Evaluation of Stent and Baffle Deformation in Hybrid Comprehensive Stage II Procedure

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INTRODUCTION

Hypoplastic Left Heart Syndrome (HLHS) is a Congenital Heart Disease (CHD) where the left side of the heart is malformed, including the deformation of the left ventricle and diminutive aortic and mitral valves. The existing three-stage palliative procedure for HLHS has potential for a multitude of complications leading to a 50% survival rate. To reduce the morbidity and mortality rate and mitigate the trauma associated with the procedure, an alternative technique, Hybrid Comprehensive Stage II (HCSII), featuring the inclusion of a stent and baffle in the left and right pulmonary arteries is proposed. The stent included in Hybrid Stage II has potential to become fractured as a result of oscillatory asymmetric external loads with high local load concentrations. A bench top study shows the effects of fluid pressure on the stent and baffle to infer long term complications.

OBJECTIVE

The objective of this study is to determine the degree to which hydrodynamic loads on the systemic side affect the baffle and stent complex deformation on the pulmonary arteries.

METHODS

MFL:

- The mock flow loop (MFL) was tuned according to the two sets of given catheter data, namely two 6 months old infants with Body Surface Area (BSA) of approximately 0.54 m^2 and 0.36 m^2
- The MFL is based on a reduced lumped-parameter model (LPM) of the HCSII circulation, comprised of upper and lower systemic compartments, as well as left and right pulmonary compartments.
- Tuning of Mock Flow Loop
  - Upper Systemic Circulation - 30% of total Cardiac Output
  - Lower Systemic Circulation - 70% of total Cardiac Output
  - Right and Left Pulmonary Circulation - 60% and 40% of Upper Systemic circulation respectively

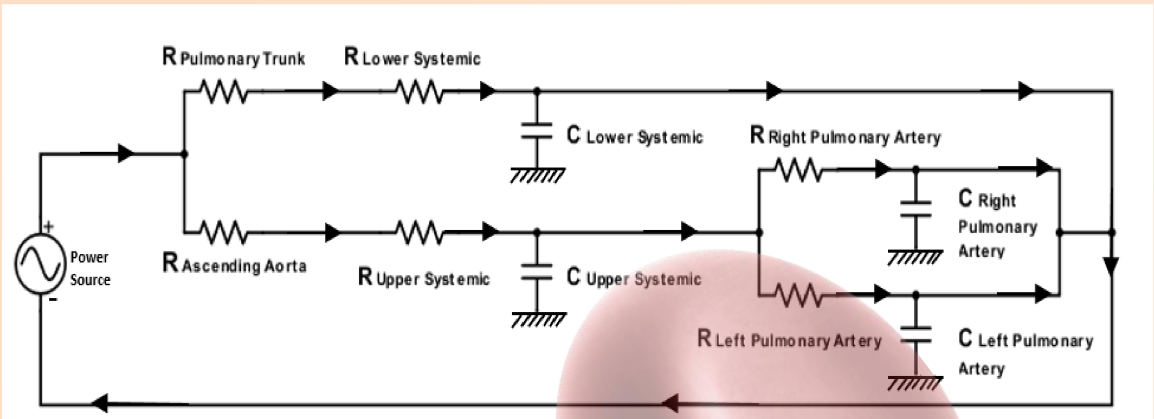

Fig. 2: Lump Parameter Model of Hybrid Comprehensive Stage II

- A custom made viscous fluid with 35% glycerin & 65% water by volume is developed as working fluid to match the viscosity of blood i.e. 4cP.
- Hemodynamic parameters were acquired via a National Instruments multichannel data acquisition board and processed using an In-house developed signal processing scheme involving FIR and IIR filters.
- Real time baffle deformation over every cardiac cycle is analyzed using an In-house video processing code developed in OpenCV.

Stent FEA:

- The FEA simulation was set up to determine stent deflection for a constant peak pressure load.
- The stent geometry was generated as a CAD model in Solidworks.
- The destination FEA code is Abaqus.
- The stent material is assumed to be isotropic 316L Stainless Steel with $\upsilon = 0.26$ and $E = 193GPa$.

MODELING AND EXPERIMENTATION

Anatomic Model

- The centerpiece is patient-specific, developed utilizing given CT scans
- The MFL consists of a centerpiece including the insertion of a single Palmaz Genesis (PG) 2510B stent covered with a baffle made of GORE PRECLUDE used for pericardial membrane patching within the main pulmonary artery bifurcation to keep systemic and pulmonary flows separated.

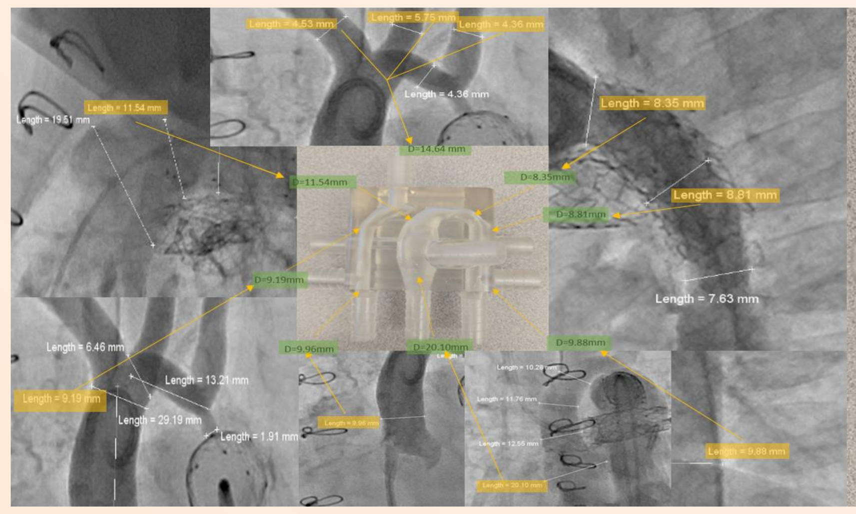

Fig. 3: Angiogram data applied to the development of centerpiece

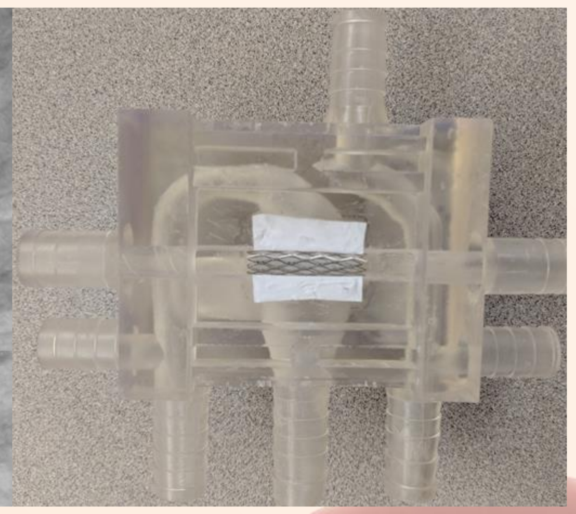

Fig. 4: Stent and baffle configuration in centerpiece

Flow Loop Configuration

- Each lump in MFL comprise of the following: a resistance valve, compliance chamber, flowmeter and pressure transducer.
- The Harvard apparatus pulsatile pump was used to replicate the patient specific cardiac outputs by adjusting following parameters.
- By tuning the resistors, the volumetric flowrate (Q) is matched to the desired flowrate observed in the patient specific catheter data.
- Three pressure transducer were connected to the centerpiece to measure Ascending Aorta, Descending Aorta and Pulmonary Trunk pressures.
- For the set flowrate and set compliance values, the analogous physiological values of pressure drops (ΔP) across the MFL lumps were compared with the pressures from the catheter data.

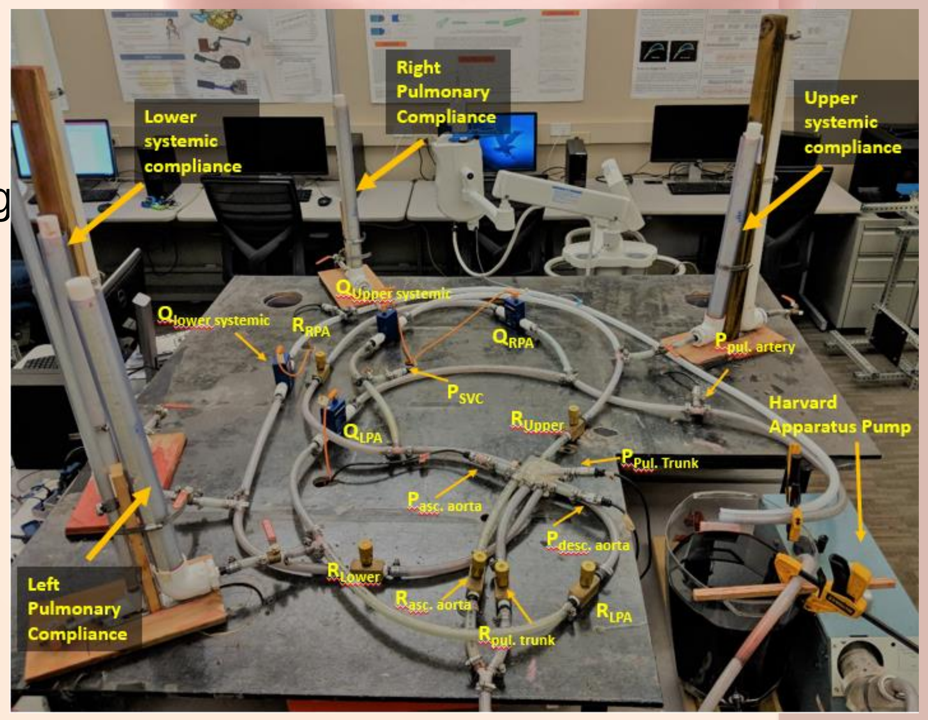

Fig. 5: HCSII MFL flow loop components

Image Configuration

- Through the inclusion of the digital video otoscope DE500, videos of the stent and baffle are captured during the testing of the MFL for evaluation.
- Videos of the stent and baffle are post-processed using a customized image processing algorithm written in OpenCV.
- Markings are placed on the baffle for reference points among the image processing technique to calculate displacement using pixel coordinates
- Stent measurements of length, thickness, and radius of curvature are collected subsequent to the running of the MFL utilizing Scanning Electron Microscope (SEM) images of the deflated stent.

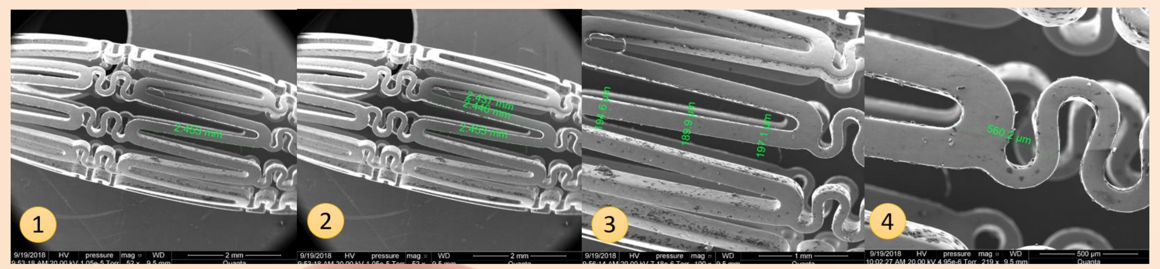

Fig. 6: SEM Images of deflated stent

Stent FEA

- The pressure load was directly applied on the stent over and area approximately equal to that of the baffle (red highlight in figure 7).
- To constrain the stent for this preliminary analysis the ends of the stent (orange highlights) are pinned as to prevent any displacement along the 3 axis.
- A uniform pressure load of about 85mmHg was the applied on the mock baffle area and a static analysis was carried out.

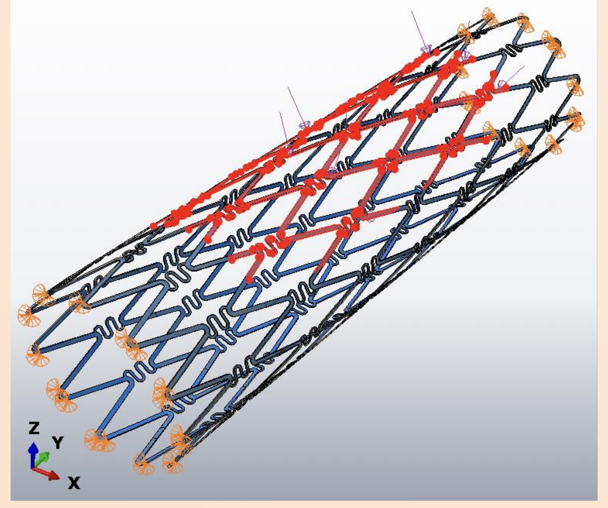

Fig. 7: Imported stent geometry.

RESULTS

MFL:

	Patient 1 Catheter Data	Patient 1 MFL Data	Patient 2 Catheter Data	Patient 2 MFL Data
Flow Rate (L/min)				
C.O.	2.99	2.94	1.75	1.7
Upper systemic	1.25	0.89	0.76	0.5
Lower systemic	1.74	2.05	0.99	1.2
Right Pulmonary Artery	0.75	0.53	0.45	0.3
Left Pulmonary Artery	0.50	0.36	0.31	0.2
Pressure Data (mmHg)				
Ascending Aorta	65	60	48	43
Pulmonary Trunk	65	60	52	48
Descending Aorta	54	45	50	44
Superior Vena Cava	9	15	15	17
Pulmonary Artery	8	11	11	16

Fig. 8: MFL data compared to given catheter data

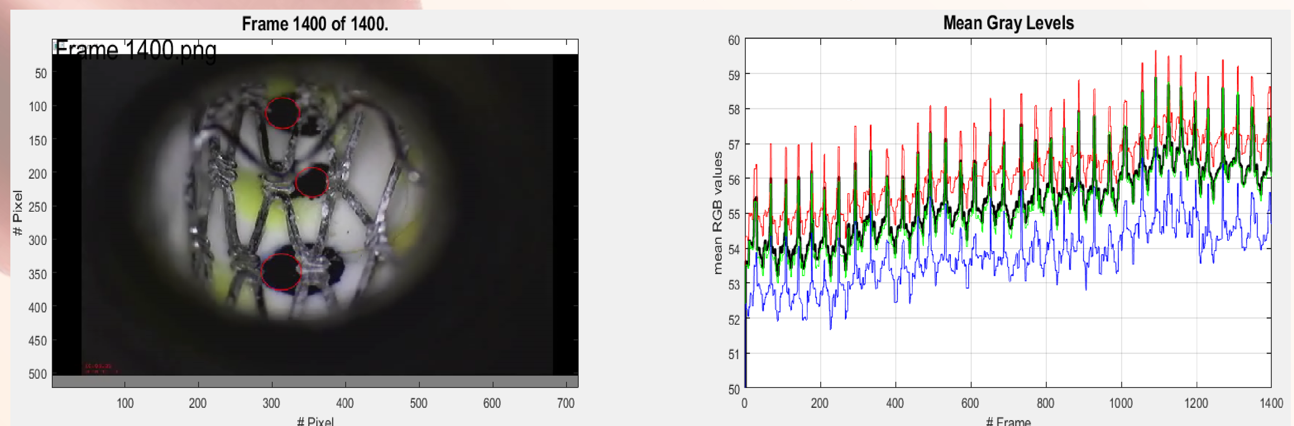

Fig. 9: RBG Values vs Pixel Values indicating pulsatile nature centerpiece mimics against the stent and baffle.

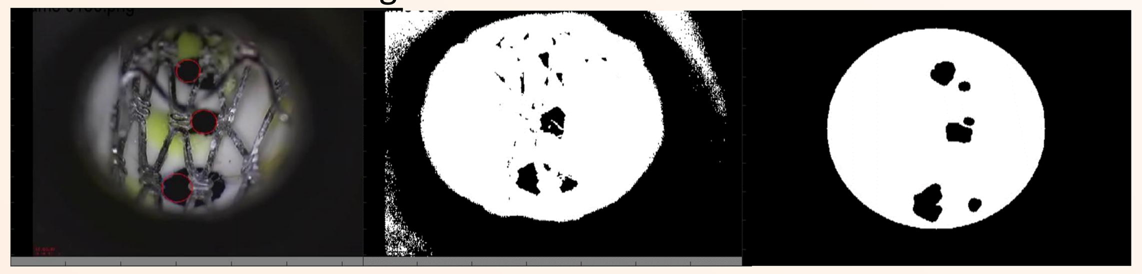

Fig. 10: Frames taken from video monitoring baffle deformation. Video processing begins with the original image (left) and is transformed to binary frames (middle), to achieve the result (right).

	Diastole		Systole	
Reference Point on Baffle	X	Y	X	Y
0	299.716	311.178	299.384	349.263
1	348.33	215.00	348.966	219.812
2	320.240	113.711	319.81	119.00

Fig. 11: Pixel coordinates compared from frame peak Diastole with peak Systole , displaying displacement of the reference points.

Stent FEA:

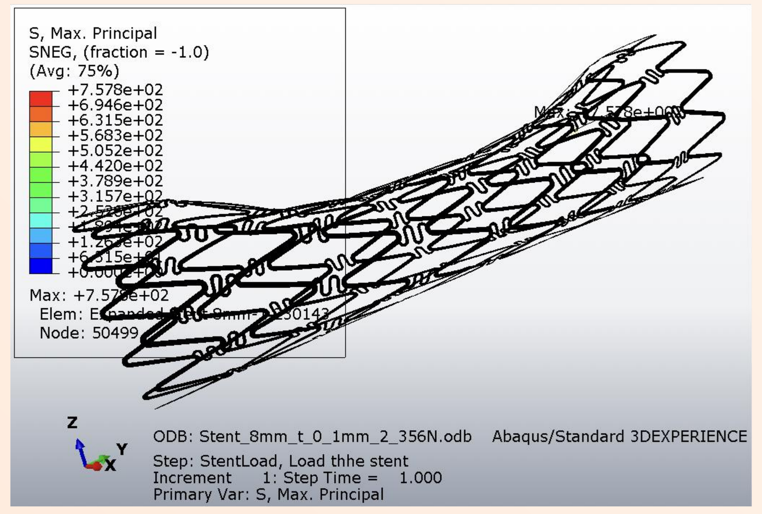

Fig. 12: Stent deformation under uniformly distributed load for a static simulation.

CONCLUSION

For 10 cycles, stent and baffle deformation is small. Results indicate the left and right pulmonary flow remain unobstructed despite cyclic deformation of the baffle, hence the likelihood of patient death due to total pulmonaries obstruction following stent.

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