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 effect 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 m² and 0.36 m².
- 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

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 Genesi (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.

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 laps were compared with the pressures from the catheter data.

Stent FEA
- The pressure load was directly applied on the stent over 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.

RESULTS

<table>
<thead>
<tr>
<th>Patient 1</th>
<th>Patient 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.D.</td>
<td>MFL Data</td>
</tr>
<tr>
<td>Lower Artery</td>
<td>1.75</td>
</tr>
<tr>
<td>Right Pulmonary Artery</td>
<td>0.95</td>
</tr>
<tr>
<td>Left Pulmonary Artery</td>
<td>0.96</td>
</tr>
<tr>
<td>Pressure Data (mmHg)</td>
<td>70</td>
</tr>
</tbody>
</table>

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 pulmonary obstructions following stent.

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REFERENCES