# STENT STRUT CONFIGURATIONS FOR PATENT DUCTUS ARTERIOSUS MORPHOLOGIES USING COMPUTATIONAL FLUID DYNAMICS ANALYSIS

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## DEDICATION

To my beloved parents, siblings and friends Thank you for all the support, sacrifice, and encouragement throughout this journey

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**ABSTRACT**

The stent implantation in patent ductus arteriosus (PDA) is an alternative palliative treatment of neonates with cyanotic congenital heart disease. However, complications such as in-stent restenosis after stent implantation have been reported by medical practitioners. Researchers identified that the stent strut configurations and the ductal morphology contributed to the problem. Thus, this study focused on improving and developing customized stent strut configurations for PDA stenting applications in different PDA morphologies. Computational fluid dynamics (CFD) analysis was used to analyse the stent performance due to hemodynamic characteristics in PDA. Experimental validation via particle image velocimetry (PIV) analysis was also performed by comparing the velocity profile with the computational analysis. Current commercial stents used in PDA stenting were compared to determine the stent strut configurations with minimal risk of in-stent restenosis formations. Hemodynamic performance parameters in reducing the risk of in-stent restenosis formation such as wall shear stress, wall shear stress gradient, oscillatory shear index, and relative residence time were analysed and compared. All the commercial stents were later scored and ranked based on each hemodynamic performance. Based on the results obtained from the commercial stent hemodynamic performance analysis, parametric stent strut configurations were developed. Two design parameters were considered, which were stent thickness and strut width. The parametric stent strut configurations were analysed using the same hemodynamic performance parameters. The parametric stents were compared with the selected commercial stents with good hemodynamic performance and later selected for structural analysis. Finally, structural analysis via fluid-structure interaction (FSI) modelling was performed to predict parametric stent strut failure due to hemodynamic forces based on the maximum displacement and von Mises stress. Results indicated that a good hemodynamic performance in reducing the risk of in-stent restenosis in commercial stents Type 3, Type 4, Type 5, and Type 6 with more minor strut connectors. Using the results obtained, parametric stent strut configuration was designed and evaluated. Stent with 0.1 mm thickness such as Type A, Type D, and Type G exhibited better hemodynamic performance in reducing the risk of restenosis formation compared to thicker stent strut. In addition, these stents were predicted to being able to withstand the hemodynamic forces from structural failure. Finally, the proposed parametric stents can reduce the risk of the formation of in-stent restenosis by approximately 20% compared to commercial stents with good structural strength to withstand the forces due to blood flow through various PDA morphologies.

# ABSTRAK

Pemasangan sten pada duktus arteriosus terbuka (PDA) adalah salah satu rawatan paliatif alternatif bagi bayi baru lahir yang menghidap penyakit jantung kongenital sianotik. Walau bagaimanapun, komplikasi selepas pemasangan sten telah dilaporkan oleh ahli perubatan. Penyelidik mendapati bahawa konfigurasi dinding sten dan morfologi duktus arteriosus adalah antara penyebab berlakunya komplikasi tersebut. Oleh itu, kajian ini bertujuan untuk menambah baik dan membangunkan konfigurasi dinding sten yang sesuai untuk digunakan dalam pemasangan sten untuk pelbagai morfologi PDA yang berbeza. Analisis perkomputeran dinamik bendalir (CFD) digunakan untuk menentukan prestasi sten disebabkan oleh ciri hemodinamik dalam PDA. Pengesahan hasil dapatan analisis CFD telah dibuat melalui eksperimen menggunakan analisis velokimetri imej zarah (PIV) dengan membandingkan dapatan analisis halaju dengan analisis berangka. Sten komersial sedia ada yang kini digunakan dalam pemasangan sten dalam PDA telah dibandingkan untuk menentukan sama ada konfigurasi dinding sten dapat mengurangkan risiko pembentukan semula stenosis. Prestasi parameter hemodinamik seperti tegasan ricih dinding, kecerunan tegasan ricih dinding, indeks ricih beralun dan masa tinggal relatif telah dianalisis dan dibandingkan. Kesemua sten komersial diberikan markah dan pemangkatan yang bersesuaian berdasarkan prestasi setiap parameter hemodinamik. Sten parametrik telah dibangunkan berdasarkan dapatan prestasi parameter hemodinamik sten komersial, dan dibandingkan dengan sten komersial yang terpilih. Dua parameter reka bentuk sten telah diambil kira, iaitu ketebalan sten dan kelebaran topang sten. Analisis sten parametrik dijalankan menggunakan parameter hemodinamik yang sama. Prestasi hemodinamik sten parametrik tersebut telah dibandingkan dengan sten komesial terbaik dari segi prestasi hemodinamik dan seterusnya dipilih untuk analisis struktur. Akhir sekali, analisis struktur dinding sten melalui analisis interaksi struktur dan bendalir (FSI) telah digunakan untuk meramal sama ada sten parametrik tersebut dapat menahan daya hemodinamik daripada patah atau gagal berdasarkan dapatan sesaran maksimum dan daya von Mises. Hasil dapatan menunjukkan prestasi hemodinamik dalam mengurangkan risiko pembentukan semula stenosis pada sten komersial Jenis 3, Jenis 4, Jenis 5 dan Jenis 6 yang mempunyai penyambung sten yang rendah adalah lebih baik. Menggunakan hasil dapatan tersebut, sten parametrik telah direka bentuk. Sten parametrik dengan ketebalan 0.1 mm seperti sten Jenis A, Jenis D dan Jenis G menunjukkan prestasi hemodinamik dalam mengurangkan risiko pembentukan semula stenosis berbanding sten yang lebih tebal. Tambahan pula, sten-sten parametrik tersebut mampu menampung daya hemodinamik daripada kegagalan struktur. Akhir sekali, sten parametrik yang dicadangkan mampu untuk mengurangkan risiko pembentukan restenosis dalam sten kira-kira 20 peratus berbanding sten komersial, dan pada masa yang sama, memiliki kekuatan struktur yang baik yang dapat menahan daya yang disebabkan oleh aliran darah dalam morfologi-morfologi PDA.

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| | | |
|---|---|---|
| ALE | - | Arbitrary Lagrangian-Eulerian |
| AS | - | Ascending Aorta |
| CCD | - | Charge Couple Device |
| CFD | - | Computational Fluid Dynamics |
| DS | - | Descending Aorta |
| FPS | - | Frame Per Second |
| FSI | - | Fluid-Structure Interaction |
| FSP | - | Flow Separation Parameter |
| GIT | - | Grid Independence Test |
| LES | - | Large Eddy Simulation |
| LPA | - | Left Pulmonary Artery |
| MB | - | Multiple Bend |
| MPA | - | Main Pulmonary Artery |
| OSI | - | Oscillatory Shear Index |
| PA | - | Pulmonary Artery |
| PAIVS | - | Pulmonary Atresia with Intact Ventricular Septum |
| PDA | - | Patent Ductus Arteriosus |
| PIV | - | Particle Image Velocimetry |
| RPA | - | Right Pulmonary Artery |
| RRT | - | Relative Residence Time |
| SB | - | Single Bend |
| TAWSS | - | Time Average Wall Shear Stress |
| TAWSSG | - | Time Average Wall Shear Stress Gradient |
| TGA | - | Transposition of Great Artery |
| TR | - | Transverse Aorta |
| WSS | - | Wall Shear Stress |
| WSSG | - | Wall Shear Stress Gradient |

## LIST OF SYMBOLS

| | | |
|---|---|---|
| $u$ | - | Flow vector |
| $\rho$ | - | Density |
| $\mu$ | - | Viscosity |
| $w$ | - | Moving mesh |
| $p$ | - | Pressure |
| $V$ | - | Velocity vector |
| $f$ | - | Forces |
| $\Gamma$ | - | Boundary domain |
| $\sigma$ | - | Stress |
| $\tau$ | - | Shear stress |
| $r$ | - | Radius |
| $T$ | - | Total time |
| $t$ | - | Time |

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# CHAPTER 1

# INTRODUCTION

Cyanotic congenital heart disease is a condition related to heart defects that are present at birth which causes bluish colour tone of the skin of newborns. As a palliative measure, surgical repair such as Blalock-Taussig shunting or palliative Norwood surgery are required in order to alleviate the effect of cyanosis on newborns. These types of surgical repair may not be suitable for newborns with insufficient weight and age. However, without necessary treatments, it may lead to morbidity and mortality. An alternative treatment for this condition was introduced, which is stent implantation in patent ductus arteriosus (PDA).

The implantation of stent in ductus arteriosus has been selected as an alternative palliative treatment for newborns with cyanotic congenital heart disease (Alwi, 2012). Stent is a tubular wire mesh that is inserted and expanded in constricted blood vessel so that the blood vessel is dilated sufficiently to restore and maintain blood flow through the vessel. The stent implantation is done when the ductus arteriosus still open so that the ductus arteriosus remained patent. This procedure is called PDA stenting (Alwi and Mood, 2013; Matter *et al.*, 2013). In PDA stenting, the stent is implanted temporarily in ductus arteriosus for 6 to 12 months or until the newborn has achieved sufficient weight necessary for permanent surgical repair or first state cavopulmonary anastomosis (Alwi, 2008). The implantation of stent in PDA has shown great promise in reducing the effect of the cyanosis in affected newborns and nowadays has been treated as a viable alternative treatment in place of palliative surgery in certain patients.

Due to the usage of coronary stent in PDA stenting, medical practitioners have identified various complications that arises post stent implantation, thus indicate that the usage of coronary stent is deemed unsuitable for PDA stenting application (Gibbs *et al.*, 1999). Complications such as in-stent restenosis, which is the narrowing of the blood vessel after stent implantation, has been identified as the most common complications after stent implantation (Gibbs *et al.*, 1999; Gewillig *et al.*, 2004). There are four stages of in-stent restenosis which are thrombosis formation, arterial inflammation, neointimal hyperplasia and arterial remodelling (Murphy and Boyle, 2010). This complication has adverse effect on the patient as the narrowing of ductus arteriosus affects the overall blood flow to the body. Further interventions are required before permanent surgical repair can take place.

Researchers had identified that flow alteration in the vicinity of stent wall contributes to the formation of in-stent restenosis. The flow alteration near to the stent wall is attributed to the stent strut design (Duraiswamy *et al.*, 2010; Gundert *et al.*, 2013) and the complexity of the ductal morphology in patients (Aggarwal *et al.*, 2019). To address this issue, understanding the effect of ductal morphology and the stent strut configuration that may lead to flow alteration near to the stented vessel are required. Design modifications may be proposed to improve the hemodynamic performance of the stent so that the stent is suitable for implantation especially in various PDA morphologies by streamlining the blood flow to avoid slow and stagnant flow which may leads to the formation of in-stent restenosis (Taib, 2016). These modified stent strut configurations are evaluated for hemodynamic performance in reducing the risk of in-stent restenosis.

The evaluation of the stent designs is completed by employing various methods including computational fluid dynamics (CFD) analysis, animal testing and clinical trials. Early hemodynamic performance study on PDA stent via CFD employed simplified straight PDA models, implanted with customizable stent to evaluate the performance of the stent (Taib *et al.*, 2013). This study indicates good hemodynamic performance as compared to commercial stents. The usage of simplified straight blood vessel, in this case artery, is quite common in evaluating the performance of stent. However, in term of PDA, various morphologies have been identified and simplified model might not adequately represent the actual hemodynamic characteristic of PDAs (Alwi, 2012).

Thus, in this study, an improved and customized PDA stent, suitable for various PDA morphologies, that may reduce the risk of in-stent restenosis formation after stent implantation. The evaluation of stent design is performed using modified patient-specific PDA models which represent several types of PDA morphologies. Customized PDA stents will be evaluated and compared with the commercial stents used in PDA stenting. To validate the computational modelling results, experimental method was implemented. Particle image velocimetry (PIV) is used to visualize the flow. As for structural analysis, single-coupled fluid-structure interaction (FSI) analysis is applied to evaluate stent structural integrity due to the hemodynamic characteristic of PDAs. In the end, customized stent strut configurations for PDA morphologies are proposed.

## 1.1 Problem Statement

Implantation of coronary stent in PDA has caused various complications including the narrowing of PDA after stent implantation, or in-stent restenosis of the PDA. Researchers had identified that the formation of in-stent restenosis is due to flow alteration near to the stent wall that caused flow stagnation and platelet adhesion. This indicates that the current coronary stent used for PDA stenting is deemed unsuitable for various PDA morphologies. Researchers identified that the formation of in-stent restenosis is due to the flow alteration near to the stent wall, causing flow stagnation and platelet adhesion. Stent strut configurations and the morphology of the stented vessel had been identified as the cause of in-stent restenosis formation.

Various morphologies of PDA had been identified and classified based on its shape, length, the origin from the aorta and the insertion onto the pulmonary artery and other parameters. Suitability of PDA stenting as a treatment is also dependent on the morphology of the PDA. Different types of PDA morphologies experience different flow characteristics as the geometry of the PDA, corresponding to its location in relation to the aorta and pulmonary artery, will introduce flow divider region, similar to the flow behaviour observed in bifurcated blood vessel. Flow disturbance is observed in the flow divider region, which may lead to the formation of neointimal build up at the wall of stented vessel. Thus, understanding of the flow behaviour in various PDA morphologies are necessary in predicting the formation of in-stent restenosis in neonates with cyanotic congenital heart disease.

Furthermore, the evaluation of stent hemodynamic performance is mostly performed on simplified model of artery. However, in the case of PDA, various morphologies were identified, in which the flow characteristics varied depending on the morphologies with significant characteristic difference as well as the forces acted on the arterial wall, as compared to straight PDA model. The flow characteristic difference may affect the evaluation of the hemodynamic performance and mechanical strength of stent, especially in patient-specific PDA models.

Therefore, further understanding on the flow behaviour near to the stent wall in various stented PDA morphologies are required to evaluate the hemodynamic performance of the stent strut configuration in PDA morphologies in reducing the risk of in-stent restenosis. This is so that customised stent strut configuration can be proposed, suitable to be used in various PDA morphologies. Further modifications of the stent strut configurations are required to meet the required hemodynamic performance in PDA morphologies, in order to fit each of the identified morphologies.

## 1.2 Research Objectives

The objectives of this study are as follows:

(a) To establish and validate the hemodynamic characteristic in different types of PDA morphologies.

(b) To establish the performance of commercial PDA stent in order to obtain the current hemodynamic performance of the stent.

(c) To customise the stent strut configurations by varying the stent strut parameters on different types of PDA morphology.

(d) To determine the effect of hemodynamic characteristic on different morphologies of stented PDA morphologies to the customised stent strut configuration.

## 1.3 Significance of Research

Initial study on numerical modelling of customized stent strut configuration on PDA was performed on simplified PDA model. The limitation of simplified PDA model is it did not fully explain the true hemodynamic behaviour of stented PDA due to the geometrical nature of PDA morphologies that are more complicated and complex. The hemodynamic characteristic in PDA is highly dependent on the geometry of the PDA morphologies themselves, which is more complex than straight vessel. The usage of patient specific model of PDA should be able to accurately predict the stent hemodynamic performance as compared to the use of simplified model of PDA since the hemodynamic characteristic mimics the actual flow in PDA. The stent can be tailored specifically for each morphology. Therefore, the stent strut configurations need to take into consideration the PDA morphological hemodynamic characteristics into the analysis of stented PDA models for better prediction of stent performance in PDA.

## 1.4 Scope of Research

The scope of research is as follows:

(a) Modified patient-specific models of PDA are used for stent strut hemodynamic performance prediction and analysis. The PDA are considered to be straight with no tortuosity.

(b) Stents similar to commercial stents are selected and evaluated for hemodynamic performance in reducing the risk of in-stent restenosis.

(c) The stent hemodynamic performance of the PDA is analysed based on the result obtained from CFD modelling and single-coupled FSI modelling. Turbulence modelling is employed in the simulation.

(d) The blood is set to be Newtonian. For CFD analysis, the arterial wall and stent is set to be rigid, while for FSI analysis, they are set to be non-rigid.

(e) In-vitro analysis via particle image velocimetry (PIV) is performed on patient-specific model of PDA to validate the hemodynamic characteristic obtained from the numerical modelling.

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