nil
9. **Date of Commencement** : 04/01/2020

10. Duration : 3 Years

11. Date of Completion : 06/04/2023

12. Objectives as approved :

To develop a methodology for the prediction of least resistant blood flow path with low energy loss using Computational Fluid Dynamics based on the vascular structure of the patient undergoing Fontan operation.

13. Deviation made from original objectives if any, while implementing the project and reasons thereof : Nil

14. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs :

The Fontan procedure is the current strategy of choice to palliate single ventricle congenital heart defects. This surgical procedure must be accomplished through several stages since a complete right heart bypass is impossible at birth (vessels are too small and pulmonary vascular resistance is too high). The end result of this procedure is referred to as a total cavopulmonary connection (TCPC), where deoxygenated blood returning from the body bypasses the heart and moves passively to the lungs. This configuration successfully separates oxygenated and deoxygenated blood, but creates a one "pump" circulatory system. The Fontan completion surgery is the last stage of the surgery in which IVC is disconnected from the heart and connected to the Pulmonary Artery.

The workflow is as follows.

WORKFLOW

MRI Scan Data
3D Model construction from the MRI Data
CFD Analysis model creation
Identification of important parameters and key functions
Prediction of blood path from the pre surgery MRI data using CFD
CFD analysis of post-surgery case to understand the flow parameters
Comparison of performance of predicted flow path and real surgery flow path

Patient Selection - All stage 2 bidirectional Glenn patients waiting for Fontan completion surgery was selected for the study. Usually this operation is done for the children whose age will be less than 15 years. Here a total of 10 patients pre-operative and post-operative MRI flow data were collected for the study. Information regarding the project study was described in Patient Information sheet were given to patients and parents. Also Informed consent and Child Assent forms were collected from patients as per the Institute Ethics committee rules. Ethical approval was obtained from Institute Ethics Committee. During the cases selection process, only cases with patients aged from 0–15 years old were included. Consent from the participants were taken and full information about the study was given to participants using Patient Information Sheet, Informed consent and child assent form.

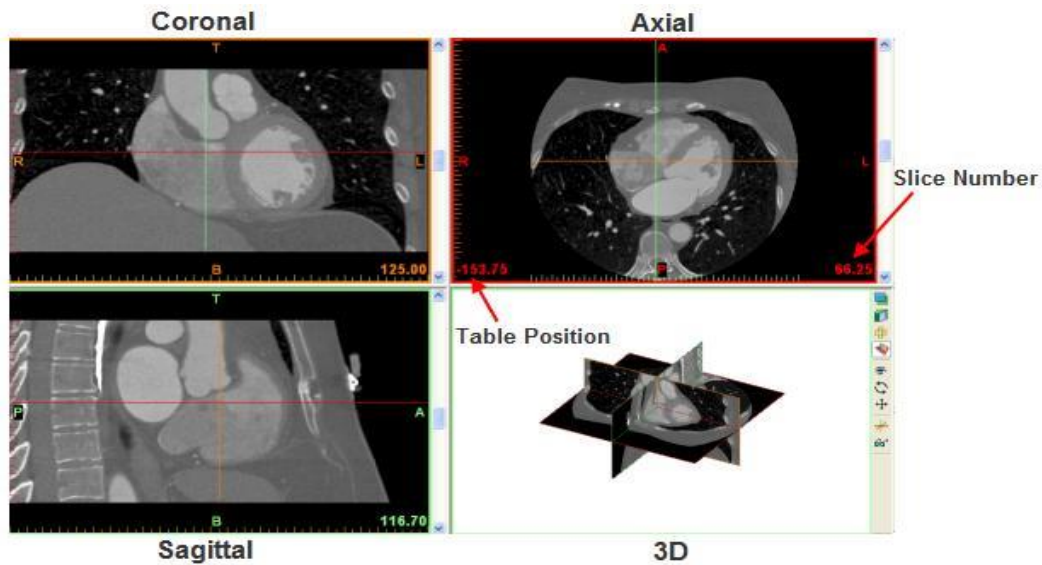
The data includes the MRI data and pressure values at IVC, SVC, LPA and RPA and also the flow values through these vessels.

Image Acquisition - Image acquisition is the first step that is already integrated into the workflow. The most common imaging methods useful for 3D printing are CT and MRI. In general, 3D models can be printed from any volumetric image dataset (slices) with sufficient contrast to differentiate tissues. All MRIs were performed at SCTIMST with Siemens 1.5 T magnetic resonance imaging systems (Siemens Medical Solutions, Malvern PA). Patients were scanned supine, head first in the scanner with ECG leads placed under a breath-held protocol. After localizers were obtained, a stack of contiguous, static, diastolic steady state free precession (SSFP) images were obtained from the diaphragm to thoracic inlet to assess anatomy and provide inputs for CFD modeling. Slice thickness was generally 1-5 mm and in plane resolution was 1.2x1.2 mm. MRI was used to assess flows in the cavae, branch pulmonary arteries, pulmonary veins and across the aortic valve. IVC flow was measured supra-hepatic.

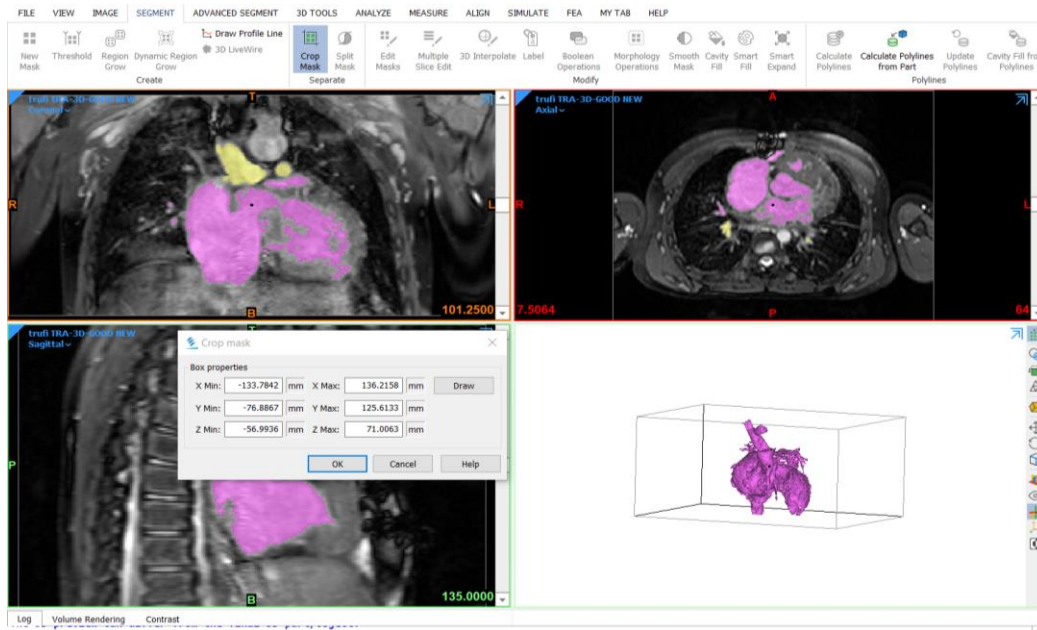
Image segmentation - Mimics (**M**aterialise's **I**nteractive **M**edical **I**mage **C**ontrol **S**ystem) is Materialise's software for processing medical images and creating 3D models. Mimics uses 2D cross-sectional medical images such as from computed tomography (CT) and magnetic resonance imaging (MRI) to construct 3D models, which can then be directly linked to rapid prototyping, CAD, surgical simulation and advanced engineering analysis.

The medical images coming from CT or MRI scanners consist of grayscale information. Mimics allows the user to create models based on the grayvalues (Hounsfield units in CT

images) within these images. A grayvalue is a number associated with an image pixel defining the shade (white, gray, or black) of the pixel. There is a direct association between material density of the scanned object and the grayvalue assigned to each pixel in the image data. Because of this, Mimics has the flexibility to create models from any geometry distinguishable within the scanned data. By grouping together similar grayvalues, the image data can be segmented, and models created. This type of segmentation is called thresholding and yields accurate models.



The data segmentation process includes thresholding, windowing, Masking, volume rendering, Interpolating, smoothing etc. and three surgical options were created for each patient by introducing a conduit between the IVC and PA. The length of the conduit and the location of the conduit joining the PA were altered to make multiple surgical options. These models were exported as geometry file.



CFD Analysis - The Analysis was done in the Ansys workbench version 18.2. The prepared geometry file from MIMICS was used here as input. The meshing was done using ICEM CFD and analysis was ran in Ansys CFX.

Evaluation Parameters - Two parameters were used to evaluate the performance of the surgical planning efficiency and configuration optimization, Power loss in the circuit and the Hepatic flow distribution.

15. Detailed analysis of results :

Publication under process. Will be updated once its published.

16. Summary sheet of not more than 2 pages under following heads :

(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

Title : RECONSTRUCTION GEOMETRY OPTIMIZATION AND METHODOLOGY DEVELOPMENT USING COMPUTATIONAL FLUID DYNAMICS EVALUATION FOR PATIENT SPECIFIC VASCULAR MODEL ACQUIRED BY MRI SCANNING

Introduction: The incidence of children born with a SVHD, in which there is one effective cardiac pumping chamber. In patients with such an anatomy, oxygenated and deoxygenated blood mix in the single ventricle.

Without surgical intervention this set of lesions is generally lethal, resulting in 95% mortality within the first month of life.

The currently accepted palliation strategy culminates in the total cavopulmonary connection (TCPC), which is generally performed in two stages, progressively separating the systemic and pulmonary circulations.

The first stage, also called a Bidirectional Glenn procedure or Hemi-Fontan , involves redirecting oxygen-poor blood from the top of the body to the lungs. That is, the pulmonary arteries are disconnected from their existing blood supply. The superior vena cava (SVC), which carries blood returning from the upper body, is disconnected from the heart and instead redirected into the pulmonary arteries. The inferior vena cava (IVC), which carries blood returning from the lower body, continues to connect to the heart. Usually this surgery is done around 4-6 month age.

The second stage, also called Fontan completion, involves redirecting the blood from the IVC to the lungs. At this point, the oxygen-poor blood from upper and lower body flows through the lungs without being pumped (driven only by the pressure that builds up in the veins). This corrects the hypoxia and leaves the single ventricle responsible only for supplying blood to the body. Usually this surgery is done around 4-5 year age.

The modifications to the original Fontan procedure, as well as improved management and care, have steadily improved surgical outcomes, reducing post-operative mortality to the level of many biventricular congenital heart disease repairs. However, Fontan patients are still susceptible to numerous, long-term complications. While most institutions now report 95% post-operative survival rates, the 10-year survival rate drops to 60–80% . The fact remains that the Fontan procedure results in a non-physiologic cardiovascular configuration where the single ventricle has to pump blood through both the systemic and pulmonary vascular beds in series. As a result, the single ventricle experiences an increased afterload (including both systemic and pulmonary vascular resistances) and decreased preload (ventricular filling). In addition, there is a significant increase in central venous pressure due to the lack of pressure step-up typically provided by the right ventricle.

Rationale : The most severe single ventricle anomalies necessitate multiple surgeries for palliation. The ventricle is bypassed during the Fontan surgery by using a conduit to route blood from the inferior vena cava (IVC) to the pulmonary circulation. The resulting configuration enables the body to function with just one functional ventricle while preventing the mixing of oxygenated and deoxygenated blood by placing systemic and pulmonary circulation in series. Though the Fontan procedure offers promising short-term outcomes, serious complications such as PAVMs, and exercise intolerance can occur as patients age. The alterations in hemodynamics brought on by Fontan physiology contribute to the emergence of these complications. Because of improvements in medical imaging technology and the planned nature of the Fontan procedure, it is predicted that using "surgical planning" to preoperatively optimize relevant hemodynamic factors may enhance patient outcomes. Engineers and clinicians work together to plan the Fontan procedure.

Preoperative image acquisition, image processing, the development of virtual surgical configuration, and numerical simulations of those suggested possibilities to find the optimum configuration are the main phases. Communication between clinicians and engineers is crucial to validate segmented images, discuss the plausibility of surgical choices, and analyzing simulation results. Ultimately, the goal of surgical planning is to evaluate the effectiveness of different surgical choices and, as a result, assist in making decisions about the type and placement of grafts.

Minimizing energy loss in the TCPC, giving a balanced HFD to the left and right lungs, and preventing excessive wall shear stress have been the main objectives of Fontan surgical planning. Extreme wall shear stress (both low and high) may be prone to clot or blood damage, respectively. Energy loss has been linked to exercise intolerance and is predicted to impair overall patient success, and HFD is a known factor in PAVM progression. Therefore, clinicians must determine which surgical consequence is most concerning for a patient when one surgical procedure is not best for all metrics. For instance, surgical planning may be motivated by the advancement of PAVMs, which would emphasize establishing balanced HFD.

The present surgical planning tools provide accurate modeling of the preoperative condition, anatomical restrictions for suggested surgical alternatives, and reasonable forecasts of the postoperative state. Further advancements on the engineering and clinical fronts are required to advance the efficacy and usability of Fontan surgical planning, building on these early triumphs. Validation using postoperative data, more accurate boundary conditions from the MRI data that will improve the quality of the prediction, and automation are the steps ahead. Globally, only a few select centers presently use Fontan surgical planning, which uses computational modeling and CFD analysis to forecast the ideal postoperative hemodynamic conditions. In India, this is still in the budding stage, and the whole process must be developed and validated in the clinical settings before this can be implemented in the patients.

Methodology : Three-dimensional models will be constructed(using MIMICS) of typical Fontan and bidirectional Glenn operations according to anatomic data derived from magnetic resonance scans. MRI data will be taken before and after surgery. Geometries will be discretised using meshing software(ANSYS Meshing). Boundary conditions to be imposed, and fluid dynamics will be calculated from a Computational Fluid Dynamics(CFD) code(ANSYS). Energy losses, flow distribution to each lung, pressures and flow field will be calculated for the circuit. Pre surgery data will be used to find path with minimum energy loss using CFD. The post-surgery model also will be analysed for various performance parameters. A comparative study between these two will be done. All the results will be validated against in vitro studies and the available patient data.

Results : Publication under process. Will be updated once its published.

Translational Potential : Even though there is not much market currently for such type of surgical planning, few companies like Osteo3D, Anatomiz3D etc already are in surgical planning for ortho related products. So there is a potential market in nearby future for surgical planning related to operations like fontan. And the service providing companies which already are using these softwares can give this as add on service for extra revenue generation.

17. Contributions made towards increasing the state of knowledge in the subject :

This is a procedure development on how to incorporate new technology into the existing procedure and can bring better outcomes for the patients.

18. Conclusions summarising the achievements and indication of scope for future work :

The study was done in a very limited sample, and in order to validate the findings of the data, we need to do the same study on larger sample. We have applied for Extramural fund with the pilot data and already received a finding to continue the study on larger sample size.

19. Science and Technology benefits accrued :

a. List of research publications with complete details :

One Publication under process.

20. Abstract: (In 300 words for possible publication in Bulletin)

a. Background:

b. Materials:

c. Results:

d. Conclusion:

Publication under process. Will be updated once its published.

21. Procurement/Usage of Equipment:

a. Details of Equipment:

b. Suggestions for disposal of equipment(s):

Nil



Saurabh S Nair
30/11/2023

Name and Signature of PIs with date)