

Design Analysis and Development of a Miniature Blood Pump

by

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Design Analysis and Development of a Miniature Blood Pump

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To my parents, wife, and son

ABSTRACT

Congenital Heart Disease (CHD) is one of the leading cause of infant death around the world. According to American Heart Association (AHA) 9.3 out of 1000 live births in Asia effect from CHD. In adults, Mechanical Circulatory Support (MCS) has emerged as a life-saving device. Due to size limitations and nature of CHD the adult devices are not suitable for pediatric patients. Thus, there is a need for miniature MCS device implantable to pediatric patients. Thus, this study aims to develop a novel blood pump for CHD patients. The device proposed in this thesis is a novel shrouded impeller axial flow pump. This type of design has never been tried experimentally in blood pumps before.

The impeller and diffuser blade angles of blood pump were obtained by performing 2D velocity triangles analysis. Computational Fluid Dynamics (CFD) analysis has been used to predict the hydraulic performance and to visualize the flow field within the pump. A number of impeller and diffuser design with varying geometric parameters were analyzed to come up with Prototype I of shrouded impeller pediatric ventricular assist device (SIP-VAD). Regions of high shear stress indicated the possible areas causing blood damage. A bench top model of Prototype I was manufactured to verify the CFD results. The impeller, inducer, and diffuser were manufactured using rapid prototyping method. Arc-shaped magnets were installed at the outer periphery of the impeller and 3-phase brushless direct current (BLDC) motor principle was used to

rotate the impeller. Comparison of experimental and CFD results revealed the reliability of the CFD model for further design modification.

CFD based blood damage analysis was performed using Eulerian stress and strain-based models. The verification of this model was performed by comparing results with in vitro blood test. Different power law function was used to find the best model for our design. Results show the strain-based model to be more accurate in predicting blood damage. Based on this model design improvement were made in prototype I. Further CFD analysis was performed to finalize prototype II design. The benchtop experimental setup was manufactured using high precision 5-axis machine tool. The in vitro hydraulic and blood test were performed. The blood damage results revealed the acceptable level of blood damage in the proposed design. Therefore, it is shows that the used of shrouded impeller design can lead to good results in miniature blood pumps.

ÖZET

Konjenital kalp hastalığı (KKH) dünyadaki bebek ölümlerinin önde gelen nedenlerinden biridir. Amerikan Kalp Derneği'ne göre, Asya'daki 1000 canlı doğumdan 9.3'ü KKH'den etkilenmiştir. Yetişkinlerde, mekanik dolaşım desteği (MDD) hayat kurtaran bir cihaz olarak ortaya çıkmıştır. KKH'nin boyut sınırlamaları ve doğası nedeniyle, yetişkinler için kullanılan cihazlar pediatrik hastalar için uygun değildir. Dolayısıyla, pediatrik hastalara uygulanabilen minyatür MDD cihazına ihtiyaç duyulmaktadır. Bu çalışma KKH hastaları için yeni bir kan pompası geliştirmeyi amaçlamaktadır. Bu tezde önerilen yeni cihaz, örtülü pervane tipi, eksenel bir akış pompasıdır. Bu tip bir tasarım kan pompalarında daha önce deneysel olarak denenmemiştir.

Kan pompasının pervane ve difüzör kanat açıları, hız bazlı 2D üçgen analizi yapılarak elde edilmiştir. Hidrolik performansı öngörmek ve pompa içindeki akış alanını görselleştirmek için hesaplamalı akışkanlar dinamiği (HAD) analizi kullanılmıştır. Örtülü pervaneli pediatrik ventriküler destek cihazının ilk prototip dizaynına ulaşabilmek için çeşitli geometrik parametrelere sahip bir dizi pervane ve difüzör tasarımı analiz edilmiştir. Analiz sonucunda bulunan yüksek makaslama stres bölgeleri, kan tahribatına neden olabilecek olası alanları ortaya çıkarmıştır. HAD sonuçlarının doğrulanması için ilk prototip modeli üretilmiştir. Pervane, indükleyici ve difüzör parçaları, hızlı prototipleme yöntemi kullanılarak üretilmiştir. Çark şeklindeki

mıknatıslar pervanenin dış çevresine yerleştirilmiş ve çarkı döndürmek için 3 fazlı, fırçasız doğru akım motor prensibi kullanılmıştır. Deneysel sonuçlar ve HAD sonuçlarının karşılaştırılması, HAD modelinin güvenilirliğini ortaya koymuştur.

HAD bazlı kan hasar analizi, Euler stres ve şekil değiştirme bazlı modeller kullanılarak yapılmıştır. Elde edilen sonuçların in vitro kan testi ile karşılaştırılması, kurulan analiz modelini doğrulanmıştır. Farklı güç kanunu işlevleri, en iyi tasarım modeli bulmak için kullanılmıştır. Sonuçlar, şekil değiştirme temelli modelin, kan hasarı tahmininde daha güvenilir olduğunu göstermiştir ve bu modele dayanarak ilk prototipte tasarım geliştirmeleri yapılmıştır. İkinci prototipin tasarımı için de daha fazla HAD analizi yapılmıştır. Masa üstü deney düzeneği, yüksek hassasiyetli, 5 eksenli takım tezgâhı kullanılarak üretilmiştir. In vitro hidrolik ve kan testleri yapılmıştır. Analiz sonuçları, kan hasarının, önerilen tasarımda, kabul edilebilir düzeyde olduğunu ortaya çıkarmıştır. Bu şekilde, minyatür kan pompalarında, örtülü pervane tasarımının kullanılmasının başarılı sonuçlar getirebileceği kanıtlanmıştır.

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NOMENCLATURE

η	hydraulic efficiency
α_1	Inducer angle
β_1	Impeller leading edge angle
β_2	Impeller trailing edge angle
α_2	diffuser leading edge angle
α_3	diffuser trailing edge angle
h	Blade height
$\dot{m}$	Mass flow rate
A	Cross-sectional area of the pipe
ρ	Density
V	Axial velocity
P_1	Inlet absolute pressures
P_2	Outlet absolute pressures
τ	Shear stress
H_{ct}	Hematocrit percentage
Q	Volume flow rate
g	Acceleration due to gravity
T	Applied Torque
ω	Rotational speed

$\Delta pfHb$	Increase in plasma free hemoglobin
<i>NIH</i>	Normalized Index of Hemolysis
<i>CFD</i>	Computational Fluid Dynamics
<i>MCS</i>	Mechanical Circulatory Support
<i>MOPSO</i>	Multi-objective Particle Swarm Optimization
<i>VAD</i>	Ventricular Assist Device
<i>RBC</i>	Red Blood Cell
<i>NHLBI</i>	National Heart, Lung, Blood Institute
<i>RBP</i>	Rotary Blood Pump
<i>BLDC</i>	Brushless Direct Current

Chapter 1 : INTRODUCTION

1.1 Overview

Heart failure is one of the leading cause of death worldwide [1]. Many treatment options are available to treat patients with heart disease. These options include medication, lifestyle change and bypass surgery [2]. Besides the availability of these options sometimes the only option remain for patients is heart transplantation. According to a survey the number of patients waiting for a heart transplant has doubled within last 15 years while the available donor heart has dropped to third. In the year 2015 2804 hearts, transplants were performed in the United States while 4134 patients were still on transplant list [3]. Due to lack of treatment options available for such patients, researchers have been trying to develop mechanical circulatory supports (MCS) devices. MCS are mechanical pumps which support the flow of failing heart. These artificial pumps are categorized into a different type which is Left ventricular assist devices (LVAD), right ventricular assist devices (RVAD), biventricular assist devices (BiVAD), extracorporeal membrane oxygenation (ECMO) and total artificial heart (TAH). In the last past decade, there has been a significant improvement in the field of adult MCS. These devices have emerged from the bridge to transplant to life-saving destination therapy.

Although there has been a significant improvement in adult MCS, the same cannot be applied to pediatric devices. Due to size limitation and different physiological properties, adult's devices are not suitable for pediatric patients. According to a recent study 8 per 1000 live births in the United States have congenital heart defects. In Asia, this number increases to 9.3 per 1000 births while in Europe it is 6.9 per 1000 births [3, 4]. Out of these, 2.3 Per 1000 live births require invasive treatment otherwise infant death may occur [5]. Based on a research in US alone between 1999 to 2006, 3098 children were registered for heart transplant list out of which 1943 patients received a transplant while 533 patients died [6]. Currently, extracorporeal membrane oxygenation is widely used for pediatric support for the period of days to weeks [7-9]. The only device commercially available for children, with body surface area (BSA) less than 0.7 m^2 (i.e. for newborns to five-year-olds), is Berlin Heart EXCOR. It is an extracorporeal device with the pulsatile flow [10, 11]. This lack of treatment options available has motivated us to develop a pediatric ventricle assist device. The device under development is intended for children of age newborns to two years. The design consideration for such a device is a flow rate of 0.25-1.5 L/min and a pressure of 63-75 mmHg [12]. The general flow requirements for adult LVAD are a flow rate of 5 L/min and a pressure of 100 mmHg [13].

An essential design feature of a rotary blood pump (RBP) for an improved hemodynamic performance is the minimization of shear stresses. The design difficulty in a pediatric pump arises due to a reduction in size. The small size of the pump leads towards small clearance gaps between moving and stationary parts. Also, in small

sizes, the velocity gradient is increased in turn increasing the shear stress. To avoid these problems a pediatric blood pump should be streamlined in design with minimal irregular flows and high-velocity gradients.

1.2 First Generation Pumps

The first generation of LVADs is either pneumatically or electrically actuated reciprocating pump. These pumps mimic the functioning of the original heart. In these types of pumps, a soft polyurethane membrane was actuated in to and fro motion either pneumatically or electrically. Inlet and outlet valves were used to control the direction of blood flow. During the intake process, polyurethane membrane moves downwards, and the inlet valve is open to allow the blood from the left ventricle into the pump. When membrane moves upwards the intake valve is closed and the outlet valve is open delivering the blood to the aorta. Despite the success of these first generation LVADs they possessed some problems. First, due to multiple parts, these pumps were large thus posing the problem of portability. Second, due to many moving parts chances of mechanical failure was great. Third, these devices posed different risks to the patients like infection, blood damage and blood clotting. Nevertheless, these devices provide gateway towards development and use of blood pumps in saving people's lives. Some of the commercially available first generations pumps are discussed in next chapter. Figure 1.1 shows the parts and working of Heartmate XVE a first-generation device.

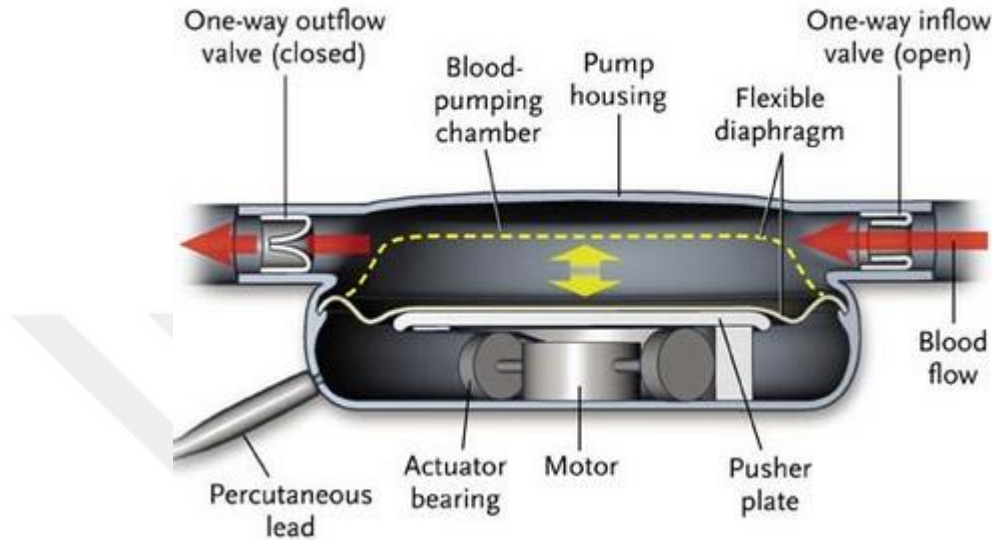


Figure 1.1: Pulsatile pump, HeartMate XVE as a first-generation blood pump [14]

1.3 Second Generation Pumps

Secondary generation pump is rotary blood pumps with mechanical pivot bearing. These types of pumps are also called dynamic pump. It consists of high speed rotating impeller which imparts the kinetic energy to the blood thus increasing its velocity (dynamic pressure). After impeller, the blood passes through a careful design diffuser section which reduces the velocity of the flow thus increasing its static pressure.

Based on the nature of operation these pumps are further divided into two types [15]

Centrifugal Pump: In this type of pumps the discharge direction of the pump is normal to the axis of rotation of the impeller. The advantage of these type of pump is

the relatively low speed of operation (typically between 1500 to 2500 rpm). The disadvantage of this type is large size.

Axial Flow Pumps: In this type of pumps the rotation axis of impeller and flow of the blood is parallel to each other. The advantage of these type of pump is small size and tubular compurgation making it better anatomical fit. The disadvantage of this pump is the relatively high speed of operation and difficult manufacturing. Figure 1.2 shows construction and working of a second-generation axial flow LVAD.

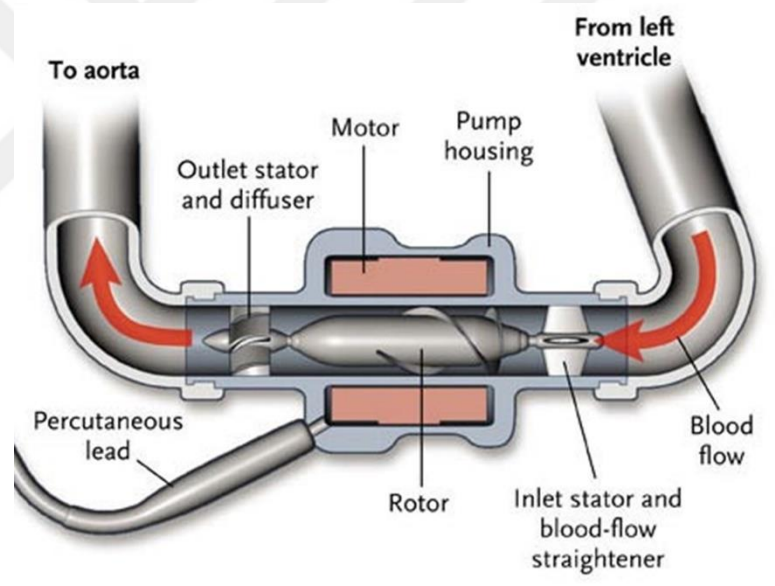


Figure 1.2: Construction and working of an axial continuous flow LVAD [14]

1.4 Third Generation Pumps

Third generation blood pump is the type of rotary blood pumps in which the rotating impeller is suspended using the active magnetic system [16]. This active magnetic system is either combined with passive magnets or hydrodynamic bearings so that less power is consumed to levitate the rotor. The most famous example of Maglev pumps is Berlin Heart Incor, Thoratec Heartmate III [17, 18]. Due to levitation of impeller in these types of pumps the blood damage occurring is minimized and thus improving hemocompatibility of the device. Hoshi et. al classified the levitation system into three main categories [19]:

1. External Drive system in which an external motor is used to rotate the impeller using magnetic coupling while a separate suspension system controls the levitation of impeller.
2. Direct drive system the impeller of the pump also acts as the rotor of the motor. Besides this, another system is built to induce the magnetic suspension into the rotor.

In the third system, both the drive and the levitation coils share the same stator core to make it like a self-bearing system. It is also called bearingless motor drive.

Figure 1.3 shows conceptual presentation of the maglev system as thrust, radial or combination of both maglev system.

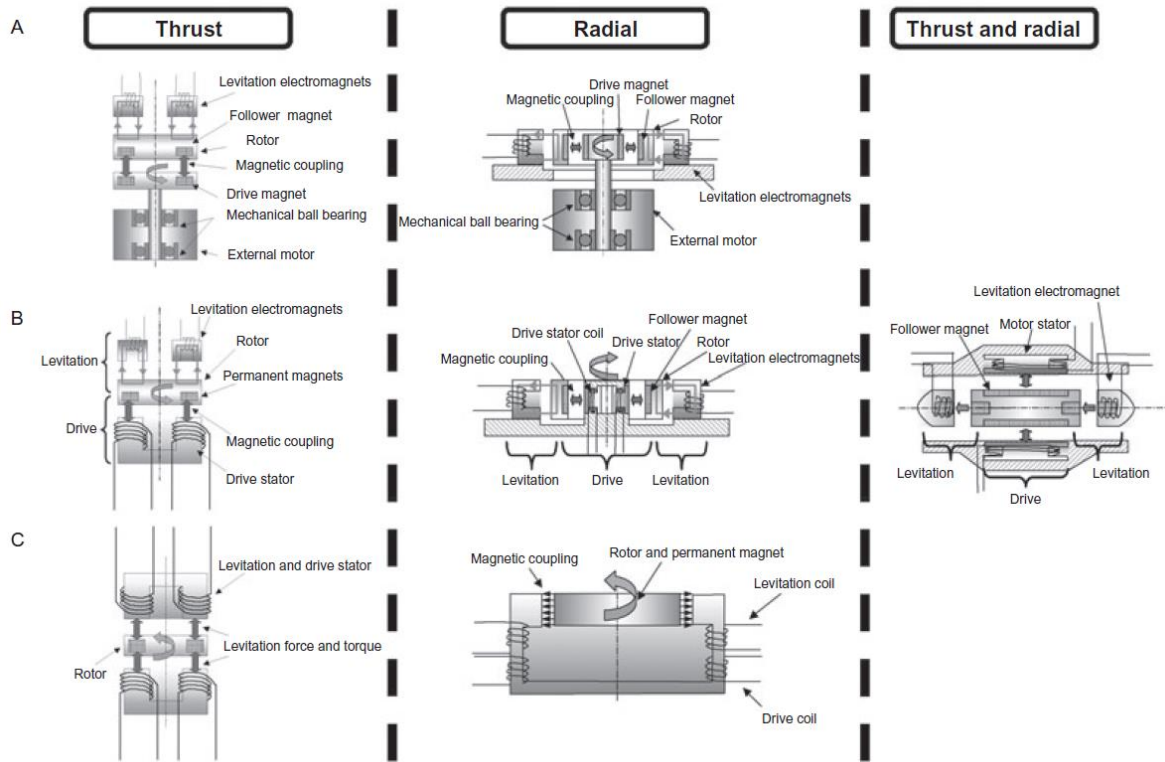


Figure 1.3: Different classifications of the maglev system [19]

1.5 Research Objectives

This thesis focuses on the development of a pediatric blood pump by achieving the following objectives:

- Provide a literature review of the requirements for pediatric VAD design and characteristics of LVADs.
- The design procedure for rotary blood pumps especially focusing on axial flow pumps.

- Propose different designs of impeller and diffuser geometries for design iterations.
- Create a computational fluid dynamics (CFD) model for numerical simulations.
- Explore the effects of different impeller and diffuser geometries on hydraulic and hemolysis performance of the pump with numerical simulations.
- Perform a hydraulic experiment to validate the hydraulic output of impeller/volute configurations.
- Determine the design modifications based on CFD and experimental study and finalize the pump design of shrouded impeller pediatric ventricular assist device (SIP-VAD).
- Manufacture the finalized design with the hemocompatible material, Stainless stress 316LS.
- Investigate the flow characteristics with blood analog fluid at different rotational speeds.
- Create an in vitro circulation loop to evaluate the blood damage potential of SIP-VAD.

Chapter 2 : LITERATURE REVIEW

2.1 Overview

The history of MCS started with the use of first heart and lung transplant machine during an open-heart surgery in 1953 [20]. Simpler roller pumps were used for cardiac support during bypass surgery procedure and temporary cardiac support. The development of long-term MCS devices started with the funding provided by National Heart, Lung and Blood Institute in the year 1964. The first LVAD was implanted in a patient in 1966 for 10 days until transplantation [21]. It was a pneumatically driven positive displacement pump. Afterward, researchers started to develop more reliable and biocompatible systems for long-term therapy. Since the introduction of rotary blood pumps (RBP), the field of adult MCS has advanced rapidly. The following section discusses some of the clinically available adult VADs.

2.2 Clinical Available Adult Ventricular Assists Devices

2.2.1 HeartMate I

The Heartmate I LVAD was developed by Thoratec Corporation is a first-generation pump which uses pusher plate interfacing with the flexible plastic diaphragm to induce a pulsatile flow. It is installed between the apex of left ventricle and aorta. This device was further divided into two types. Initially, HeartMate IP was

pneumatically driven device and was replaced by Heartmate XVE which was electrically driven device [22].

The size of Heartmate XVE is Ø110 x 40 mm and the weight is 1190 g. It can be implanted in the patients having body surface area (BSA) less than 1.5 m². The device can provide the flow rate of 10 L/min at 120 beats per minute (bpm) of pusher plate frequency. Due to high reliability, this device was approved by Food and Drug Authority as destination therapy in 2003 [23]. Since then it has been used in more than 4500 patients making it one the most successful LVAD in the world.

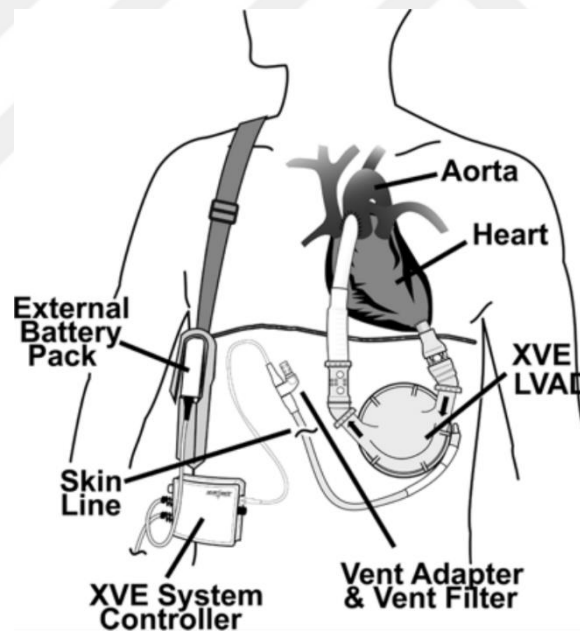


Figure 2.1: HeartMate XVE system with cannulation

2.2.2 Berlin Heart “EXCOR”

Berlin Heart “EXCOR” is a first-generation device which provides circulatory support using an external circuit(paracorporeal). The pump chamber is made up of polyurethane and to make it biocompatible it is coated with heparin. It a pneumatically actuated device available in different sizes. The adult version of the devices has priming volumes of 50, 60 and 80 ml, whilst pediatric pumps have volumes of 10, 20 and 35 ml [24, 25]. The largest pump in the series (80 ml) can provide the flow rate of 10 L/min at the frequency of 150 bpm. The pediatric pump got FDA approval in the year 2008 and up till now more than 2000 devices have been implanted worldwide. Figure 2.2 shows different versions of Berlin heart excor available.



Figure 2.2: Berlin Heart Excor (left to right) 10 ml, 20 ml, 35 ml, 50 ml and 60 ml [26]

2.2.3 Abiomed “AB5000”

The Abiomed AB5000 is a first generation pneumatically driven device. It also paracorporeal in nature and uses compressed air to actuate polyurethane diaphragm.

The pump chamber is 230 g in weight. It can be used as LVAD, RVAD, and BVAD and replacement of this device does not require additional surgery. It got FDA approval in 2003 but it is less common than other clinical first-generation devices [27, 28].

2.2.4 Thoratec “IVAD/PVAD”

The Thoratec PVAD and IVAD are first generation devices which are actuated pneumatically. The PVAD is a paracorporeal device that was FDA approved for in 1995. The IVAD is an incorporeal device and was approved in 2004. Both can deliver around 7 L/min at the rate of 100 BPM. IVAD has relatively smaller size and weight (125 mm×80 mm×50 mm and 339 g) as compared to the PVAD (125 mm × 80 mm×60 mm and 417 g) [29]. The number of patients which are supported by PVAD and IVAD is more than 4400 and 560 respectively [30].

2.2.5 Thoratec “HeartMate II”

The Heartmate II is an incorporeal second-generation pump with axial flow. The operation speed of this device is from 6000 to 15000 rpm with flow rate reaching up to 10 L/min maximum. The design conditions (5 L/min and 100 mmHg) is achieved at 9000 rpm. The size and weight of the devices are Ø40×60 mm and 375 g respectively [31]. More than 5000 patients have been implanted with this device [32].

2.2.6 Jarvik Heart “Jarvik 2000 FlowMaker”

The Jarvik 2000 is an incorporeal second-generation pump with axial flow. It can deliver the flow rates from 3 to 7 L/min at the rotational speeds from 8000 to 12000. This is a small size device having dimensions $\varnothing 25 \times 55$ mm and the weight of the device is 75 g [32]. Up to now, it has been implanted in more than 350 patients [33]. One of the patients using this device survived for more than seven years before receiving a heart transplant.

2.2.7 MicroMed Cardiovascular “Heart Assist 5 Adult VAD”

The Jarvik 2000 is an incorporeal second-generation pump with axial flow. It can deliver the flow rates up to 10 L/min at the rotational speed of 12500 rpm. This size of the device is $\varnothing 25 \times 86$ mm and the weight of the device is 95 g. Since its clinical trial began in 1998, it has been used to support more than 440 patients [34, 35].

2.2.8 Berlin Heart “InCOR”

The Berlin heart InCOR is a third-generation axial flow pump. It is a long-term incorporeal device having magnetically suspended rotor. The rotor of this device is actively suspended while the radial suspension is achieved using passive permanent magnets. It is largest of axial flow device having dimensions of $\varnothing 30 \times 120$ mm and the weight of 200 g [36]. This device can achieve a maximum flow rate of 7 L/min at 10000

rpm. The first human clinical trial occurred in June 2002. Since then it has been implanted more than 500 times worldwide [22].

2.2.9 WorldHeart “Levacor”

The Levacor LVAD is third-generation centrifugal pump use for long-term implantation. The rotor of this device uses hybrid suspension system with active and passive magnetic system. It is a large size pump as compared to axial pumps with the dimensions of $\varnothing 75 \times 35$ mm with the mass of 440 g [37]. This device can achieve the desired flow rate of 5 L/min at the rotational speed of 2000 rpm. The clinical evaluation began in 2006, with only 17 patients supported by the device to date [38].

2.2.10 Terumo “DuraHeart”

The DuraHeart LVAD is the heaviest rotary blood pump with the weight of 540 grams. It is a third-generation device with the radial flow. The rotor of the pump is suspended using a combination of hydrodynamic lubrication provided by a spiral groove at the back of the rotor and magnetic bearing system. The size of DuraHeart is $\varnothing 72 \times 45$ mm [39]. It can achieve a maximum speed of 2600 rpm delivering the flow rate of 10 L/min. Clinical trials of this device started in 2004 and since then more than 118 patients have been implanted with this device.

2.2.11 HeartWare “HVAD”

The HeartWare HVAD is a third-generation, radial flow pump. It draws blood from a built-in inflow cannula inserted directly into the ventricular cavity. The impeller is suspended by a combination of passive magnetic and hydrodynamic forces created using a tapered thrust axial bearing. The device is one of the smallest ($\varnothing 50$ mm) and lightest (145 g) of the blood pumps [40]. It can operate from 1800 to 4000 rpm, delivering up to the maximum flow rate of 10 L/ min.

2.2.12 CircuLite synergy

The Circulite synergy is the smallest long-term clinically available device. The device has dimensions of $\varnothing 12 \times 50$ mm with the weight of 25 g. This is a second-generation device support using pivot bearing support. The operating speed of the device is from 20000 to 28000 rpm providing the flow rate of 2.5 to 3 L/min. This flow rate is enough to provide to partial support of the failing heart. Currently, it has been installed in more than 27 patients and clinical trials are still ongoing [41].

2.3 Pediatric Blood Pumps

In the previous section, we discussed clinically available adult devices. Some of these devices are also used in pediatric cases but due to the different physiology of a child's body, it is important to develop a device for pediatric patients. In adults, the general flow rate requirements are 5 L/min and pressure of 100 mmHg. While in

children due to growth in body with the age there is necessary of a device which can support the pediatric patient with its growing age. Table 2.1 shows the change in blood flow requirement with variation in age.

Table 2.1: Flow rate requirement at different ages [12]

Age	Average Heart Rate (beats/min)	Flow Rate (L/min)	Pressure Rise LV (mmHg)
1 day	122	0.9	63.5-70
5 days	130	1	63.5-70
10 days	148	1.2	63.5-70
50 days	150	1.2	70
100 days	144	1.2	70
1.37 yrs	112	1.8	73.5-76
2.7 yrs	110	2.2	73.5-76
5 yrs	110	2.3-3.0	76
7 yrs	110	2.6-3.4	76
9 yrs	85	2.9-3.8	78

13 yrs	85	5	80
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2.4 NHLBI Pediatric Circulatory Support Program 2004

Due to a limited number of pediatric patients, the incentive to develop a cost-effective circulatory support is less. To overcome this issue the National Heart Lung and Blood Institute in United States started a program in 2004 [42]. This program is known as Pediatric Circulatory Support Program (PCSP). Five research group were awarded the total grant of 20 million dollars. The objective of this program was to develop a reliable MCS device specifically for pediatric patients. This program concluded in 2009. Despite some development was made but at the end of five-year tenure, none of the devices was permitted clinical used [43]. The brief description of these devices is discussed below:

2.4.1 Pediaflow TM (PF1, PF2, PF3)

The Pediaflow is a trademark name of the device started to develop in the University of Pittsburgh. It is a miniature device intended for infant patients. During the development of this device under PCSP 3 versions of the device (PF1, PF2, and PF3) were manufactured and test. The first two designs (the PF1 and PF2 models) demonstrated the feasibility of the device achieving the flow rate to 2.0 L/min achieving a pressure rise of 80 mmHg. A 4-pole motor was designed to achieve the

desired speed up to 18000 rpm. The operating range of these model was 0.25 to 2.0 L/min and pressure head of 80 mm Hg. The priming volume of PF1 and PF2 were 63.6cc and 35.5cc respectively. The third model in Pediaflow series is PF3 a magnetically levitated pump achieving flow rates of 0.3-1.5 L/min. It can provide the circulatory support for patient utpo 25 kg weight [43-47].

2.4.2 *PediPump*TM

The Pedipump is trademark name of pediatric VAD which was under development in Cleveland clinic. It was targeted to provide the support from newborn up till the patient reaches the weight of 25 kg. It is a mixed flow pump having a passive magnetic bearing. The primary blood flow was provided by an impeller with three blades. The blood exiting the impeller passes through an annular gap containing diffuser blades then over motor which rotates impeller thus cooling it during operation. The mark IV of this pump was 64.5 mm in length and 10.5 mm in diameter. During in vivo testing, the device was able to achieve flow rate rage of 1.7-2,0 L/min achieving pressure rise of approximately 60 mm Hg [48-51].

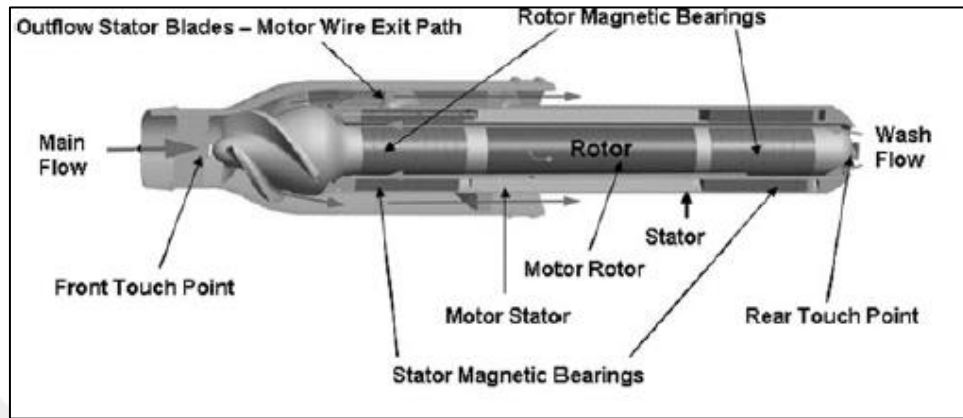


Figure 2.3: Section view of pedipump mark IV [50]

2.4.3 Pediatric Cardiopulmonary Assist System (pCAS)

The pCAS system is an ECMO system for pediatric patients developed by Ension incorporation. This system expands upon the current design of ECMO by providing reduced surface area and priming volume. As this is an ECMO system thus it contains pump oxygenator, controller, arterial cannula and arterial bubble trap. The system was intended to provide partial or complete support to patients from 2 kg to 25 kg [43].

2.4.4 Jarvik 2000

Jarvik Heart, Incorporation developed the pump for both infant and child size. It was based on the design of Jarvik adult pumps. The final designs of the pumps can provide the flowrate from 0.25 L/min to 3 L/min. Initially, this design has the problem

of thrombus generation and this causes the pump to stop working after some period of time. This problem was resolved using blood immersed conical bearings [33, 52, 53].

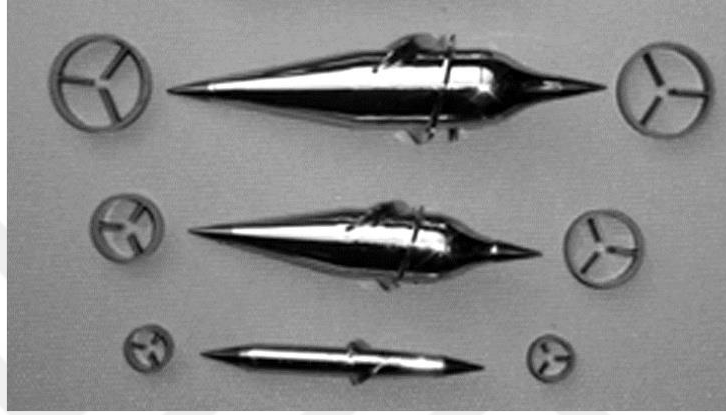


Figure 2.4: Different size models of Jarvik 2000 [54]

2.4.5 Penn State Pediatric VAD

The Penn State Pediatric VAD is a pneumatically-actuated pulsatile pump. The design of this device is based upon Thoratec PVAD™ developed at Penn State. It has been developed for two sizes: An infant VAD with a priming volume of 12 mL and child VAD with a priming volume of 25 mL. This is only pulsatile flow pump under PCSP [43].

2.5 PumpKIN

By the end of PCSP in 2009, there was no device clinically approved for pediatric patients. In October 2008 another request for a program named PumpKIN(Pump for Kids, Infants, and Neonates) was published by NHLBI. Awards of this program were

made in January 2010. Three of the previous companies in PCSP(Enison, Jarvik Heart and University of Pittsburgh) received the awarded contract [54]. The fourth awardee of this program was the University of Maryland in partner with Levitronix. The description of these devices is given in Table 2.2. According to an article published by J. Timothy Baldwin(Head of PCSP and PumpKIN) in 2017, the clinical trials of Jarvik 2015 will start in near future [53].

Table 2.2: PumpKIN trial devices

Device	Size	Flow Rate(L/min)	Flow Type	Operation Type
pCAS	2-12 kg	0.7-2.0	Pulsatile	ECMO
PediPL	3.2-25 kg	3.0	Pulsatile	ECMO
PediaFlow (PF4)	Neonates-2 years	0.3-1.5	Mixed Flow	Implantable
Jarvik 2015	Infant-25 kg	0.25-3.0	Axial Flow	Implantable

2.6 Short-Term VADs for Pediatric

Short-term pediatric VADs have a simple circuit with no oxygenator, allowing the support for an average of 7 to 14 days. Following are some clinically available short-term pediatric devices.

2.6.1 RotaFlow

RotaFlow is a temporary centrifugal VAD having 50 mm. It is made of polycarbonate material and requires 32 ml of priming volume. It is a paracorporeal device capable of providing flow rate from 0 to 10 L/min.

2.6.2 Levitronix PediMag

The Levitronix PediMag is a pediatric-specific pump having magnetically levitated impeller. This device can deliver up to 1.5 L/min flow and is portable, facilitating patient transfer in emergency situations. It can be paired with an oxygenator to provide ECMO.

2.7 Long-Term VADs

Berlin Heart EXCOR is the only long-term VAD available (FDA approved in December 2011) for neonates and infants in the US and is the most commonly used pediatric VAD throughout the world. It has been implanted in more than 325 pediatric patients in the US and more than 1,000 pediatric patients worldwide. The Berlin Heart is a paracorporeal VAD with the pulsatile flow and is used solely as a bridge to transplant. It works with a mobile driving unit. Before Berlin Heart, there was no pediatric longterm VAD in the US. The EXCOR is the first true pediatric VAD

to gain widespread use across the US and has been used both as an LVAD and BiVAD. The technical description of this device is already provided in section 2.2.2.



Chapter 3 : DESIGN OF ROTARY BLOOD PUMP

3.1 Overview

Rapid advancements have been made in the field of artificial heart pumps for last a couple of decades. Introduction of Rotary blood pumps (RBPs) have increased the reliability and operational life of blood pumps. The most important feature of a blood pump is its hydrodynamic and hemolytic performance. The hydrodynamic performance includes

the achievement of required pressure and flow rate. While hemolytic performance requires minimum damage to red blood cells (RBCs) and no clot formation during pump operation. The blood damage due to the operation of the blood pump is known as

mechanical induced hemolysis. In this thesis, mechanical induced hemolysis is referred as hemolysis. While the blot clot phenomena are called as thrombosis. The shear stress induced in the blood by pump operation should be minimized to achieve less hemolysis. The thrombosis formation is eliminated by the streamline performance of the pump i.e. there should be no recirculation and stagnant regions inside the pump. Besides this, a feasible design of the blood pump should be small, efficient in power consumption and good in the performance. However, numerous challenges emerge with the reduction of pump size. The conventional methods of pump design

focus only on the nominal requirement for flow rate and pressure head and does not incorporate hemolytic performance. Figure 3.1 shows the process flow diagram while designing a blood pump. The shear stresses and recirculation regions should be minimized for better hemolytic performance. This is a challenging task in a small pump, as the velocity gradients increase with size reduction and therefore increasing the shear stress levels. Also, the small size creates problems in terms of embedding the magnets inside rotor for motor and maglev system. In order to resolve these problems, a novel design was suggested in which the axial impeller blades are fully enclosed between the hub and the shroud. As a result, the relative velocity between the blades and shroud become zero decreasing the chance of blood damage. Besides this, it provides a relatively large circumferential area for embedding the magnets for brush-less direct current (BLDC) motor and a constant surface area for either the maglev system or hydrodynamic lubrication. Thus, the enclosed impeller design can increase the magnetic efficiency of the pump and reduce the blood damage.

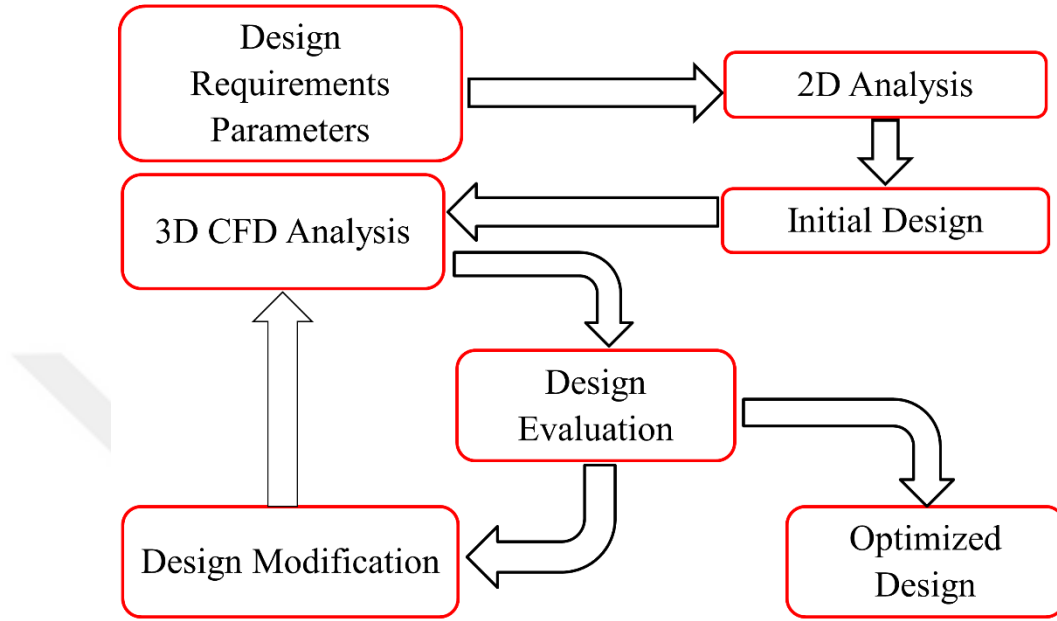


Figure 3.1: Process flow diagram while designing a blood pump

3.2 Basic Pump Theory

Based on the principle of operations the pumps are divided into two types: Positive displacement pumps and rotary pumps [55]. In rotary pumps the momentum change in

fluid occurs as it passes through a set of rotating blades called impeller [56]. This transfer

of momentum increases the velocity of fluid thus, in turn, increasing the dynamic the pressure of the fluid. This velocity of the fluid is converted into static pressure by passing the fluid from a stationary section called diffuser. Before the impeller blades there is a set of the stationary blade to induce the fluid into the impeller section at a

specific angle called inducer. Following sections present a brief introduction to axial flow pumps.

3.2.1 Axial Flow Pump

In an axial flow pump, the flow direction of the fluid is parallel to the rotation axis of impeller. It is useful in applications where the relatively high flow rate is required at a relatively low head. The advantage of axial pumps as rotary blood pump is its relatively small size and tabular configuration make it better anatomical fit in the human body. The disadvantage of this type of pump is its relatively high operational speed [57]. In blood pumps, the axial flow design requires speed in the range of 10,000 rpm. This can be a formula for high shear stresses during operation causing blood damaged. Figure 3.2 shows a schematic diagram of the blades of an axial pump.

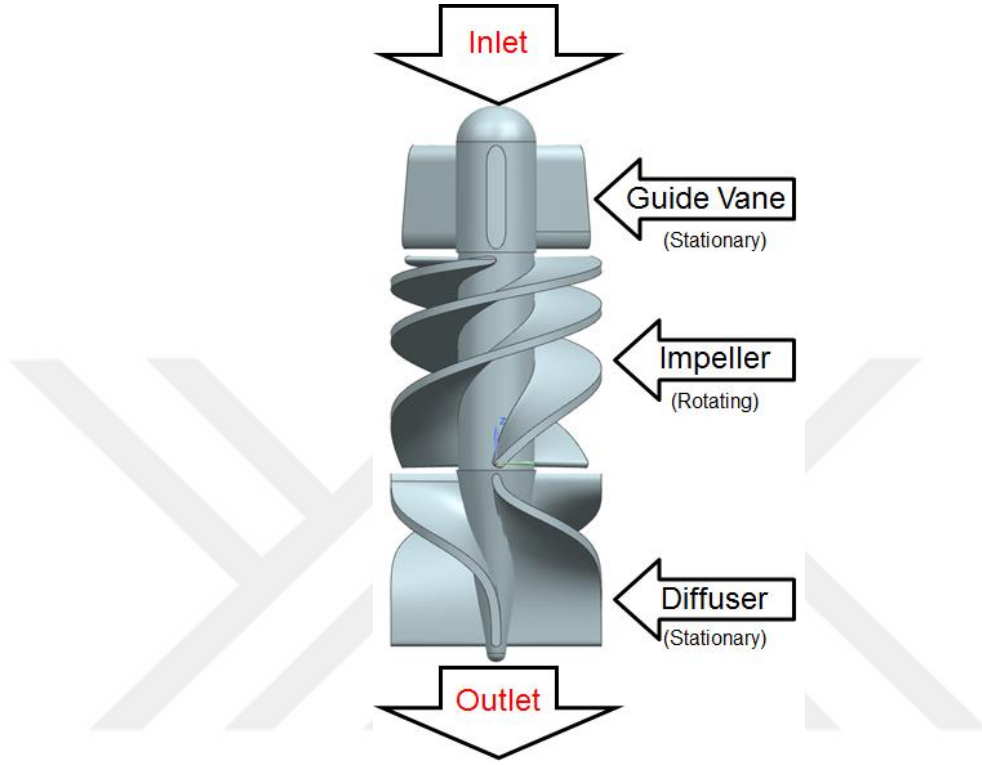


Figure 3.2: Axial flow pump nomenclature

3.3 Pump Terminologies

This section describes some of the basic pump terminologies

3.3.1 Pressure Head

It is the total pressure provided by pump minus the frictional losses. Bernoulli's equation can be applied for steady state conditions to estimate the head. The net head is represented by neglecting viscous effect in the flow by [58]:

$$H = \left(\frac{p_2}{\rho g} + \frac{v_2^2}{2g} + z_2 \right) - \left(\frac{p_1}{\rho g} + \frac{v_1^2}{2g} + z_1 \right) \quad (3.1)$$

Where subscripts 2 and 1 are used to represent outlet and inlet of the pump respectively

3.3.2 Hydraulic Efficiency

The hydraulic efficiency (η) of a rotary pump is the ratio of the differential pressure generated by the pump to the torque required to drive the impeller shaft. It is a representation of how much effectively a pump is converting the momentum of the impeller into the kinetic energy of the fluid. It can be represented as [16, 59]:

$$\eta = \frac{\dot{m}}{\rho} \left(\frac{P_2 - P_1}{T\omega} \right) \quad (3.2)$$

Where η represents the efficiency of the pump, P_1 and P_2 are pump inlet and outlet absolute pressures (Pa) respectively, T is the applied mechanical torque (N.m), $\dot{m}$ is the mass flow rate (kg/s), ρ is the density (kg/m³) of the fluid and ω represents the rotational speed (rad/s).

3.3.3 Flow Rate

The flow rate of the pump is the rate of change of the volume of the fluid passing through a cross-section area. It can be calculated as:

$$\dot{V} = Av \quad (3.3)$$

Where $\dot{V}$ volume flow rate (m³/s), A is the cross-section area (m²) and v is the normal velocity (m/s) of the fluid passing through the particular cross section.

3.3.4 Meridional Section

Due to axisymmetric nature of the axial flow pump, it is convenient to use cylindrical the coordinate system instead of cartesian coordinates. The meridional section is the blade section at a constant angle. The flow field is often described in terms of velocities along the meridional direction. Figure 3.3 shows the view of a mixed flow pump and meridional section [60].

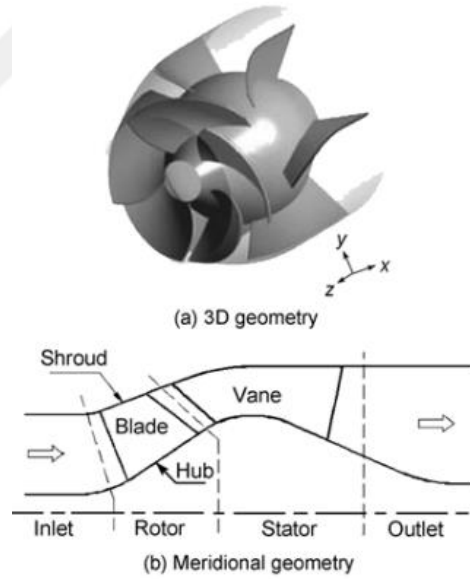


Figure 3.3: Mixed flow pump and its meridional view [60]

3.3.5 Blade Angle

Blade angles are used to describe the shape of the blade. The pump's geometric parameters include inducer blade angle (α_1), impeller blade leading edge angle (β_1), impeller blade trailing edge angles (β_2), diffuser blade leading edge angle (α_2), diffuser blade trailing angles (α_3). These angles are taken from the axial axis of the pump. The wrap angle of the impeller blades (θ) is described as the total angle from start to the end of the blade with the reference line. Any changes in these parameters can directly affect the performance of the pump [61].

3.3.6 Velocity Triangles

The 2D velocity triangle analysis of the blades provided a good estimation of the blade angles of inducer, impeller, and diffuser [62]. Due to the rigid body dynamics, the rotational speed of the rotor changes from the hub to the shroud. Figure 3.4 shows the velocity triangle of the pump. Here, u represents the linear velocity of the blade, w represents the relative velocity between moving blade and fluid while v is the absolute velocity of the fluid. The subscript 1 represents the exit of inducer and inlet of the impeller, subscript 2 represents exit of impeller and inlet of diffuser and 3 represents exit of diffuser blades.

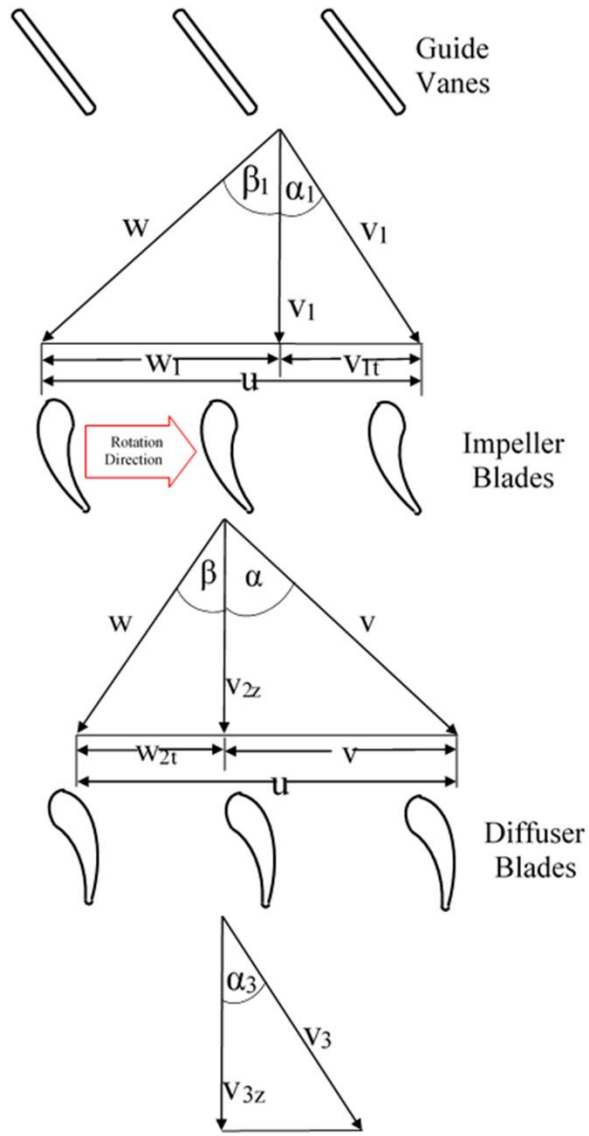


Figure 3.4: Velocity triangles for axial flow pump

Applying principle of momentum, the torque required to achieve specific pressure is

$$T = \rho \dot{V} (r_2 v_{t2} - r_1 v_{t1}) \quad (3.4)$$

In this equation, the $\mathbf{r}_2$ and $\mathbf{r}_1$ represents the outlet and inlet radius of impeller and subscript t represents the tangential component of absolute velocity.

The head of the pump can be estimated as [63]:

$$H = \frac{u_2 v_{t2} - u_1 v_{t1}}{g} \quad (3.5)$$

3.4 Computational Fluid Dynamics Analysis

Computational Fluid Dynamics (CFD) is a numerical analysis based technique to solve the flow domain of a fluid [64, 65]. Recently CFD has played a significant role in the optimization of the device's design. It is an excellent analysis tool, not only facilitating the prediction of hydraulic and hemodynamic performance of the pump but also identifying its recirculation and the blood clotting regions [66, 67].

The 2D analysis of blades can provide the blade angles of the pump. In order to see the effect of other design parameters such as wrap angles of impeller and diffuser, radial gap, blade height and a number of the blade a comprehensive three-dimensional analysis is required. CFD is an excellent tool to analyze the flow domain. It can not only provide the fluid velocities but can also be used for blood damage analysis in pumps.

The fluid flow is governed by continuity and momentum equations also known as Navier-Stokes equations. The Navier Stokes equation in conservative form is [68]:

$$\text{Continuity: } \frac{\partial \rho}{\partial t} + \frac{\partial}{\partial x_i}(\rho u_i) = 0 \quad (3.6)$$

$$\text{Momentum: } \frac{\partial}{\partial t}(\rho u_i) + \frac{\partial}{\partial x_j}(\rho u_j u_i) = -\frac{\partial p}{\partial x_i} + \frac{\partial \tau_{ij}}{\partial x_j} \quad (3.7)$$

Where u is velocity vector and p is pressure and τ_{ij} represent stress-tensor. The blood is an incompressible fluid which means that its density remains constant. After application of this constraint steady state Navier-Stokes equation in incompressible conservative form takes shape as

$$\text{Continuity: } \frac{\partial u_i}{\partial x_i} = 0 \quad (3.8)$$

$$\text{Momentum: } \rho \frac{\partial u_i}{\partial t} + \rho \frac{\partial}{\partial x_j}(u_j u_i) = -\frac{\partial p}{\partial x_i} + \frac{\partial}{\partial x_j}(2\mu S_{ij}) \quad (3.9)$$

Where S_{ij} represent the strain rate tensor and can be given by

$$S_{ij} = \frac{1}{2} \left(\frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i} \right) \quad (3.10)$$

3.4.1 Turbulence

Due to the high rotational speed of impeller and high velocities turbulence condition exists in rotary blood pumps. In turbulence, the flow field becomes a random function of space and time. In order to solve it, the pressure and velocities are decomposed into the mean and fluctuating component.

Figure 3.5 shows the mean and fluctuating component of velocity. Mathematically it can be represented as [69]:

$$u_i = U_i + u_i' \quad (3.11)$$

$$p_i = P_i + p_i' \quad (3.12)$$

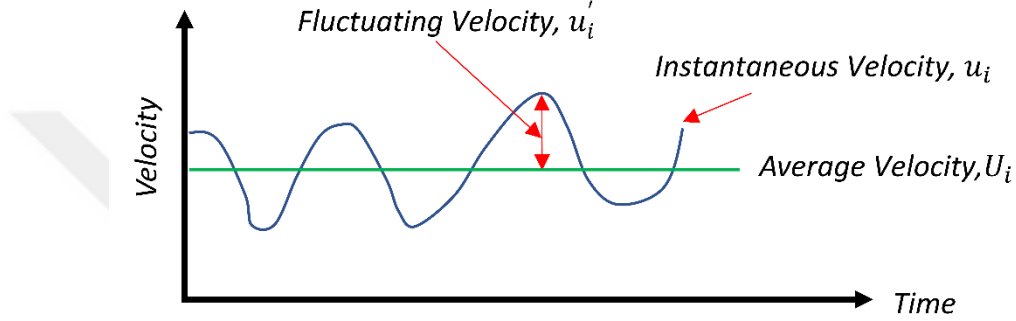


Figure 3.5: Instantaneous and fluctuating component of turbulence velocity

By introducing these components into incompressible Navier-Stokes equation additional terms are introduced but no additional equation is introduced to solve these unknowns. To solve these unknown terms additional turbulence model equations are introduced. There are many turbulence models exists like Spalart-Allmaras, k-omega and k-epsilon [70-72]. The use of proper turbulence model is very important otherwise it may lead to inaccurate and misleading results. k-epsilon is one of the most commonly used turbulence model because of its robustness. During the design of blood pumps, many researchers have successfully used this model with reasonable accuracy [66, 73-76]. In chapter 7 we have compared different turbulence models and found out that k-epsilon is giving fastest convergence and minimum residual thus it is used in our studies. The following section provides a brief description of this model.

3.4.2 k-epsilon model

The standard k-epsilon is based on modeling the transport equations for turbulence kinetic energy and dissipation rate. It is a relatively simple model which often converges easily. In this model, the turbulence kinetic energy (κ) is obtained from following transport equations [68, 77]:

$$\frac{\partial \kappa}{\partial t} + U_j \frac{\partial (\kappa)}{\partial x_i} = -\overline{v'_i v'_i} \frac{\partial \overline{v}_i}{\partial x_j} - \rho \varepsilon + \frac{\partial}{\partial x_i} \left(\left(\mu + \frac{\mu_t}{\sigma_k} \right) \frac{\partial \kappa}{\partial x_i} \right) \quad (3.12)$$

The energy dissipation rate is derived from phenomenologically, and its transport equation is:

$$\frac{\partial \rho \kappa}{\partial t} + \frac{\partial (\rho \varepsilon \overline{V}_i)}{\partial x_i} = \frac{\partial}{\partial x_j} \left(\left(\mu + \frac{\mu_t}{\sigma_\varepsilon} \right) \frac{\partial \kappa}{\partial x_j} \right) + C_1 P_k \frac{\varepsilon}{\kappa} - C_2 \rho \frac{\varepsilon^2}{\kappa} \quad (3.13)$$

The Reynold viscosity is represented as a ratio of kinetic energy and dissipation rate

$$\mu_t = \rho C_\mu \frac{\kappa^2}{\varepsilon} \quad (3.14)$$

The coefficients C_1 , C_2 , σ_k , σ_ε and C_μ are obtained using data fitting of experiments.

3.5 CFD based Hemolysis estimation

CFD-based prediction of the hematologic capability of the device is very important. In the past, there were some models which predict the blood hemolysis for rotary blood

pumps, but experimental validation of such models in a particular design is important for further improvements. According to the power law model, flow-induced hemolysis in the blood pumps is proportional to shear stress and exposure time. The correlation is given below [78-80]:

$$HI = C\tau^\alpha t^\beta \quad (3.15)$$

Where τ is shear stress, t is exposure time and C , α and β are parameters related to the experiment. In the current study, the parameter proposed by 5 different studies was used. Values of these parameters are given in Table 3.1.

Table 3.1: Different blood damage models

Models	C	α	B
Giersiepen et al. [78]	3.62×10^{-5}	2.416	0.785
Gesenhues et al. [81]	2.32×10^{-7}	1.4924	0.33
Fraser et al. [2]	1.745×10^{-6}	1.963	0.7762
Heuser et al. [82]	1.8×10^{-6}	1.991	0.765
Zhang et al. [83]	1.228×10^{-5}	1.9918	0.6606

In the shear stress model, τ is replaced by the equivalent scalar shear stress calculated in complex 3D flows. In 2004, Garon and Farianas introduced the Eulerian approach in the stress-based model [84, 85]. In this method, the computation of blood damage along the pathlines is replaced by volume integration of a damage function

over the computational domain. This method eliminates the problems associated with particle tracking, such as residence time and incomplete tracer particles. In the same year, Arora et al. proposed the strain-based model for estimation of blood damage [86, 87]. In this technique, the shape of deformed RBCs was represented by a morphology tensor S . The authors reported very good agreement between the experimental and numerical results for hemolysis calculations. This method used particle tracking (Lagrangian method) to compute the hemolysis index. Pauli et al. used the same strain-based technique in transient Euler-based technique for the hemolysis estimation in blood pumps [88].

In this research, both Euler-stress-based models and strain-based model were applied on the transient computational model of the pump, computational NIH levels were obtained and compared with the experimental results. The numerical NIH level in both cases was calculated using [86]:

$$NIH[g/100L] = 100 \times HI \times (1 - H_{ct}) \times H_b \quad (3.16)$$

Where H_{ct} is blood hematocrit and H_b is the hemoglobin content (150 g/L for a healthy individual).

3.5.1 Stress-based model

In the stress-based method, shear stress used in equation 6 is replaced by the equivalent shear stress. This incorporates both the principle and shear stress acting on the fluid and can be represented using [89, 90]:

$$\tau = \sqrt{\left[\frac{1}{6} (\tau_{ii} - \tau_{jj})^2 + (\tau_{ij})^2 \right]} \quad (3.17)$$

Where τ_{ii}, τ_{jj} represent principle stress and τ_{ij} represents pure shear stress, respectively.

3.5.2 Tensor-based (strain) model

In tensor-based method shape of deformed RBCs was represented by morphology tensor. The effective shear stress contributing to the damage of blood cells can be calculated as [86, 88]:

$$\tau_{eff} = \mu_{blood} G_{eff} \quad (3.18)$$

Where G_{eff} represents the intensity, which is directly related to the instantaneous shape distortion (D_{ef}) of a blood cell. Given a distorted blood cell with length ‘L’ of the major axis and length ‘B’ of the minor axis, the instantaneous shape distortion can be found using equation 3.19:

$$D_{ef} = \frac{L-B}{L+B} = \left[\frac{\sqrt{f_1^2 + f_2^2 G_f} - f_1}{f_2 G_f} \right] \quad (3.19)$$

Where G_f represents the intensity of flow, the value of f_1 is 5.0 s^{-1} and that of f_2 is 4.2298×10^{-4} , which depends on the physical properties of RBCs [88]. After performing the calculations, the effective shear stress can be calculated as:

$$G_{eff} = \frac{2f_1 D_{ef}}{(1 - D_{ef}^2)f_2} \quad (3.20)$$

Using equation 3.18 reveals

$$HI = C(\mu_{blood} \times G_{eff})^\alpha t^\beta \quad (3.21)$$

3.6 Manufacturing and Hydraulic Performance Testing

In order to validate CFD model of the pumps, it is necessary to manufacture and test prototype pump for hydraulic performance before in vitro and in vivo testing. In hydraulic performance test blood mimicking fluid with 65% water and 35% glycerin mixture is used as working fluid. The setup consists of a fluid reservoir, pressure sensors for measuring differential pressure, flow rate sensors and pump assembly. Pump assembly consists of pump body, casing, electromagnets and motor controller. The system flow diagram is shown in Figure 3.6. Two pressure sensors one before inlet and one at the exit of the pump assembly is installed to find the differential pressure. The pump is rotated at constant speed. The flow control valve is used to control the flow

rate passing through the circuit. As the flow rate changes, there is a change in differential pressure. The flow rate is observed using ultrasonic flow rate sensor while the speed of the motor rotating impeller is controlled using feedback control system. The speed of the motor is measured using hall effect sensors while the motor is operated using brushless direct current (BLDC) motor.

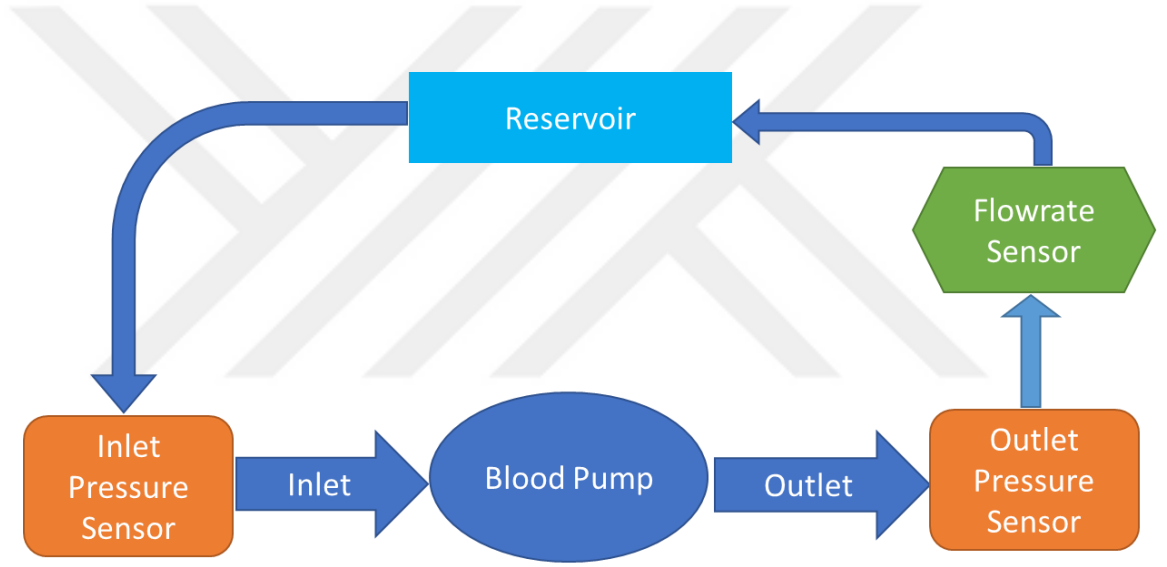


Figure 3.6: System diagram for hydraulic performance test

3.7 Blood Test

After performing hydraulic performance tests, hemolysis test was performed. Fresh blood was collected from the healthy human donor (protocol number 2015.213.IRB2.082 issued by institutional review board of Koc University), anticoagulated with sodium heparin (15 IU/ml). The hematocrit of blood samples was adjusted to 30.5 % and a 6-hour test was performed. Samples were collected at 30-

minute intervals during the first 3 hours and then, the collection routine was performed on an hourly basis. Plasma free hemoglobin concentration was measured spectrophotometrically via a modified cyanmethemoglobin technique [91]. The Normalized Index of Hemolysis (NIH) level was calculated using the following formula [92]:

$$NIH(\frac{g}{100L}) = \Delta pfHb \times \frac{(100 - H_t)}{100} \times Vol \times \frac{100}{Q \times \Delta t} \quad (5)$$

Where $\Delta pfHB$ is the increase in plasma free hemoglobin (g/L), Vol is the volume (L), H_t is the hematocrit percentage, Q represents the volume flow rate (L/min) and Δt is the sampling time (min).

Chapter 4 : PROTOTYPE I: DESIGN AND MANUFACTURING

4.1 Overview

The previous chapter discussed design procedure related to rotary blood pumps. This chapter discusses the design of the first prototype pediatric blood pump developed in MARC. The blade angles were estimated using velocity triangle analysis. The ANSYS Fluent® was used as CFD analysis software. As this is a pediatric pump the flow requirement changes with the age of the patient. This research focuses on developing a pump from the newborn age up to the age of two years. The flow rate range for this condition is 0.25-1.5 L/min and the pressure range is 63.5-73 mm Hg. A unique feature of the device under development is shrouded impeller design of the axial pump. In this design, the relative velocity between impeller blade and shroud is zero.

4.2 Pump Design

This section discusses design step involves while designing the pump. These steps involve blade angle calculations, impeller design, diffuser design.

4.2.1 Conceptual Model

Figure 4.1 shows conceptual model for shrouded impeller pediatric blood pump in which impeller blades and shroud are in contact. Permanent magnets and bearing are also installed at the outer surface. Permanent magnets are actuated using BLDC operation provided by a radial bearing. The idea behind this design is due to zero relative velocity between impeller blades and shroud is zero which can reduce the shear stress caused by blade tip. Also, by embedding the permanent magnets outside shroud reduce the distance between the electromagnet and permanent magnet thus, in turn, increases the efficiency of the motor. Also, the high circumferential area can facilitate ring magnet for passive stability in the maglev system.

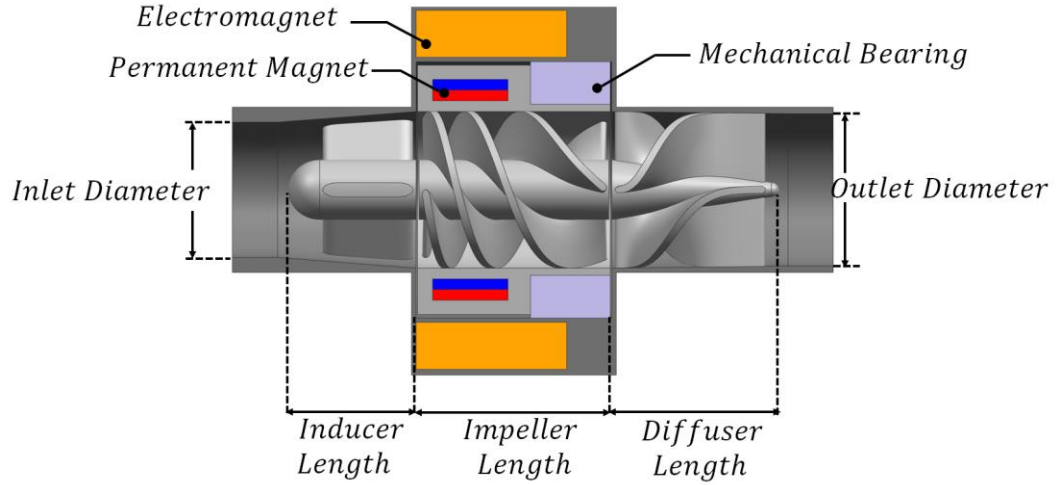


Figure 4.1: Cross-sectional view of Prototype I

4.2.2 Blade Angles

Velocity triangle method was employed to obtain the angle for angles of inducer, impeller and diffuser blades. In order to estimate blade angles, the mean velocity in the aorta of a person is required. A value of 1.1 m/s was taken for the mean aortic velocity. Fine et al. measured the inward and outward flow velocities of blood from LVAD during systole and diastole. Using their measurements, the inlet velocity was set to be 0.9 m/s and the outlet velocity to 1.6 m/s. To estimate cross-section area of inlet and outlet pipe the maximum flow rate of 0.07 kg/s (corresponding to 4 L/min). Using equations

$$A = \frac{\dot{m}}{\rho V} = \frac{0.07 \left(\frac{kg}{s}\right)}{1050 \left(\frac{kg}{m^3}\right) * 0.9 \left(\frac{m}{s}\right)} = 7.41 \times 10^{-5} m^2$$

$$D = \sqrt{\frac{4 * (7.41 \times 10^{-5} m^2)}{\pi}} = 9.71 \times 10^{-3} m$$

To limit the size of the pump the maximum impeller diameter of the pump was selected to be 11mm and hub diameter to accommodate axial stability permanent magnets was selected 4mm. The hub to tip ratio is 0.36. In axial flow pumps, it is preferred that the fluid entering and leaving the pump should be axial in direction. Due to this reason, the inducer blade angle and diffuser exit angle should be at zero

degree with respect to reference axial axis. This makes the tangential component of absolute velocity entering and exiting the pump to disappear. Thus, the axial component of fluid entering and exiting fluid have a magnitude of 0.9 m/s and 1.6 m/s respectively. Due to rigid body dynamics, the linear velocity of the blade varies from hub to shroud thus three angles at hub, center, and the tip of impeller blades was estimated.

4.2.3 Impeller Design

The velocity triangle calculations can only provide the blade inlet and exit angles. In order to find the effect of impeller helix angle on the performance of the pump, simulations were performed with varying wrap angles. In these simulations, the hydraulic efficiency of the impeller blades was recorded. It was observed that the minimum hydraulic efficiency was obtained at 180° wrap angle. And as the wrap angle increased the hydraulic efficiency increased, to 360° . After 360° the hydraulic efficiency started decreasing. A third order polynomial was fitted to the results as shown in Figure 4.2. The optimal angle for maximum efficiency was found to be 400° . The number of blades was selected to be 3 in order to provide fluid appropriate cross-sectional area. If the number of blades is increased, then at higher wrap angle the blades will intersect with each other thus blocking the path of the fluid. Consequently, if the number of the blade has decreased the momentum transferred to the fluid will

also decrease reducing the efficiency of the pump. This compromise must be made by using 3 blades impeller.

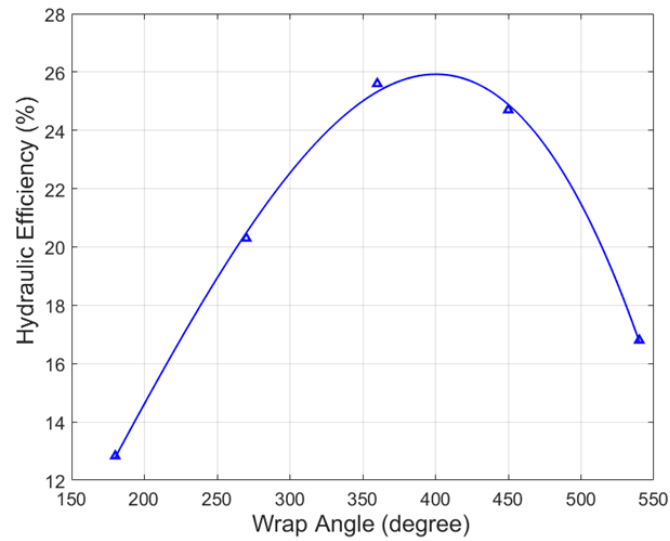
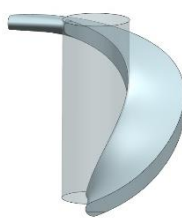


Figure 4.2: Impeller blade wrap angle (θ) vs hydraulic efficiency

Wrap 180°



Wrap 270°



Wrap 360°



Wrap 540°



Figure 4.3: Single impeller blade with different wrap angles

Table 4.1: Hydraulic efficiency of different impeller blade wrap angles

Impeller blade Wrap Angle (degree)	Rotational Speed (rpm)	Pressure Change (mm Hg)	Torque (N.mm)	Mass Flow rate (kg/s)	Hydraulic Efficiency (%)
180	11750	59.64	2.40	0.05	12.82
270	11750	71.23	1.81	0.05	20.3
360	11750	80.16	1.77	0.055	25.6
450	11750	73.06	1.52	0.05	24.8
540	11750	31.71	0.98	0.05	16.8

4.2.4 Diffuser Design

To find the optimal number of blades for the diffuser, the analysis was performed with 3, 4 and 5 blade diffusers.

Table 4.2 shows the properties achieved for different diffuser configurations. In terms of hydraulic efficiency, the 3-blade diffuser was at a disadvantage with a minimum efficiency of 13%. The efficiencies of the 4-blade diffuser (26%) and 5-blade diffuser (28%) were comparable. When pressure changes were observed the 3-blade diffuser still performed the worst (25.52 mmHg). However, between the remaining two, the 4-blade diffuser far superseded the 5-blade diffuser (80.16 mmHg and 58.84 mmHg

respectively). Thus, based on this analysis it was decided to use the diffuser with 4 blades. The wall shear stress distribution shows that a larger area of high shear stress is present in the 5-blade design relative to the 4-blade design. It is interesting to observe that in both cases the higher stress area is present at the entrance of diffuser blades. This shows the effect of interaction between stationary and rotating parts that have a high effect on blood damage and hemolysis.

Table 4.2: Maximum shear stress and hydraulic efficiency using a different number of diffuser blades

Number of Blades	Rotational Speed (RPM)	Mass Flow Rate (kg/s)	Pressure Change (mmHg)	Torque (N.mm)	Hydraulic Efficiency (%)	Max. Shear Stress (Pa)
3	11750	0.05	25.52	1.01	13	1870
4	11750	0.055	80.16	1.78	26	2017
5	11750	0.055	58.84	1.61	28	3042

4.3 BLDC motor design

Permanent magnets were installed in a shroud of the impeller (rotor) to rotate the impeller at high-speed. The electromagnets(stator) were used to actuate the rotor and brushless DC motor concept was used. The advantage of using BLDC motor is that it

does has no contact bushes unlike another motor so it has relatively simple construction and more reliability. The downside of using BLDC is it requires an additional controller to switch the direction of electromagnets. In our initial setup, single-phase DC motor was used but due to its limitation of speed the setup was modified to sensorless BLDC motor drive. A detailed description of these designs is discussed in following subsections.

4.3.1 Single Phase Motor

Two electromagnets were installed at 180° angle apart. The speed of the rotor was controlled using pulse width modulation (PWM). H bridge circuit used to switch the magnetic poles of electromagnets. Arduino board used to in introduce PWM frequency while L293 microcontroller was used for H bridge IC. The rotor a hall effect sensor was measured using hall effect sensor. The problem associated with this drive was no self-starting and limited rotational speed. In dry-run the rotor was able to reach 13000 rpm, but during the hydraulic test, the system was able to achieve maximum rotational speed up to 6810 rpm which was very less than our requirement (10000 rpm). To cope with this problem, a multiple rotor senseless drive was designed and used.

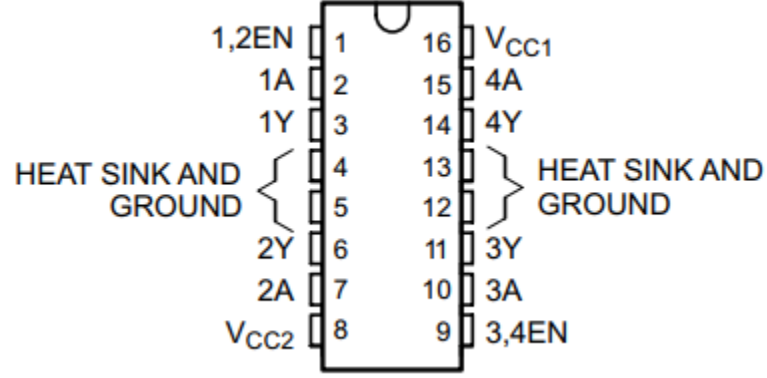


Figure 4.4: Pin configuration of L293 microcontroller

4.3.2 Three-Phase BLDC Motor

A three-stage BLDC requires three Hall sensors to identify the rotor's position. In view of the physical position of the Hall sensors, there are two sorts of commutation sequence which can be used to actuate the rotor. A 60° angle phase shift and a 120° angle stage move. Consolidating these three Hall sensor signs can decide the correct commutation succession.

A nine-pole and six pole electromagnet stators were built to actuate the rotors. Six poles rotor is required to use with nine pole stators while 8-pole rotor is required with the 6-pole stator. Figure 4.5 shows the winding scheme of both 6 and 9 pole stator configuration. The capital letters show winding in a clockwise direction while small letters represent anticlockwise winding scheme.

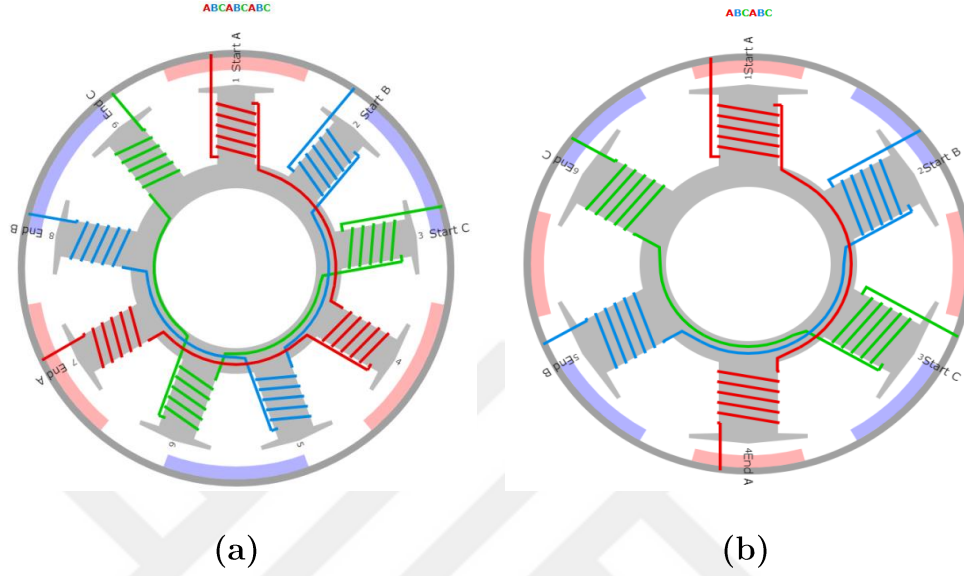


Figure 4.5: (a) 9-pole stator (b) 6-pole stator [93]

A 3-phase inverter circuit was built to drive the BLDC motor as shown in Figure 4.6. Three Hall Effect sensors equally spaced along circumference were placed on the stator to detect the position of the rotor in one complete electrical rotation. PWM voltage with a frequency of 20 kHz was used to drive the electromagnets. The current to the stator of the 3 phase BLDC motor was measured by the sensor ACS758. The outer casing of the system was made of Stainless Steel 316LS, which minimized the effect of induced eddy currents in the outer casing. are mounted on the stator at 120° intervals, while the three-phase windings are in a star formation. For every 60° rotation, one of the Hall sensors changes its state; it takes six steps to complete a whole electrical cycle.

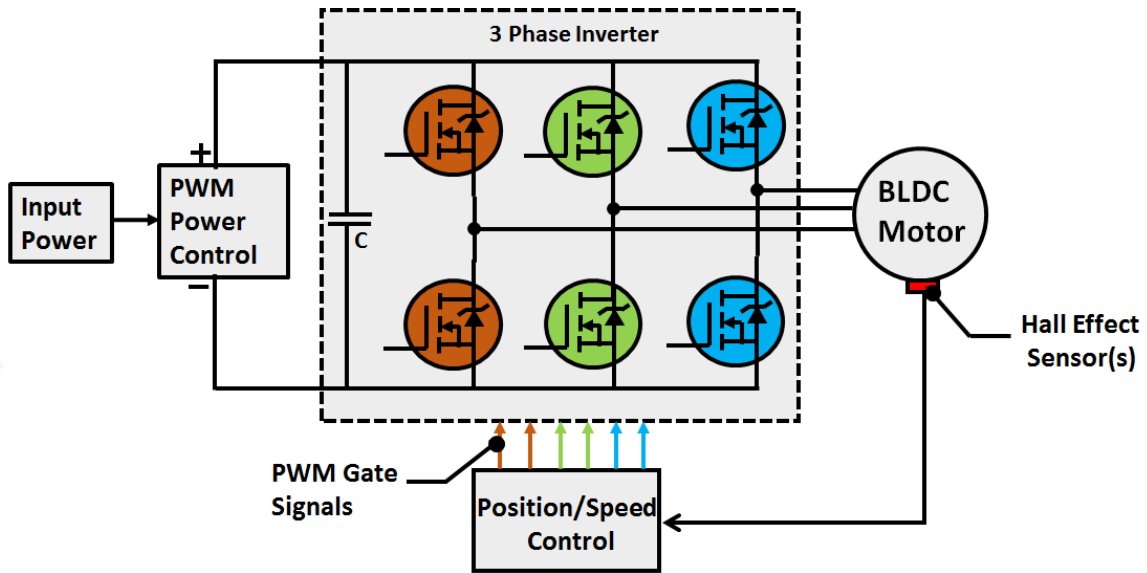


Figure 4.6: Three phase inverter circuit for BLDC Drive

In a sensorless drive BLDC motor system there is no need of hall effect sensors to detect the position of the rotor to provide commutation sequence. This drive uses back electromagnetic force (BEMF) signal generated in stator electromagnet due to the motion of permanent magnets. The variation of sensor output with respect to BEMF signal is shown in Figure 4.7. The sensor signal changes state when the voltage polarity of the BEMF crosses from positive to negative or from negative to positive. The BEMF zero-crossings provides precise position data for commutation.

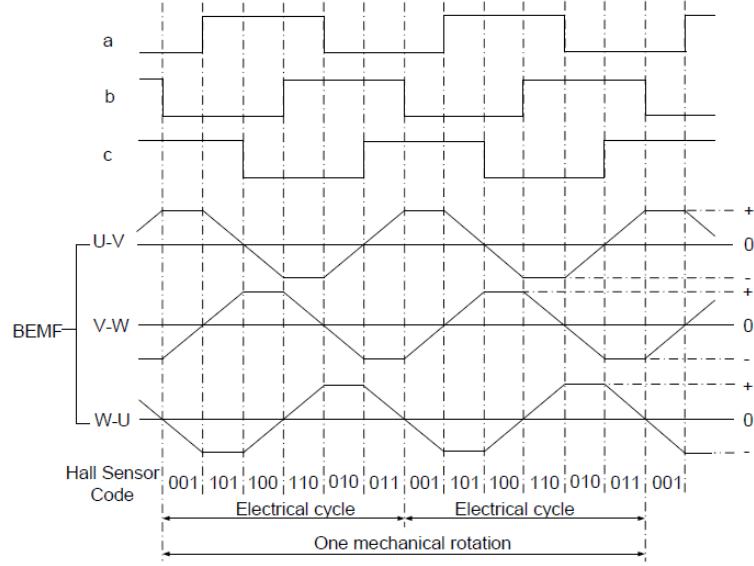


Figure 4.7: Variation of hall effect sensor output with respect to BEMF signal in BLDC motor drive [94]

This sensorless commutation simplifies the structure of pump and relatively cheap. In hydraulic performance and blood tests, this sensorless drive was used. The drive was implemented using the commercially available drive for RC helicopter motors. A potentiometer was used to vary the speed of motor and hall effect sensor was used to measure the speed.

4.4 Manufacturing

The impeller, diffuser, and inducer of this system were manufactured using stereolithography (STL) technique. The model of these parts was modeled in Siemens NX software and was converted into STL file. The machine utilized for printing has an accuracy of fewer than 25 microns in z-direction while 100-micron accuracy in x

and y directions. After printing the parts were given alcohol solution bath and ultraviolet (UV) light curing. Figure 4.8 shows 3D printed parts after curing and magnets installed in the outer periphery of the shrouded impeller.

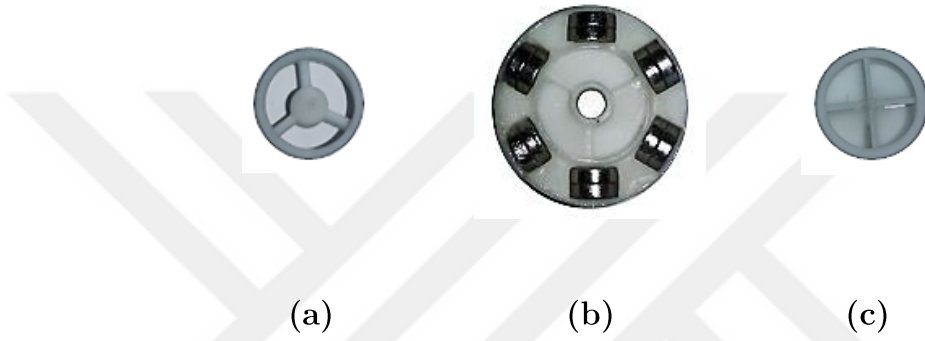


Figure 4.8: 3D printed (a) Flow straightener (b) Impeller (c) Diffuser

Single phase motor prototype was machined using plexiglass glass blocks. This machined casing has two parts and between these casing parts, the 3D printed parts were sandwiched. M2 screws were used to join the casing. Figure 4.9 shows plexiglass casing after machining.



Figure 4.9: Machined plexiglass for single phase motor design

The problem associated with the design was the leakage of fluid between the gap of electromagnet and rotor poles and also the rotational speed achieved using single phase was 6810 rpm. In order to solve this problem a tubular type design was manufactured which can accommodate multiple pole stator and axial compressive casing prevented the leakage. The Teflon tape used for leakage in the pump. The outer casing of the system was made of Stainless Steel 316. Figure 4.10 three-phase BLDC pump during the hydraulic performance test.

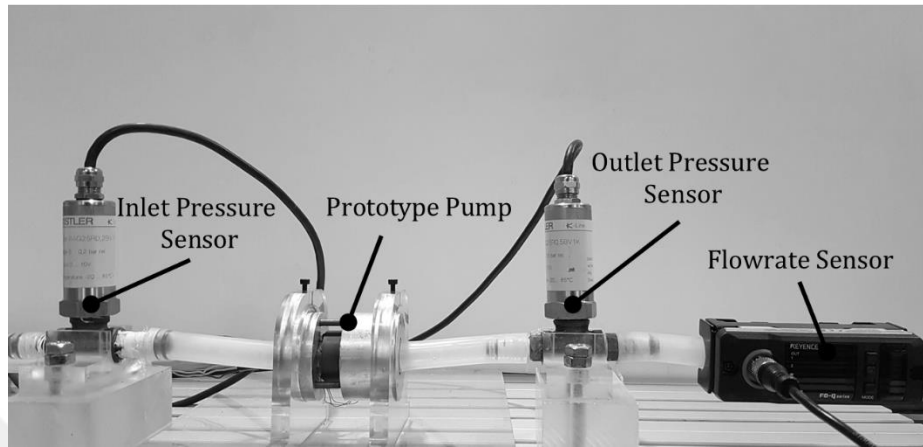


Figure 4.10: Prototype I during the hydraulic performance test

4.5 Axial Stability Analysis

The rotating impeller provides an axial force to the fluid, increasing its velocity and consequently its dynamic pressure. As a reaction, an axially uplifting force is exerted on the impeller, causing it to contact with the flow straightener. This increases the friction in the system. In order to avoid this, axial magnets were installed in the hub of the flow straightener, impeller, and diffuser. The schematic diagram of magnets is shown in Figure 4.11.

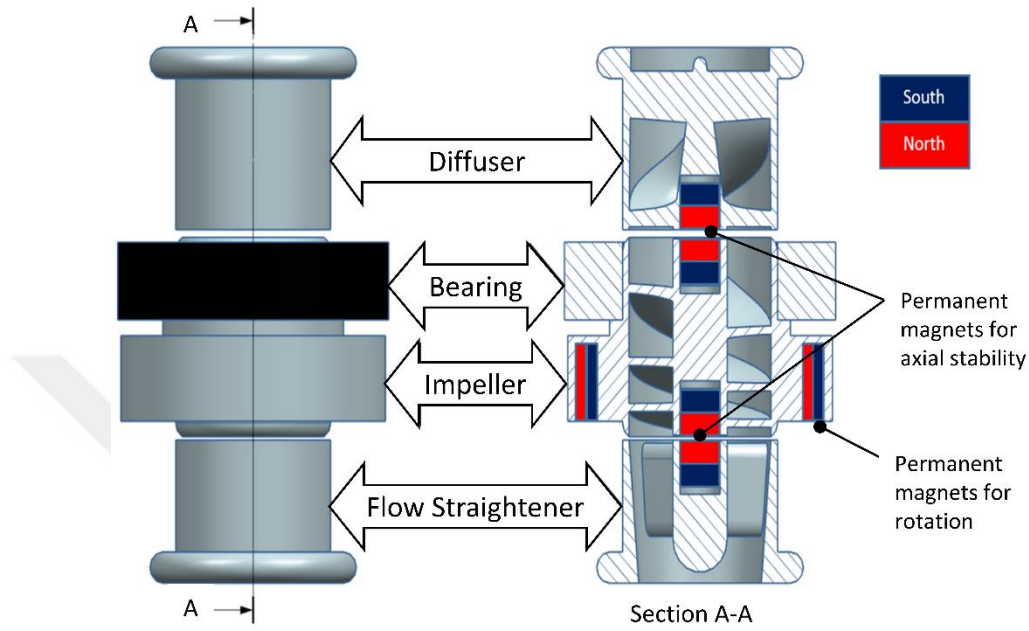


Figure 4.11: Cross-sectional view of flow straightener, impeller, and diffuser showing the placement of permanent magnets in the system

CFD calculations showed that the maximum lifting force is 0.9 N at 11750 rpm and 2 L/min. Magnets of diameter 3mm and height 1.5 mm were installed inside the hub. The repelling force between the two single magnets was measured using a dynamometer. Figure 4.12 shows the dynamometer data for the repelling force between two magnets. The region highlighted in red shows the repelling force at 200 microns with an average force of 0.89N. Thus, a pair of magnets were installed in the flow straightener and the impeller while a single magnet was used in the diffuser. The clearance distance between the rotating impeller and the stationary flow straightener and diffuser was set to 200 microns. This configuration positioned the impeller exactly in the center and thus reduced the friction and increased the axial stability

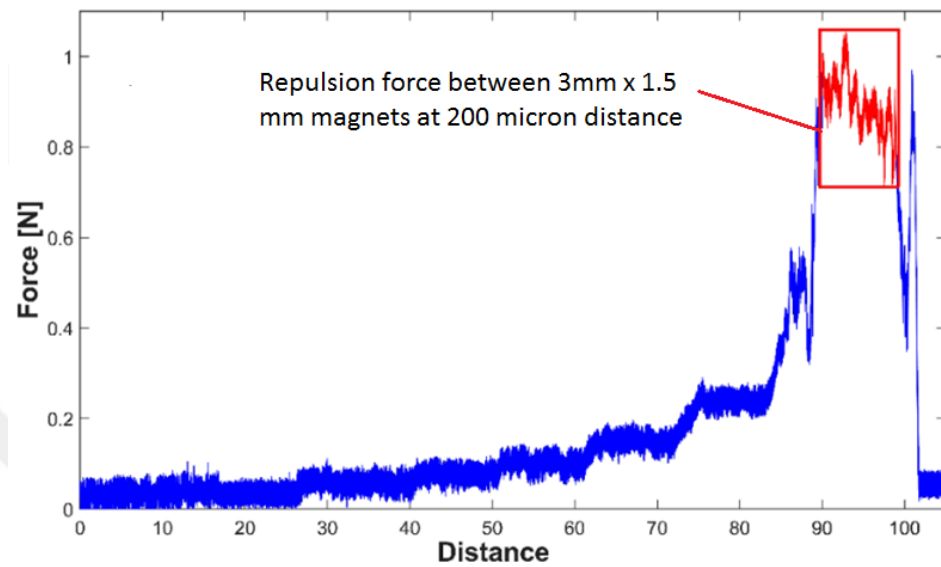


Figure 4.12: Dynamometer force data for repulsion force between two Ø3 mm×1.5 mm neodymium magnets

Chapter 5 : PROTOTYPE I: ANALYSIS EXPERIMENTATION AND DISCUSSION

5.1 Overview

This chapter presents the results, analyses and discussion of prototype I. The primary focus of the SIP VAD's flow design was to streamline the blood flow path with no secondary flow and minimize the shear stress regions. By comparing the hydraulic performance of computational and experimental data the validity of design and proof of concept was established. Hemolysis test was performed and compared with the computational results. In CFD analysis both “stress-based” and “strain-based” models were used. Based on this analysis high shear stress regions were identified and further design modifications for better hemodynamic performance were suggested.

5.2 CFD Preprocessing

5.2.1 Boundary Conditions

The blades of the inducer and the diffuser were selected to be stationary walls with no-slip boundary condition. Rotating wall boundary condition was used for the hub, the shroud and the blades of the impeller, with a relative velocity of the adjacent cell

zones selected to be zero. The mass flow rate was chosen as the inflow condition and the pressure as the outflow condition.

5.2.2 Mesh and Grid Independence

The inducer, impeller, and diffuser were modeled separately. Interfaces were used to join these blocks. The angle of inflow cannula was 90 degrees while outflow cannula angle was 45 degrees, as shown in Figure 5.1.

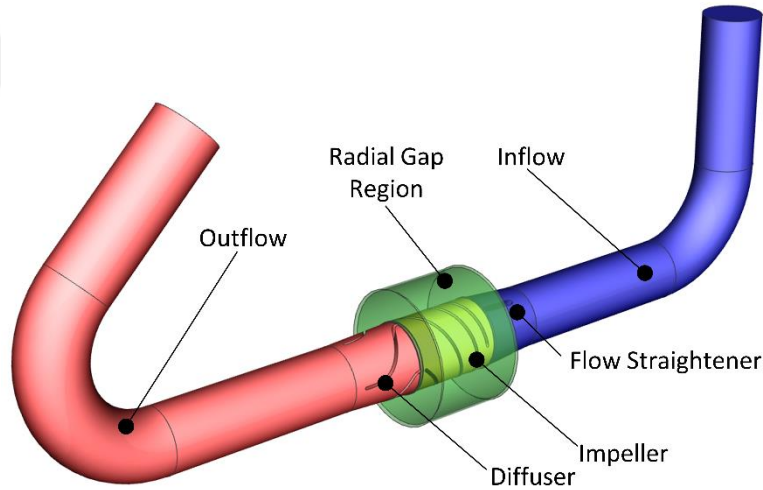


Figure 5.1: Computational model for CFD analysis

Mesh independence was checked using tetrahedron element sizes 0.25mm, 0.20 mm and 0.12 mm. Quadrilateral shaped, boundary layer elements, with a size of 30 microns, were generated on the walls of the inducer, impeller, and diffuser blades. Wall y^+ was 3, therefore, enhanced wall treatment was used. A total of 14.2 million mesh elements

were created using an element size of 0.12 mm. The convergence criteria were set to be 10^{-5} residual. It took approximately 30 hours for the solution to converge on an HP Z840 workstation. Figure 5.2 shows the mesh generated for the flow region in the flow straightener, the impeller, and the diffuser.

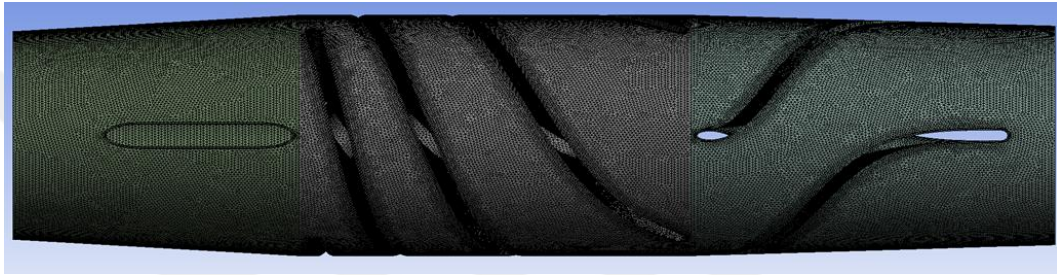


Figure 5.2: Mesh Generated

5.3 Hydraulic Performance

To obtain the performance curve for the pump the speed of the pump was adjusted between 8500 to 11750 rpm. At each rotational speed, flow rates with a magnitude of 1,2,3 and 4 L/min were simulated. At each point, the pressure and torques were calculated. Figure 5.3 shows the performance graph obtained using CFD.

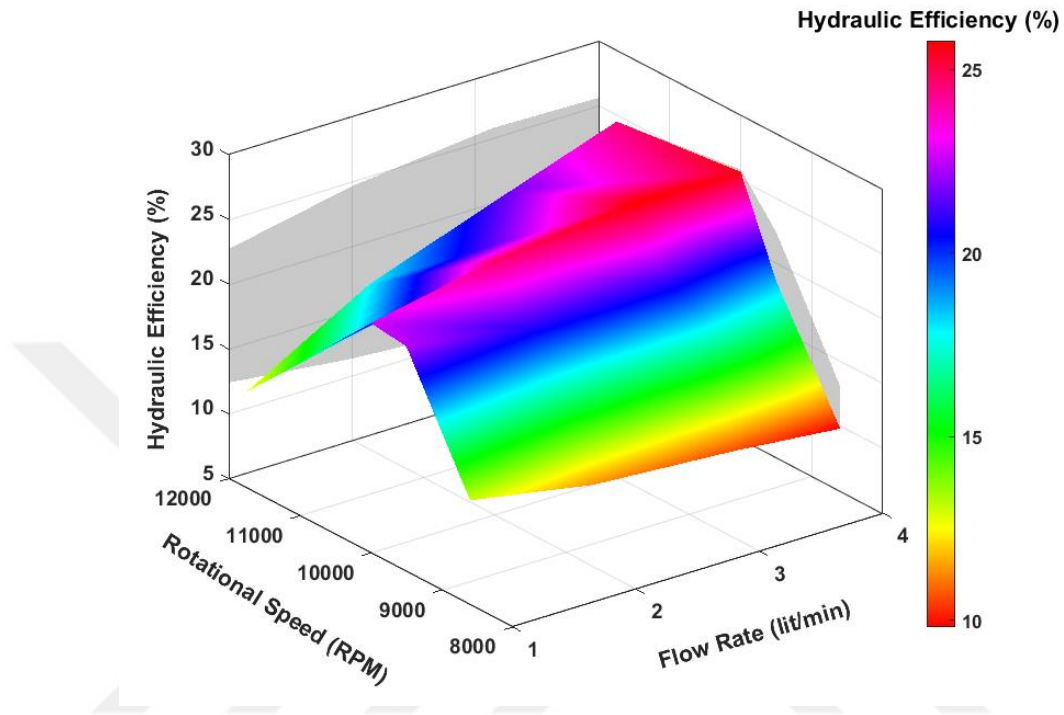


Figure 5.3: Variation of hydraulic efficiency with respect to rotational speed and flow rate

For each rotational speed and flow rate, the pressure rise across the pump was determined. The operating conditions of 1.5 L/min at 75 mmHg was achieved at 10000 rpm. Figure 5.4 shows the hydraulic efficiency at different rotational speeds and flow rates. The maximum efficiency obtained is approximately 26%. The efficiency ranges from 10% to 26%, which is typical for a blood pump.

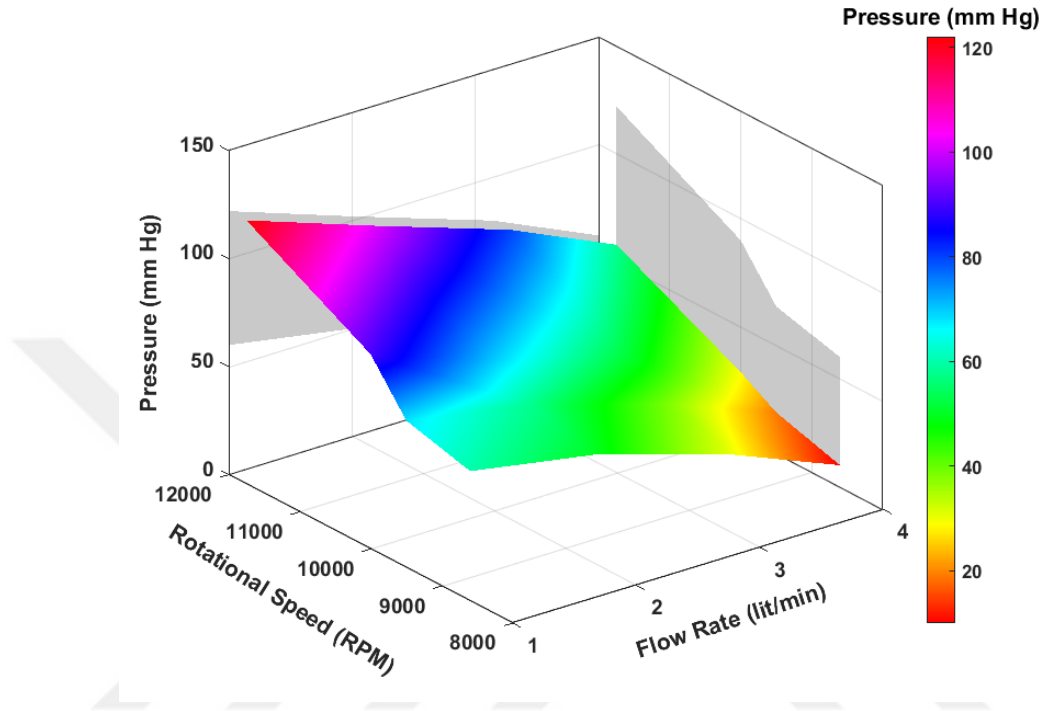


Figure 5.4: Pressure generated with respect to rotational speed and flow rate

A bench top test model was developed to analyze the experimental performance of the pump. Figure 5.5 shows the comparison of CFD results with experimental data. The maximum difference between simulation and experiment was not more than 6 mmHg. The difference between both results was due to the relative inaccuracy during the manufacturing of the parts. The experimental validation shows the proof of concept for using a fully enclosed axial flow pump as LVAD. These results promoted the possibility of using enclosed impeller design and perform blood tests.

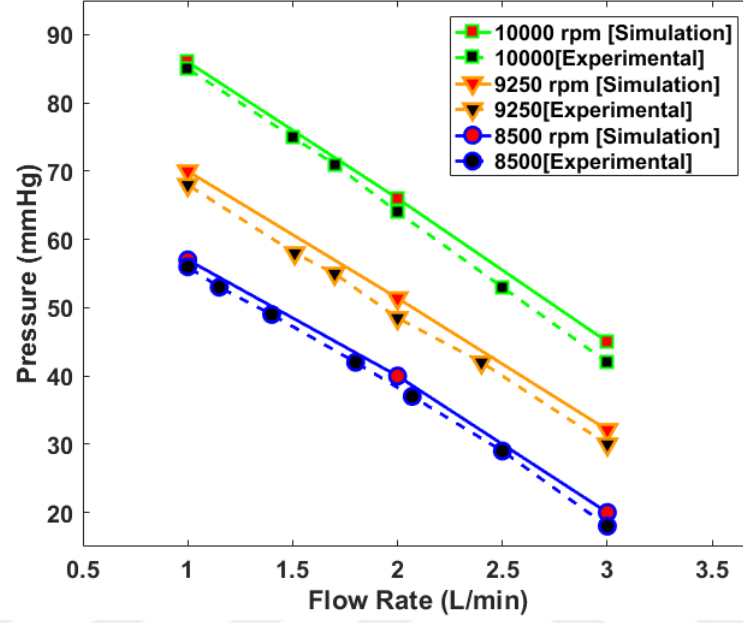


Figure 5.5: Comparison of CFD and experimental results for hydraulic performance

5.4 Pressure Contours

This section shows the variation of pressure contour as the flow rate increased from 1 L/min to 4 L/min with an increment of 1 L/min at 8500, 9250, 10000 and 11750 rpm. It can be observed that there is a decrease in overall pressure as the flow rate increase.

5.4.1 8500 RPM

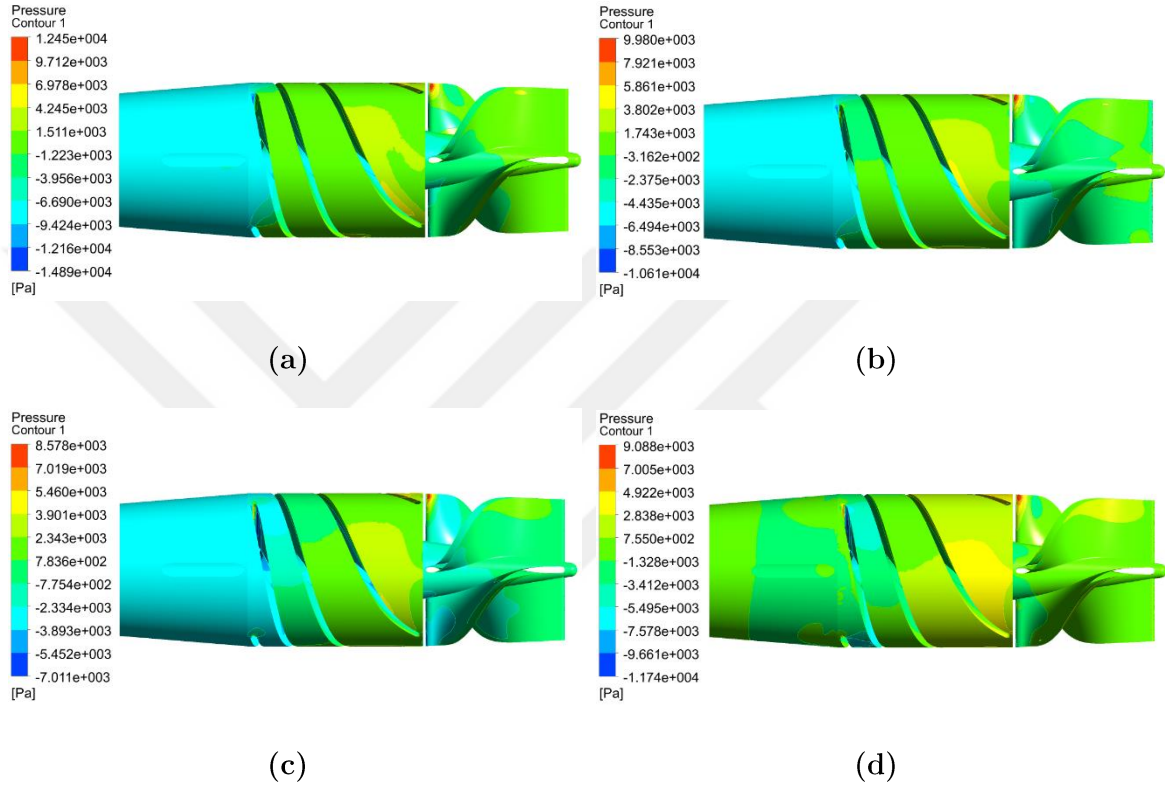


Figure 5.6: Pressure contours at the rotational speed of 8500 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.4.2 9250 RPM

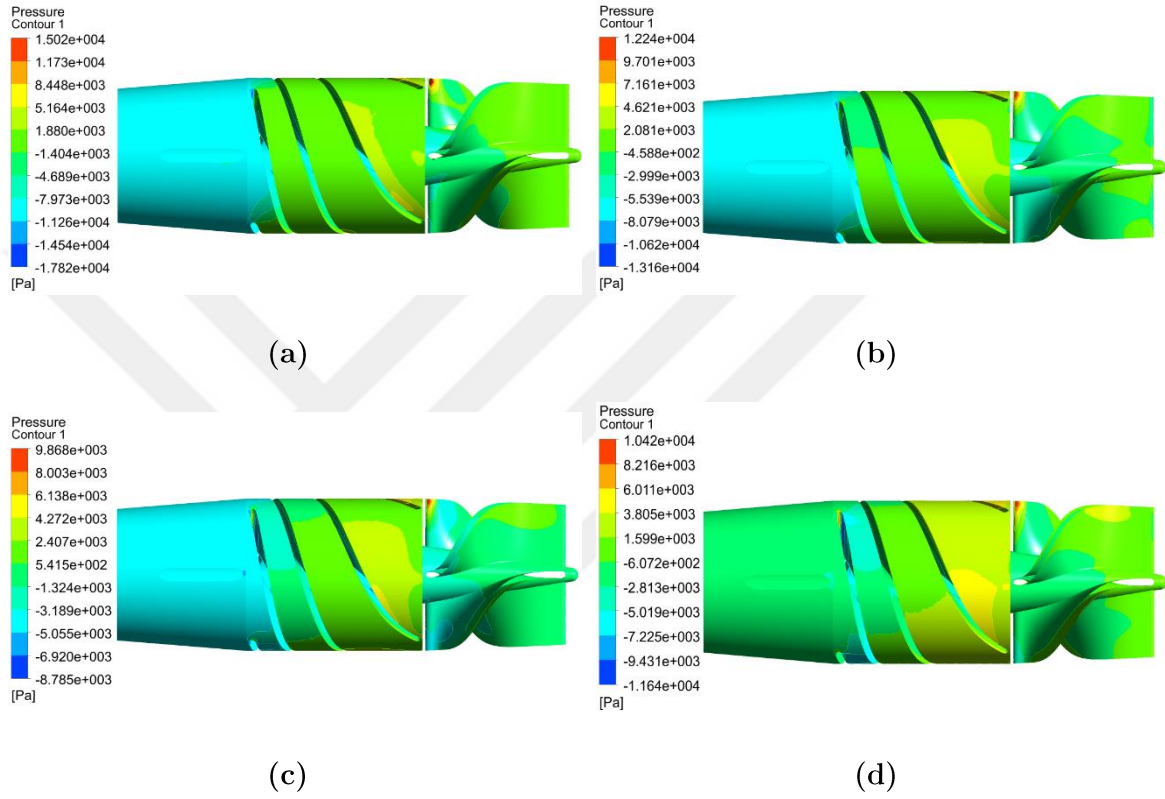


Figure 5.7: Pressure contours at the rotational speed of 9250 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.4.3 10000 RPM

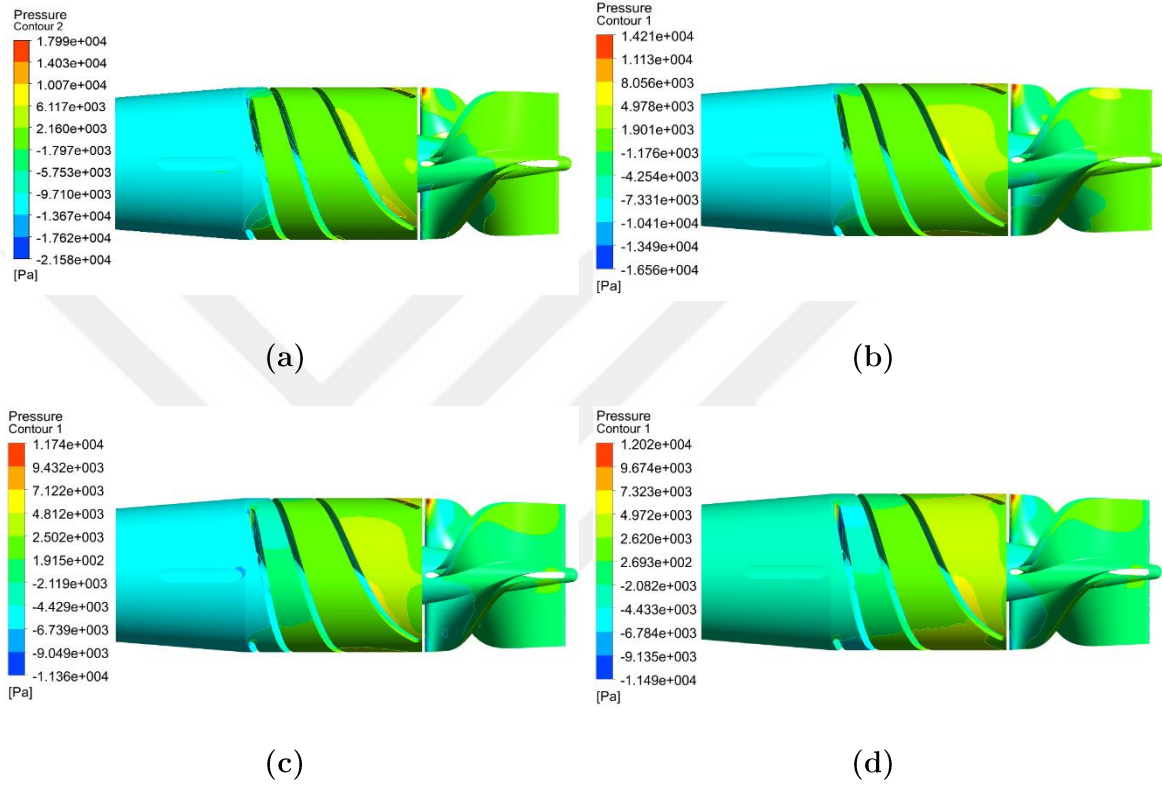


Figure 5.8: Pressure contours at the rotational speed of 10000 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.4.4 11750 RPM

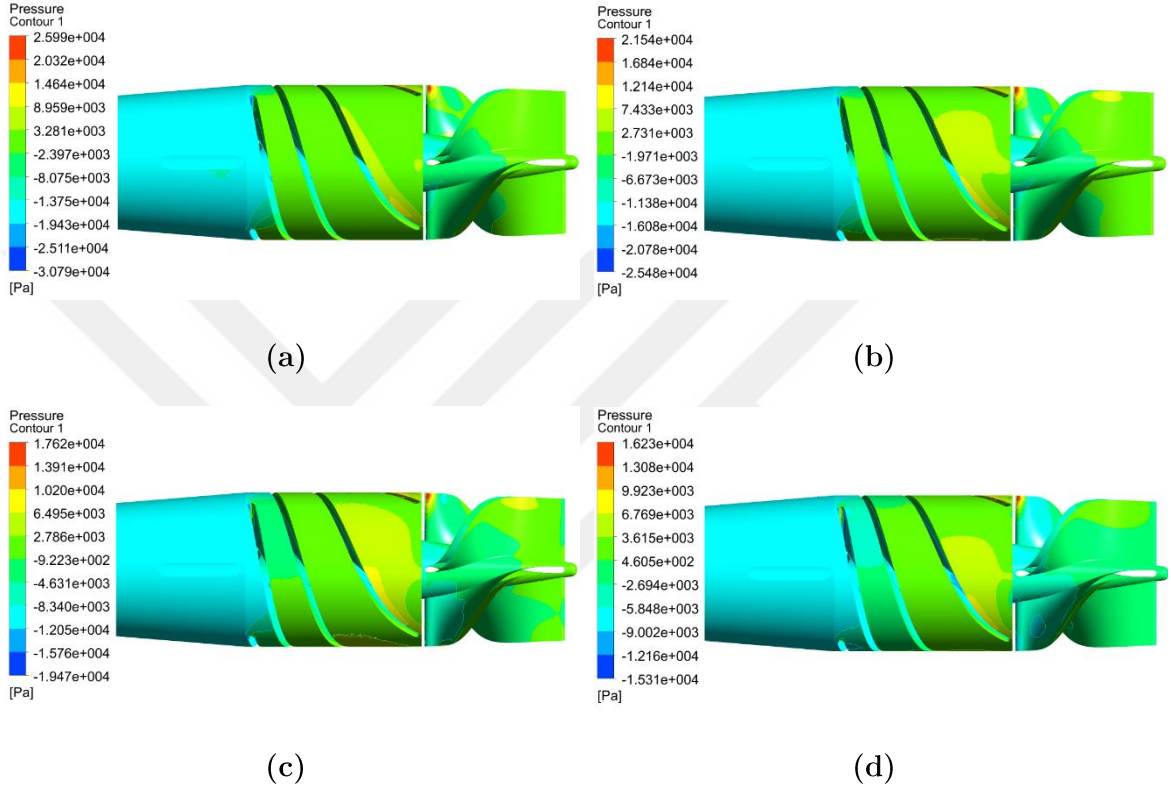


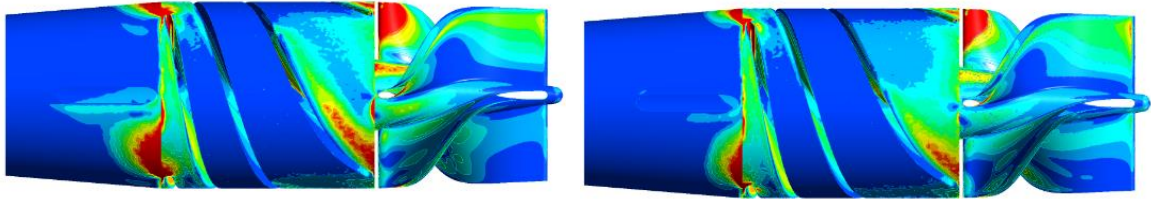
Figure 5.9: Pressure contours at the rotational speed of 11750 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.5 Wall Shear Stress

Wall shear stress is the measure of the effect of stationary walls on the boundary layer of fluid. The increase in wall shear indicates the effect of geometry at that particular region on fluid and high rate represent the possibility of high blood damage.

The following section shows the contour of wall shear at every simulation point. The area in red color indicated the wall shear of more than 250 Pa and they are more prone to blood damage. In every case, the observed WSS is high at the connection of moving (impeller) and stationary parts (inducer and Diffuser). It can also be observed the at the exit of impeller due to the high exit angle of impeller blade WSS is higher. As the flow rate increase at constant rotational speed (consequently pressure drops) the area having high WSS decreases. Also, increase in rotational speed at a constant flow rate (consequently increase in pressure) increases the high-stress area. It can be observed by comparing the WSS contour at the flow rate of 1 L/min and rotational speeds of 8500 rpm and 11750 rpm.

5.5.1 8500 RPM



(a)

(b)

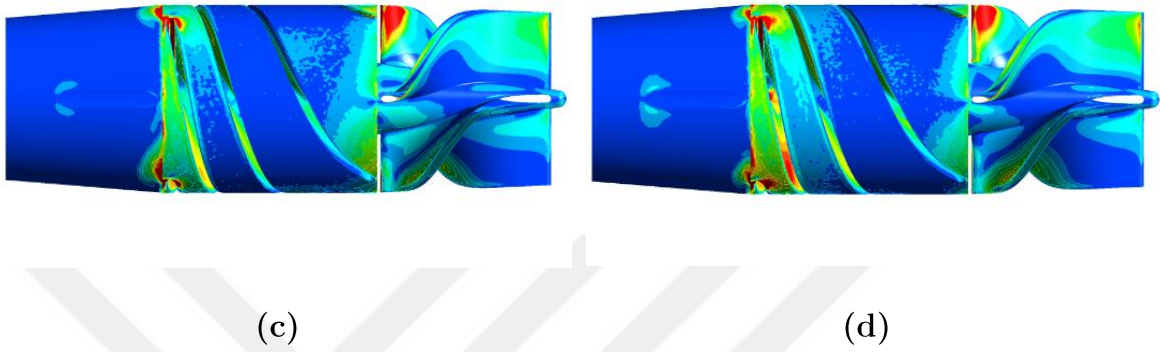
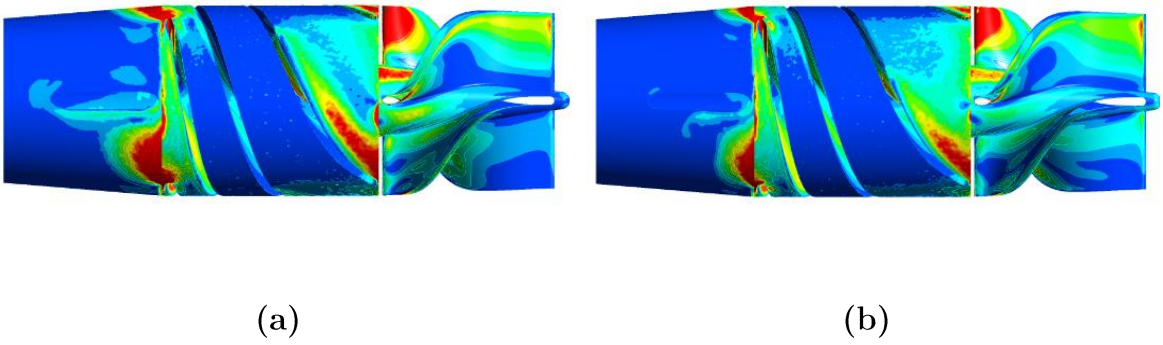


Figure 5.10: Wall shear stress contours at the rotational speed of 8500 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.5.2 9250 RPM



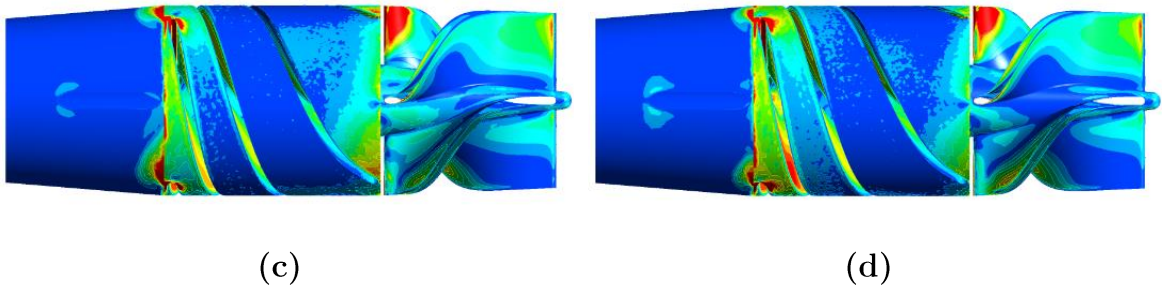


Figure 5.11: Wall shear stress contours at the rotational speed of 9250 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.5.3 10000 RPM

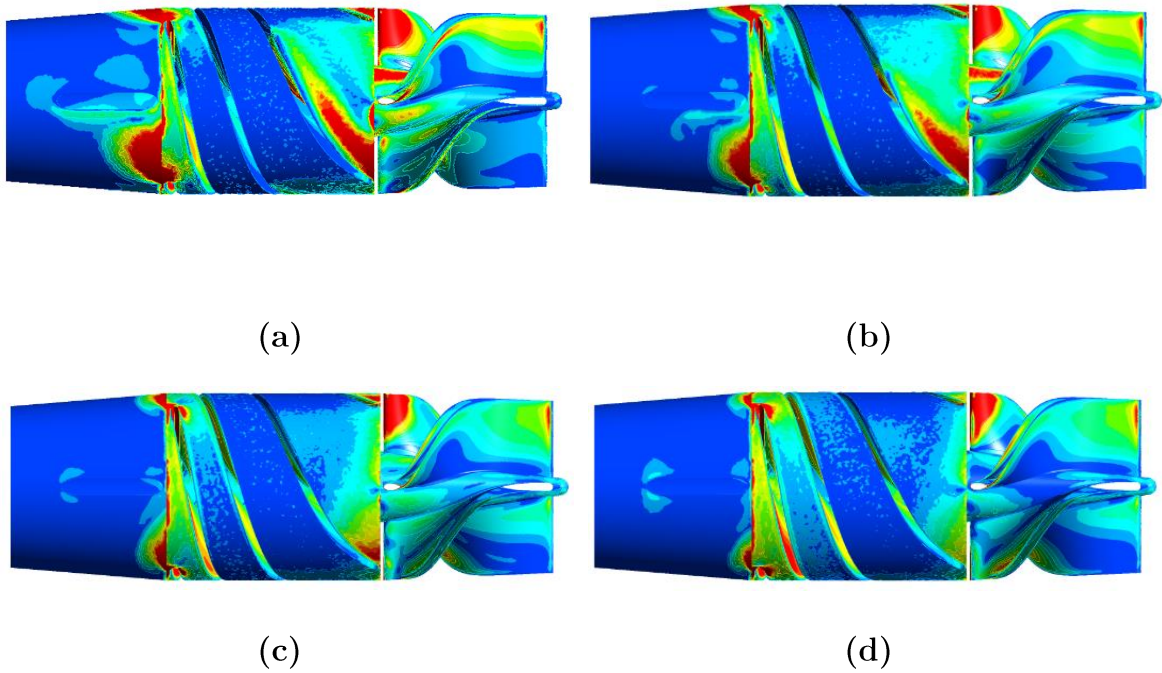


Figure 5.12: Wall shear stress contours at the rotational speed of 10000 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.5.4 11750 RPM

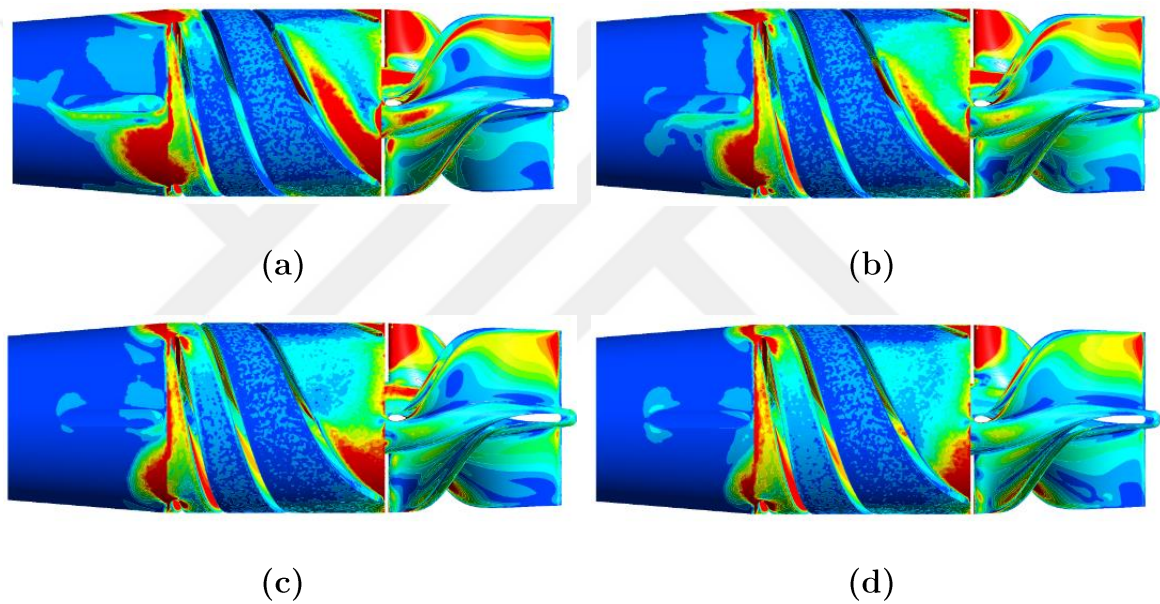


Figure 5.13: Wall shear stress contours at the rotational speed of 11750 rpm (a) 1 L/min (b) 2 L/min (c) 3 L/min (d) 4 L/min

5.6 Flow Field

One of the important aspects of designing a pump is its streamlined structure. The flow recirculation and separation region are undesired for the better hemodynamic performance of the pump. The velocity vector and streamlines are used to check these

areas. Figure 5.14 shows the streamline at the flow straightener section of the pump. It can be observed the smooth flow is occurring in this section and no turbulence can be observed. The velocity vector shows that at low flow rate there is a flow separation occurring at the exit of diffuser but as that flow rate increases this separation of flow disappears.

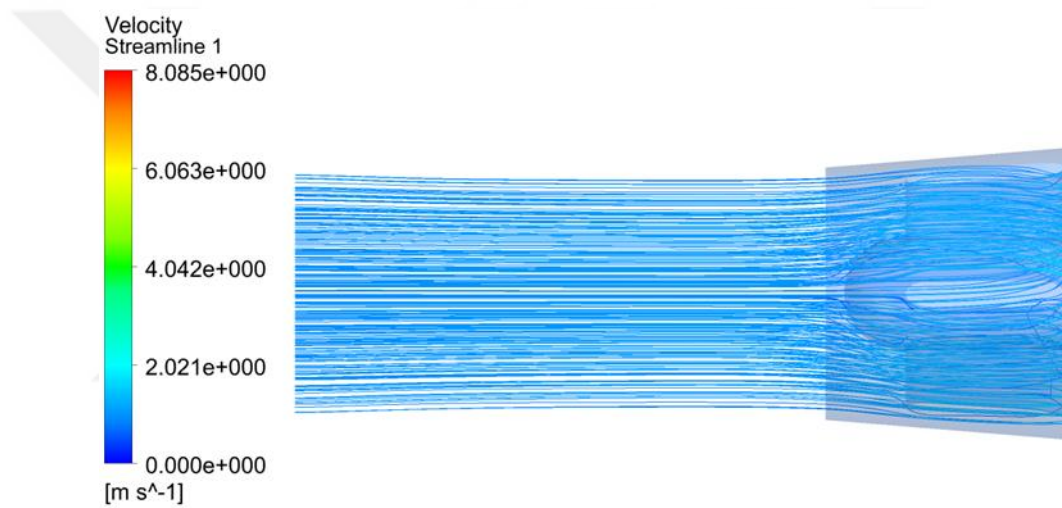
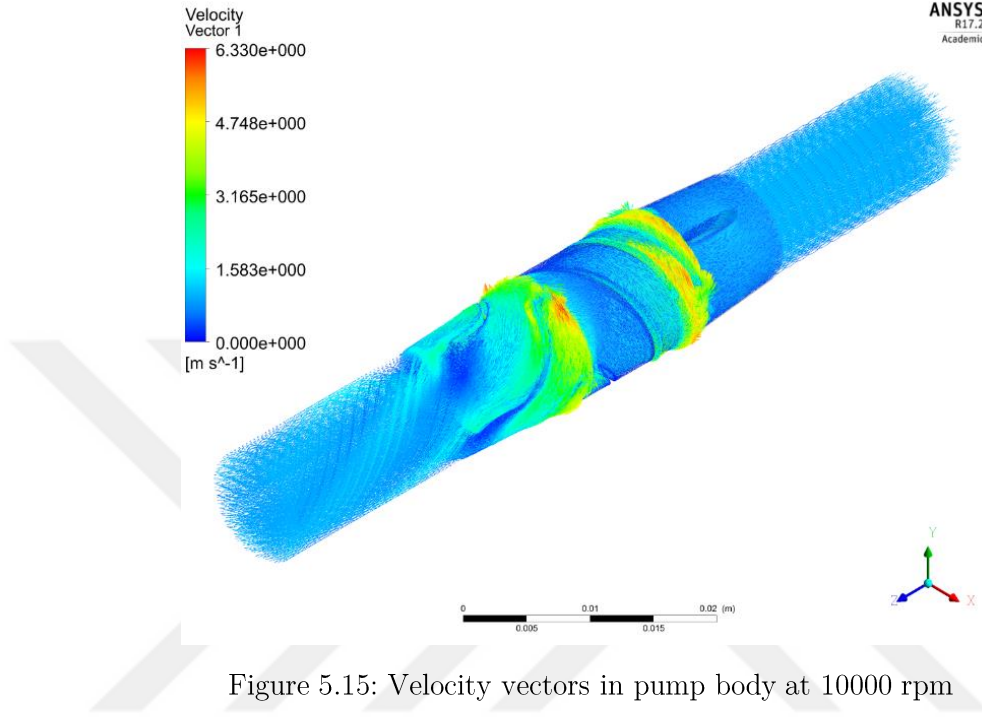


Figure 5.14: Velocity streamline at inducer section



5.7 Hemolysis

In this research, both Euler-stress-based models and strain-based model were applied on the transient computational model of the pump, computational NIH levels were obtained and compared with the experimental results. The rotational speed of the pump for the blood test was 10000 rpm, and therefore the time step size (Δt_s) for transient analysis was $1.67e-4$ with 36-time steps to simulate one complete revolution and rotating mesh was used for the impeller fluid body region. Table 5.1 shows the average NIH values for stress- and strain-based models for different HI constants. The constants estimated by Gesenhues et al. using strain-based model predicted the results more accurately, therefore it was used for the analysis.

Table 5.1: NIH estimation for different power-law models using stress and strain-based methods

Models	HI Stress Based	HI Strain Based	NIH stress (g/100L)	NIH Strain (g/100L)
Giersiepen et al. [78]	9.16e-5	2.65e-5	0.962	0.27
Gesenhues et al. [81]	7.3e-5	2.06e-5	0.766	0.216
Fraser et al. [2]	2.81e-5	1.04e-5	0.294	0.11
Heuser et al. [82]	3.25e-5	1.47e-5	0.341	0.154
Zhang et al. [83]	1.82e-3	3.61e-4	19.11	3.79

Hemolysis test was conducted in a closed loop for 6 hours. Damage of blood in the test as determined by the NIH calculation was 0.186 g/100 L. This value is higher than the desired limit of 0.01 g/100L in adult blood pumps [95]. However, in a publication related to the evaluation of the performance of pediatric Jarvik 2015 the author's used a threshold of 0.1 g/100L for pediatric patients [53]. Although, the value of 0.186 g/100L is still higher than this threshold it is not such an unrealistic value to discard this design. The further improvement for current design is discussed in next chapter.

5.8 Discussion

The chapter presented the results and analysis of shrouded impeller design for LVAD devices. The advantage of this design lies in its compactness and the reduced distance between rotor magnets and stator electromagnets. Furthermore, a good hydraulic performance was achieved as the desired flow rate and the pressure was obtained. Although the experimental tests with blood showed a higher level of hemolysis than the desired value, this was an initial step towards the development of a new design for VAD.

To understand the reasons behind the high levels of hemolysis and shear stress, a CFD-based hemolysis estimation was performed. The analysis showed that there were high-stress levels around the rotating impeller and at the inlet of the diffuser and impeller. Several factors can account for these high-stress levels. First, high-velocity gradients were generated at the diffuser opening due to the small size and large helix angle of the diffuser. To resolve this problem, reducing the helix angle of the diffuser and the exit blade angle of the impeller was proposed. Additionally, the high-stress levels at the inlet of impeller were the result of using three inducer blades with three impeller blades. Through simulations, it was found that by increasing the number of inducer blades from three to four and decreasing their thickness from 1 mm to 0.5 mm, the design can be improved. Another parameter that affects hemolysis directly is the gap between the rotating part (enclosed impeller) and the stationary parts (inducer, casing, and diffuser). The NIH level predicted from the transient strain-based model

was reduced from 0.216 g/100L for a gap of 250 microns (current design value) to 0.083 g/100L for 1000 microns. However, the objective of this setup is to minimize the gap, ensuring the maximum efficiency of the motor. To cope with this problem, it is suggested that the flow through this region should be minimized. Practically, to achieve this, baffle rings should be used on the outer surface of the impeller and inner surface of the stator. These baffle rings create hindrance to the entrance of flow. In addition, when using radial bearings ABEC 5 or higher series, sealed bearings should be used with tight fit tolerance to prevent blood from entering into this zone. Another factor responsible for the large hemolysis can be the surface roughness of the pump body. Analysis of the surface finish on the top part of the impeller blade using white a light interferometer revealed an average roughness of 22.21 microns. This is significantly higher for an MCS device. With the additive layer manufacturing technique advancing rapidly, improved surface finish parts to solve such problems can be manufactured in the future.

The present study represents a step forward in the development of enclosed impeller pump. With the advancements in the field, required improvements in the manufacturing techniques and design will be performed in the future.

Chapter 6 : PROTOTYPE II: DESIGN ANALYSIS AND RESULTS

6.1 Overview

This chapter discusses the design improvement made in shrouded impeller design based on the results presented in Chapter 5 : . This design has distinctive design features and parameter optimizations for minimization of recirculation flow and reduction in high-stress regions that cause blood damage. CFD simulations were performed to analyze the optimized design. The bench-top prototype of SIP-VAD was manufactured with biocompatible stainless steel. A study on the hydrodynamic and hemodynamic performance of the SIP-VAD was conducted with predictions from CFD and actual experimentation values, and these results were compared. The attainment of desired values and a close match between CFD predictions and experimentation results show the feasibility of shrouded impeller design of axial flow pump.

The primary focus of the pediatric VAD's flow design is to streamline the blood flow path with no secondary flow and low shear stress regions. The study demonstrates the feasibility and reliability of the shrouded impeller design for VAD and the proof of concept. This chapter discusses the methodology adopted for the designing of a pediatric LVAD, which includes three-dimensional CFD analyses, manufacturing of a benchtop prototype and experimentation. A three-dimensional model of the pump was

created using design improvements based on the earlier prototype of SIP-VAD. CFD analysis was used to assess the hydraulic performance of the device. Also, high shear stress regions and velocity vectors were used to analyze the blood damage and clotting regions. A benchtop model was manufactured to analyze the performance of the pump. By comparing the hydraulic performance of computational and experimental data the validity of design and proof of concept was established. In vitro tests showed that proper manufacturing and limiting the path of fluid through the motor well region can lead to a pump with good hemodynamic performance.

6.2 Design Modifications

The internal flow region of the previous SIP-VAD design consisted of 1) a flow straightener region with three blades; 2) a rotating impeller with three blades; 3) a diffuser section with 4 stationary blades. CFD analysis revealed high-stress regions at the exit of the impeller, inlet of the diffuser, and the fluid covering the shrouded impeller and motor housing (motor well region). Following section discuss the design modifications of different components of SIP VAD for better performance

6.2.1 Impeller

The WSS analysis of previous design identified three problems

- I. Higher inlet angle of impeller blade causing high stresses
- II. Flow separation at low flow rates at the exit of the impeller
- III. High exit and causing raise of WSS at higher pressures

In order to reduce shear stress at the exit and inlet of the impeller, the impeller blade angles were decreased. To avoid flow separation at low flows the splitter blades were introduced at the and splitter blades were introduced to avoid flow separation. The height of splitter blades was 0.6 times the length of the impeller blades. To accommodate the rotating blades inside the shroud in such a way that there is a tight fitting between them, the cross-sectional area of the impeller blades was made conical. The inlet diameter of the impeller blades was 9.5 mm and exit diameter is 11 mm. Figure 6.1 shows design of prototype II.

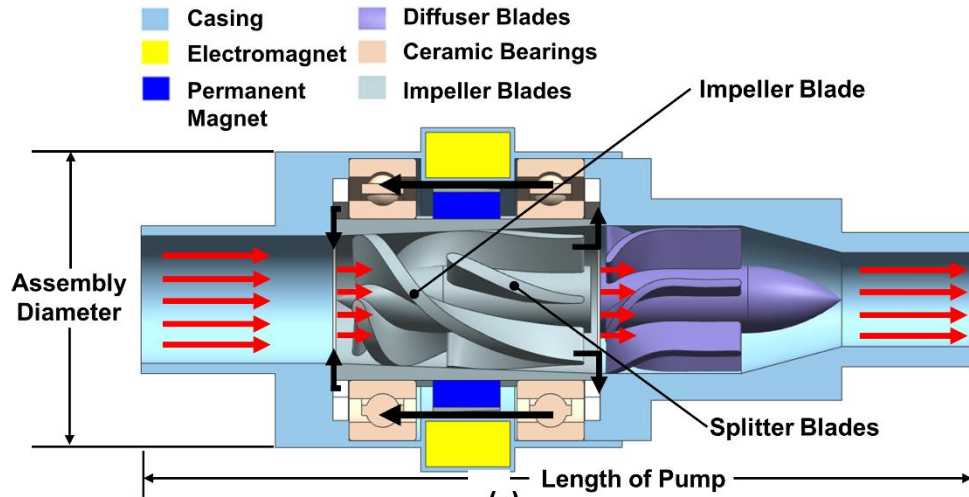


Figure 6.1: Schematic diagram of the shrouded impeller pump model. The red arrows show the primary path for fluid flow and the black arrows show flow through the motor well region. The Teflon seal ring at the front and back of the bearings block the flow of blood from motor well regions to minimize the blood damage

6.2.2 Diffuser

The in previous design there was swirling observed at the exit of the diffuser. Theoretically, the observed swirling flow may be reduced by increasing the number of diffuser blades. Comparison of the 8-blade diffuser with 6-blade diffuser proved this, but the number of the blade is limited by manufacturing capabilities. To manufacture an 8-blade diffuser a small milling tool must be used which causes the chattering phenomenon, and this creates inaccuracies in production and may cause the tool to break frequently. Also, an increase in blade number causes an increase in the contact area between the fluid and structure, which may induce extra hemolysis. Thus, the best compromise was found using 6-diffuser blades.

6.2.3 Motor Well Region

To minimize the flow from the motor well region, annular Teflon seal rings were introduced so that the blood damage caused by this region is kept to a minimum. Figure 6.2 shows the placement of Teflon seal ring used to prevent blood from entering the motor well region. Red Blood Cells (RBCs) are of bileaflet shapes with a diameter of $8\text{ }\mu\text{m}$. The distance between the Teflon seal ring and rotating radial ceramic bearing is $25\text{ }\mu\text{m}$ to minimize the flow of RBCs through the motor well region. The reason behind $25\text{ }\mu\text{m}$ gap is to avoid contact between moving impeller or bearing with Teflon seal ring so that there is no additional heat production. In the previous model of the

pump single ceramic bearing was utilized which produced axial instability. The use of two bearings not only provided axial stability but also provided better sealing because two Teflon seal rings were used in front and back of impeller as shown in Figure 6.1. Also, to force the flow inside the shroud region, flow straightener was eliminated, and the entrance of the impeller region was manufactured in a conical shape. The dimensions of the pump are given in Table 6.1.

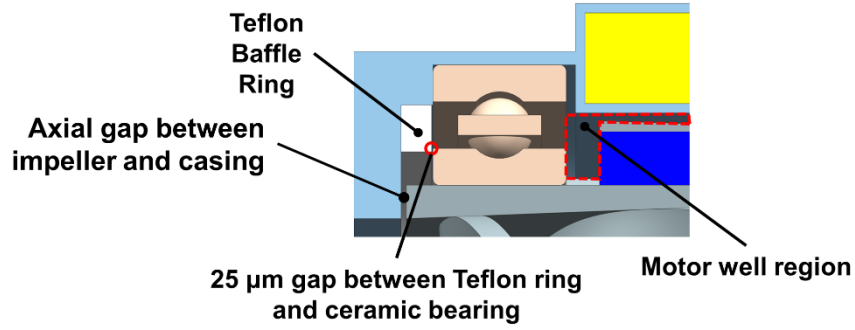


Figure 6.2: The magnified view of Teflon seal ring used for prevention of blood flow through the motor well region

Table 6.1: Dimensions of prototype II

	Dimensions
Impeller blade axial length	18 mm
Number of impeller blades	6(3 main,3 splitters)
Diffuser Blade axial length	10 mm
Number of diffuser blades	6
Inlet diameter of impeller blades	9.5 mm

Outlet diameter of impeller blades	11 mm		
The diameter of diffuser blades	11 mm		
Impeller Blade Angles (degrees)	Inlet	Exit	Wrap
	20	0	180
Diffuser Blade Angles (degrees)	15	0	60
Impeller Blade Thickness	1 mm (from the inlet to 75% of length) the linear decrease from 1.0 to 0.5 mm		
Diffuse Blade Thickness	0.5 mm		
The diameter of the pump	22mm		
Length of the pump (Including 10 mm for inlet and outlet cannula from each size)	55 mm		
Outer Diameter of Rotor magnets	16 mm		
Inner Diameter of Rotor magnets	12 mm		
Length of Rotor magnets	5 mm		

6.3 CFD simulation

The flow conditions in the miniature blood pump are expected to be turbulent. The two-equation $k-\varepsilon$ model was used in addition to continuity and momentum equations to solve the flow domain. Blood was treated as an incompressible Newtonian fluid, with a density of 1055 kg/m^3 and viscosity of 0.0035 kg/ms , which corresponds to blood with a hematocrit level of 33%. Steady-state simulations were performed using frozen rotor technique for hydraulic performance evaluation. A transient analysis was performed for blood damage analysis using Euler strain-based model. ANSYS Fluent® was used for analysis and damage index and shear stress was defined by the user-defined functions.

6.3.1 Boundary Conditions

The blades of the diffuser were selected to be stationary walls with no-slip boundary condition. The rotating wall boundary condition was used for the hub, the shroud and the blades of the impeller, with the relative velocity of the adjacent cell zones selected to be zero. The mass flow rate was chosen as the inflow condition and the pressure as the outflow condition.

6.3.2 Grid Independence

The inflow cannula, outflow cannula, impeller, diffuser, and motor well region were modeled separately. Interfaces were used to join these blocks. Mesh independence was

checked using tetrahedron element sizes 0.25mm, 0.28 mm and 0.3 mm. A total of 1585411 mesh elements were created using an element size of 0.28 mm. The convergence criteria were set to be 10^{-4} residual. Minimum mesh quality of 0.2 with an average value of 0.89 was achieved. The average orthogonality of the element was 0.876.

6.3.3 Hemolysis Estimation

Strain-based hemolysis estimation was performed as discussed in sections 3.5.2 and 5.7. Power law model by Gesenhues *et al.* [81] was used. The rotational speed of the pump for the blood test was 10000 rpm, and therefore the time step size for transient analysis was 1.67×10^{-4} sec with 36-time steps to simulate one complete revolution and rotating mesh was used for the impeller fluid body region. The quantitative value of NIH was estimated to be 0.0048 g/100L.

6.4 Manufacturing

6.4.1 5 Axis Machining

All parts were manufactured using biocompatible stainless steel 316LS. The impeller and diffuser blades were manufactured using high precision Mori Seiki 5 axis machine. The 3-dimensional model of impeller and diffuser blades were modeled in Siemens NX software. The CAM package of NX was used to generate a toolpath for

machining. The figure shows toolpath simulation for blade roughing process of the impeller.

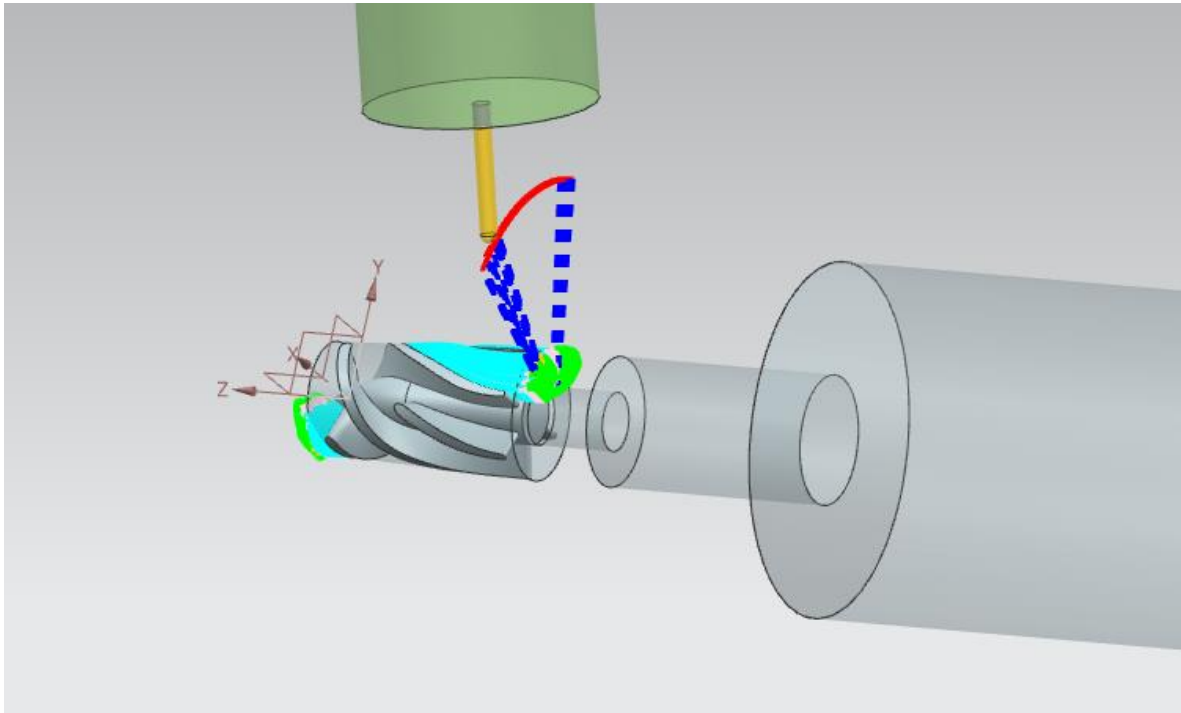


Figure 6.3: CAM simulation of impeller blade using Siemens NX

After checking the CAM simulations for safety and correct toolpath, G code was generated to machine the impeller and diffuser blades. The part blanks were made using high precision CNC lathe. The machining of impeller blades consisted of blade

and splitter roughing, hub finishing, blade finish and splitter finish processes. Figure 6.4 shows impeller during the machining process.



Figure 6.4: Impeller during the machining process

The machined parts were removed from vice after completion of the finishing process. The Visual examination shows the feed marks produced due to the radius of curvature of the tool. In order to obtain good surface quality, the parts were hand polished to achieve mirror-like surface. Figure 6.5 and Figure 6.6 shows the impeller and diffuser blade after finishing machining process.



Figure 6.5: Impeller of prototype II after machining



Figure 6.6: Diffuser of prototype II after machining

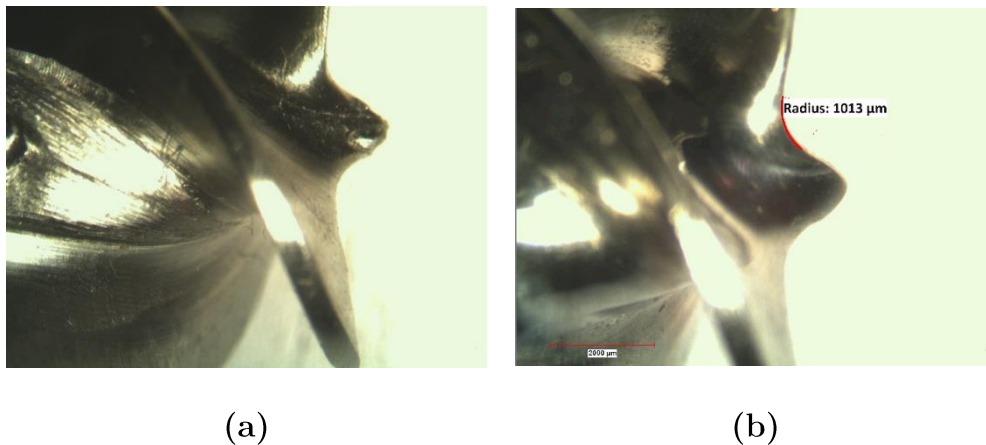
6.4.2 Polishing

Each part was hand polished to achieve a high level of surface finish. The polishing included using wet emery paper of different grades and the using diamond particles polisher with different particle sizes. First of all, polishing stones with various grain sizes were utilized in order to get rid of feed marks left from milling operations. Since these stones leave some scratches on the surface, abrasive metal brushes were used with the hand-type rotary head. Following that abrasive sandpapers were implemented starting with coarsest up to finest grit sizes. Finally, in order to come up with a smooth surface finish, the last step is the implementation of the diamond by means of the rotary head.



Figure 6.7: Polishing equipment containing sandpaper, diamond polish and rotary head [96]

Figure 6.8 shows the microscope image of impeller entrance before and after polishing. It can be observed there were clear feed marks after machine finishing of the impeller. These feed marks make the surface rough and using polishing those marks were eliminated.



(a)

(b)

Figure 6.8: Microscopic image of impeller entrance region (a) Before polishing (b) after polishing

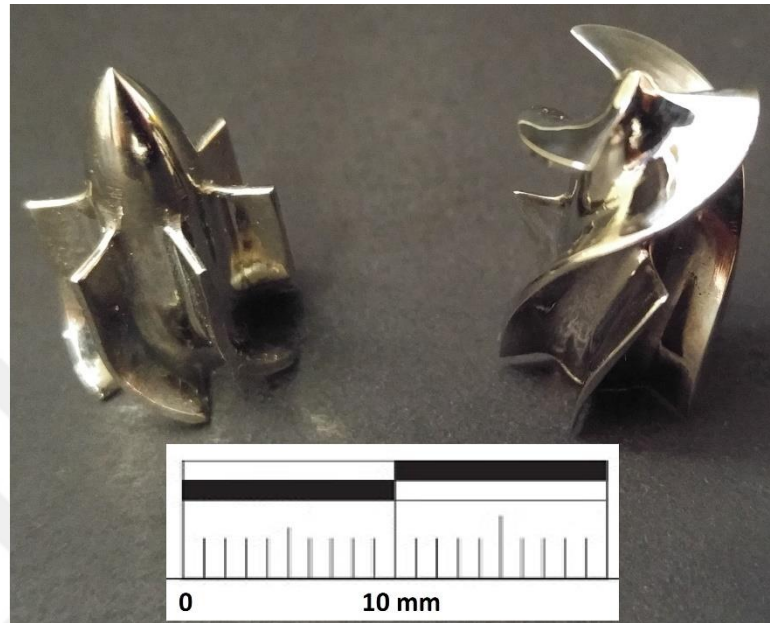


Figure 6.9: Manufactured and polished diffuser (left) and impeller(right)

6.5 CFD Hydraulic performance

Figure 6.10 shows the hydraulic performance curve of the pump. Each point on the graph shows simulation point at a specific speed and flow rate. Generally, in infants (newborns to two-year-olds), blood has a flow rate ranging from 0.25 L/min to 1.5 L/min and the pressure lies between 63 mmHg and 75 mmHg. Thus, the design point of the current pump was selected to be 1.5 L/min with a pressure rise of 75 mm Hg. The results demonstrated a pressure rise range of 29-84 mmHg for the flow rates of 1-3 L/min over 9000-11000 rpm. It can be observed that the simulation predicted the design point to be achieved at 11000 rpm.

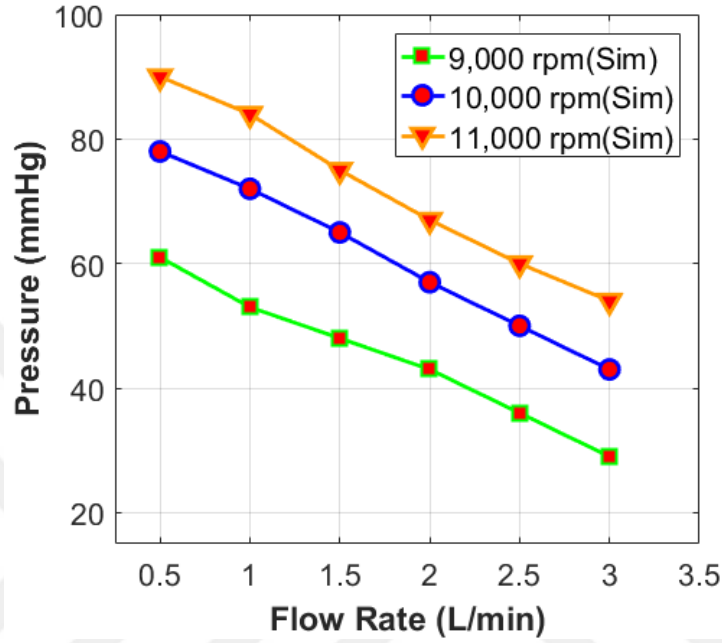


Figure 6.10: CFD based performance evaluation of prototype II

6.6 Scalar Stress

Figure 6.11 shows the mesh elements within the pump body having a scalar stress greater than 250 Pa. The region where these high-stress elements occur is at the interface of the rotating impeller and stationary diffuser. Blood passing through this region is more prone to hemolysis. However, this region is unavoidable because of the interaction between the moving and stationary parts. Besides this, there were no other regions showing significant hemolysis. Figure 6 shows the stress histogram of the elements. It can be observed that approximately 82% of the particles have a scalar stress less than 50 Pa. This shows good hemodynamic properties, but very low-stress

areas may cause platelet activation. The average shear stress in impeller is 12.53 Pa while in the diffuser is 8.62 Pa.

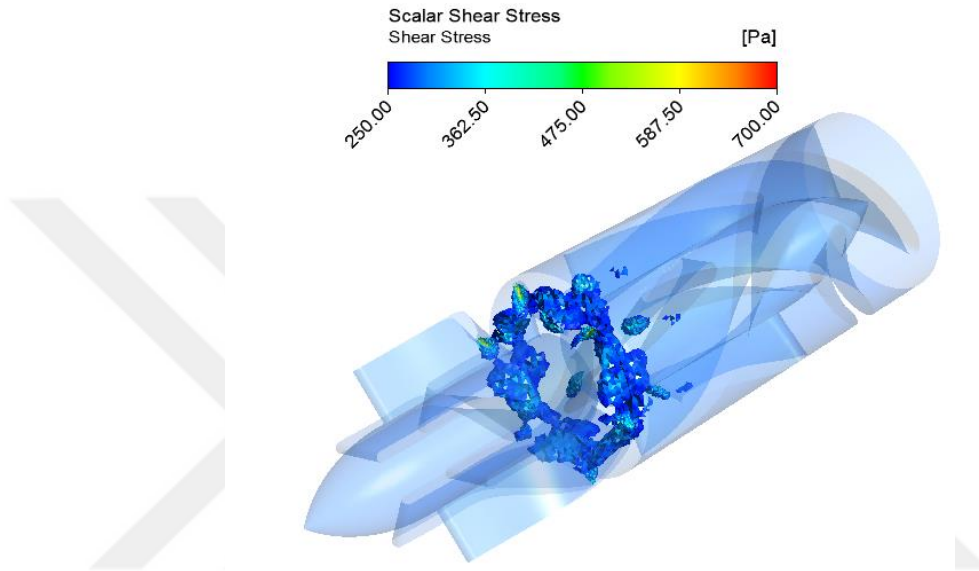


Figure 6.11: Elements representing volume having scalar shear stress more than 250 Pa

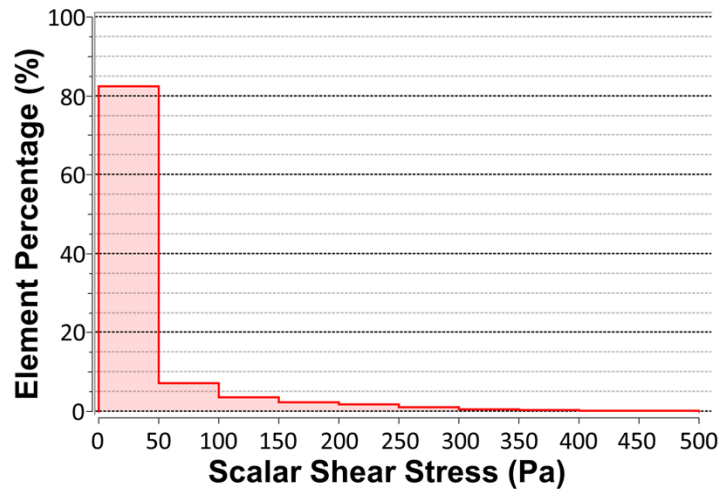


Figure 6.12: Shear stress histogram showing percentage distribution of stress in an element with increments of 50 Pa

The Figure 6.13 shows the comparison of wall shear stress of previous and current design. The flow condition for previous design is 9250 rpm and flow rate of 3 L/min while for current design is 9000 rpm and flow rate of 3 L/min. The contour showing the red colors are the areas of 250 Pa stress. It can be observed that the previous design has a relatively large area for high shear stress region.

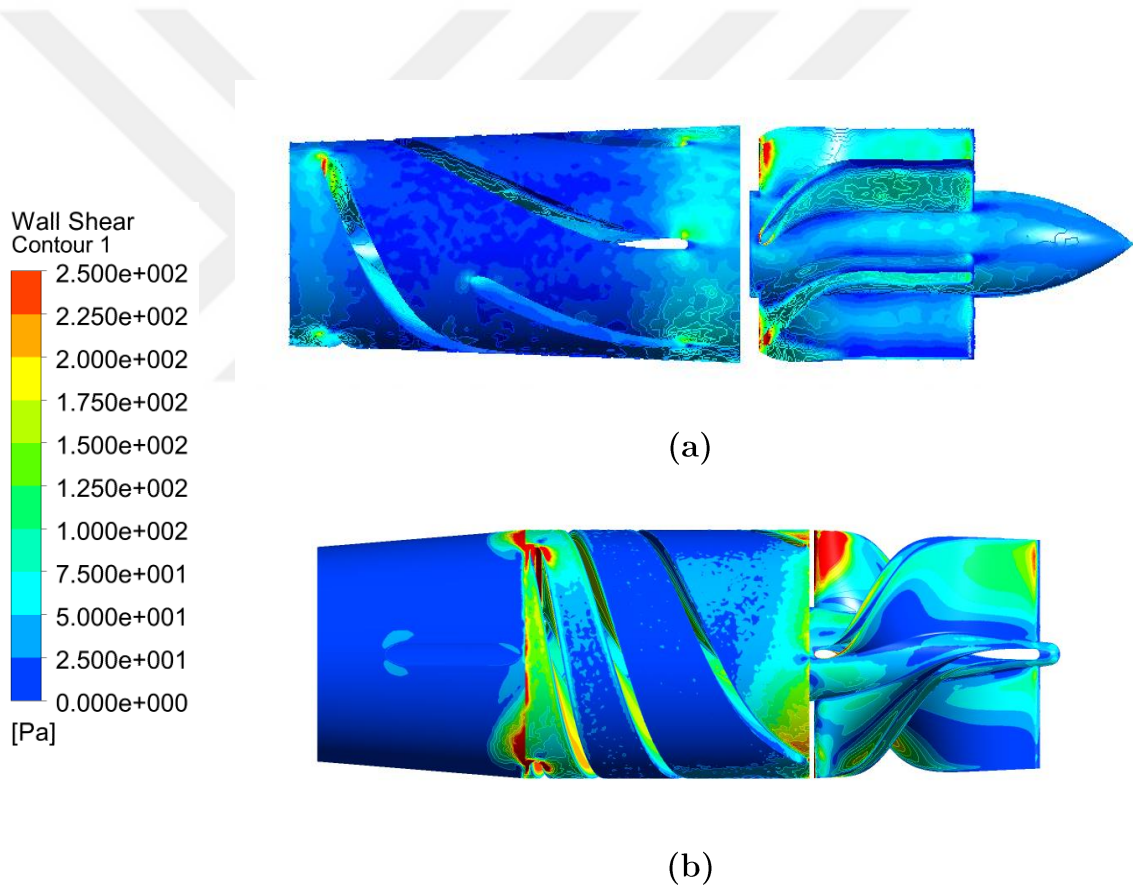
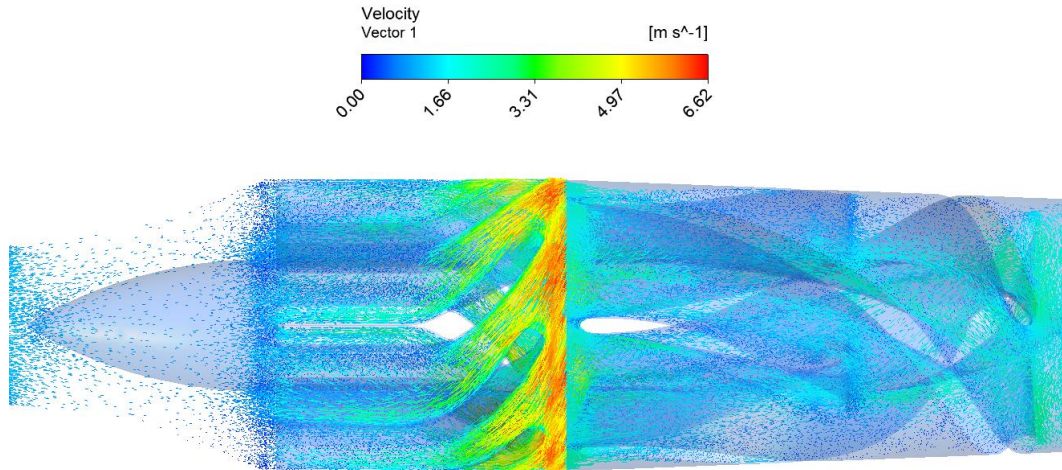


Figure 6.13: Wall shear stress contour (a) Prototype II (b) Prototype I

6.7 Velocity Vectors

Figure 6.14 shows the velocity vectors of the pump at 11000 rpm and 1.5 L/min flow rate with 6-blade diffuser. The impeller region shows an absence of recirculation region; however, some recirculation was present at the exit of the diffuser section. Theoretically, the observed swirling flow may be reduced by increasing the number of diffuser blades. Comparison of the 8-blade diffuser with 6-blade diffuser proved this, but the number of the blade is limited by manufacturing capabilities. To manufacture an 8-blade diffuser a small milling tool must be used which causes the chattering phenomenon, and this creates inaccuracies in production and may cause the tool to break frequently. Also, an increase in blade number causes an increase in the contact area between the fluid and structure, which may induce extra hemolysis. Thus, the best compromise was found using 6-diffuser blades.



(a)

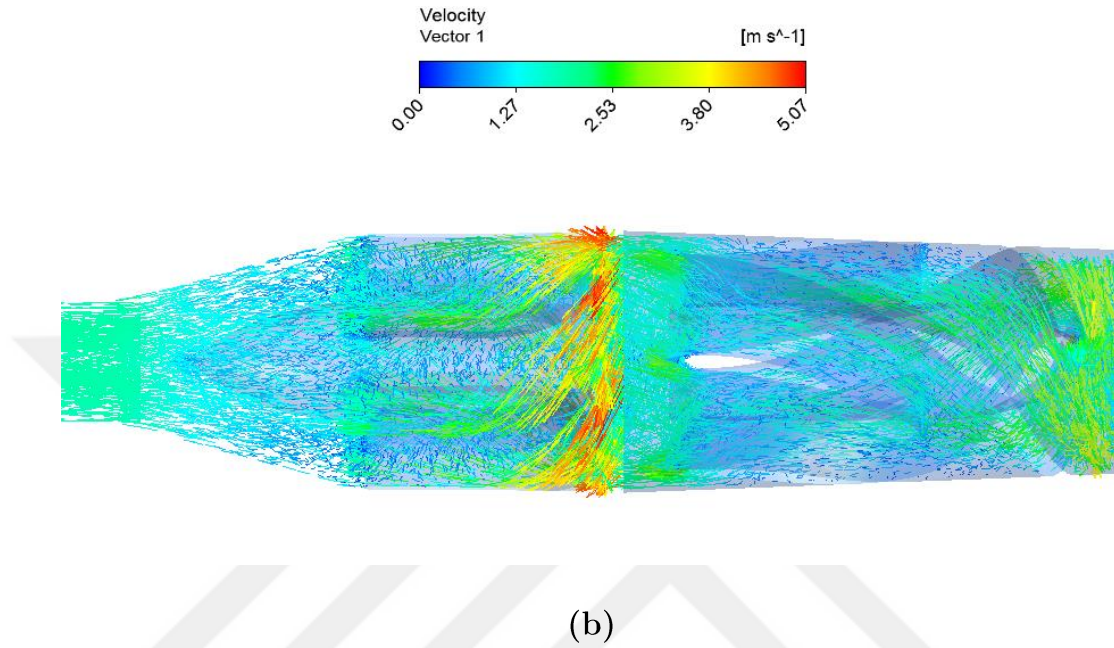


Figure 6.14: Velocity vectors of the pump at 11000 rpm and 1.5 L/min. The fluid enters from the right side into the impeller showing no sign of recirculation. (a) 8-blade diffuser
(b) 6-blade diffuser

6.8 Experimental results

Figure 6.15 shows the comparison of CFD and experimental hydraulic performance results. There is a close correlation between the predicted and measured performance of the pump. A maximum difference of 4 mm Hg pressure was observed at 11000 rpm and 1 L/min flow rate. This error is due to the difference in modeling and manufacturing of the setup.

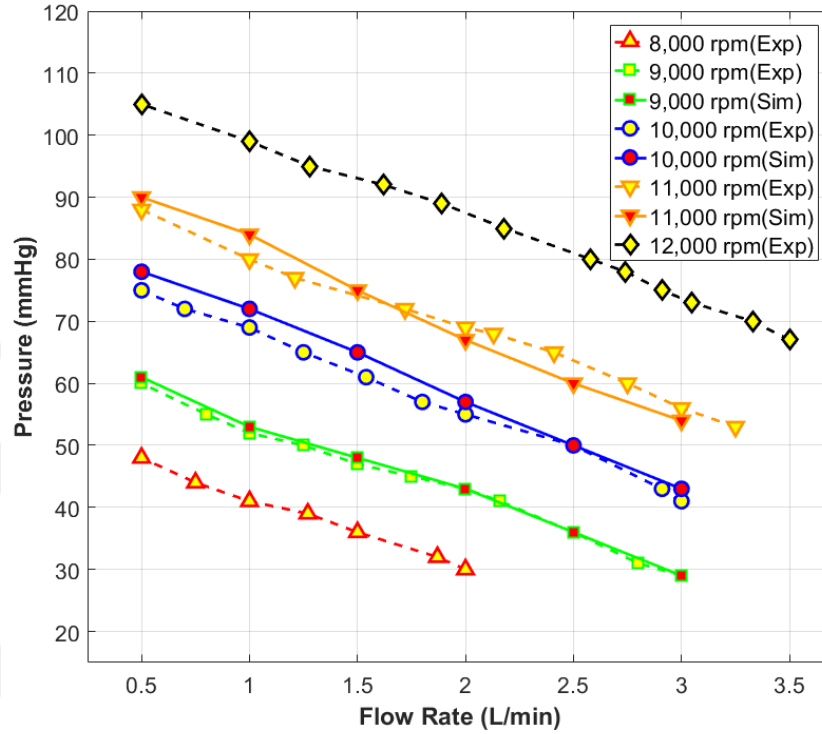


Figure 6.15: Comparison of experimental and CFD performance results

The hemodynamic performance was measured by performing a six-hour blood test. The results of the test revealed an average NIH level of 0.00674 g/100L. The quantitative difference between experimental and numerical value is 0.00194 g/100L. The main contributing factor of this additional hemolysis is the motor well region. Although annular baffles were used to minimize the effect of this region on blood damage but sealing it completely for such high speed is not possible. The NIH value is below the threshold level of 0.01 g/100L but for more reliability, it is better to have NIH level as low as possible. Nevertheless, this shows the possible potential for using shrouded impeller in heart pumps. Figure 9 shows the disassembled pump after a blood

test. The thin red layer inside the ceramic bearings showed the possible area of blood damage. Also, there are some blood streaks in diffuser region which can cause thrombosis for long-term use. Upon close examination, it was observed that there is some gap between diffuser blades and casing. This gap was the result of eccentricity during turning operation in the lathe machine. Although these machining inaccuracies cannot be eliminated in the real world, to make the device more hemodynamic these inaccuracies should be minimized as much as possible.



Figure 6.16: Disassembled pump after blood test diffuser (left) and impeller (right)

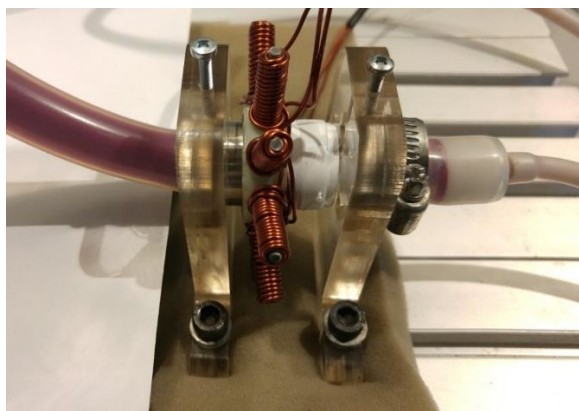


Figure 6.17: Pump during a blood test



Figure 6.18: Blood reservoir

6.9 Discussion

This research presented the feasibility of a shrouded impeller design for pediatric VAD. The advantage of this design is compactness and reduced distance between rotor magnets and stator electromagnets. Also, a good hydraulic performance was achieved since the desired flow rate and the pressure was obtained. The experimental tests with blood showed hemolysis within the threshold value, presenting an initial step towards the development of a new design for VAD.

Based on previous experiences it was deduced that without preventing blood from entering the motor well region the advantages of this design cannot be achieved. To achieve this, two major design changes were adopted: 1) Provide annular ring in front and back of radial bearing. These rings not only prevented blood from entering the motor well region but also worked as an axial retainer for the bearings; 2) Instead of using flow straightener conical shape impeller was used. This caused the primary flow to pass through a shrouded region of the impeller. The CFD analysis showed that

current design can achieve 75 mmHg pressure with a flow rate of 1.5 L/min at 11000 rpm. To compare the CFD data with experiment a benchtop model was manufactured using stainless steel 316LS. The blades and other parts were hand polished to achieve a high-quality surface finish. In CFD analysis it was observed that by using a higher number of diffuser blades less recirculation occurred in the flow, but due to limitations of the manufacturing process, a compromise was made to use six blade diffuser. In order to analyze blood damage, strain-based Euler model was used. The transient analysis of the pump model showed the quantitative value of NIH as 0.0048 g/100L. But this analysis ignored the region within the bearing and motor well due to the complexity of the flow. To check the accuracy of the model blood tests were performed and an average NIH value of 0.0062 g/100L was calculated. The quantitative increase in NIH valued is a result of those ignored regions during simulation. But this value is less than the threshold value of 0.01 g/100L. This gives us the hope of using such design and to improve it further. The improvement in current design is made by further preventing blood entering into the high-stress region. It is thus suggested that more accurate machining be used with accuracy greater than 2-microns and a solid surface with very less dynamic friction like Teflon should be used as baffles. Furthermore, the technique used currently can be helpful in the prevention of blood damage caused by a motor well region in centrifugal pumps.

Chapter 7 : COMPUTATIONAL OPTIMIZATION OF RADIAL TIP CLEARANCE

7.1 Overview

In axial flow rotary blood pumps (RBPs), the radial clearance between impeller and casing plays a critical role in the blood trauma and performance. This chapter explores the effects of radial clearance (δ) on the hydrodynamic and hemolytic performance of a Prototype I and II. CFD based parametric study is performed. The parametric analysis provided the functional relation between efficiency and hemolysis with respect to the dimensionless radial clearance. Multi-Objective Particle swarm optimization (MOPSO) algorithm was implemented to obtain a set of optimized points for the radial clearance. The comparison of CFD analysis and MOPSO showed the validity of the results. The results indicate that the combination of CFD and MOPSO algorithm while designing blood pump is a time efficient procedure.

One of the key regions of an axial flow RBP, which significantly affects the hemolytic as well as hydrodynamic performance, is the clearance between the impeller and its casing [5]. This gap acts as shear zone as the velocity gradients are maximum in this region. Graefe *et al.* have reported that the clearance between moving and stationary parts in blood pumps is the most significant design parameter affecting hemolysis in centrifugal blood pumps [97]. Kosaka *et al.* studied the effects of axial

gap on hemolysis in a hydrodynamically levitated centrifugal pump [98]. Besides this, research has been conducted to optimize the radial clearances in centrifugal pumps [13, 99, 100]. Studies have shown that the feasible range of clearances is highly dependent on the bearing mechanism used to stabilize the pump. For example, devices using hydrodynamic bearing require small clearances while the devices with the active magnetic bearing system can have relatively large clearances. Rezaienia *et al.* performed computational analysis to study the effects of both radial and axial clearance in a centrifugal pump [89]. Apel *et al.* performed computational analysis of micro axial flow pump intended for the adult patients [101]. In this study, authors showed the radial gap region is a most critical region in the entire pump, but there was no further study conducted to optimize this region. Chua *et al.* and Khan *et al.* conducted numerical and experimental studies with enclosed impeller axial pumps [4, 102]. According to these studies, by limiting recirculation flow around enclosed impeller can lead to the efficient design of axial pump. However, to our knowledge, there is no literature available regarding the effects of radial clearance gap on the hemolytic and the hydrodynamic properties of an axial flow pediatric pump. In axial flow pumps, the tip leakage flow occurs due to the pressure difference between inlet and exit. Increase in radial gap causes the leakage flow to increase in reducing its hydraulic efficiency while a decrease in this clearance may lead to high shear stress causing blood damage. Thus, the tip clearance gap should be optimized to obtain maximum efficiency and minimum blood damage.

In this chapter, a combination of CFD analysis and multi-objective particle swarm optimization (MOPSO) algorithm is applied to optimize the radial clearance gap in a pediatric axial flow pump. The experimental verification of CFD model is obtained by performing hydraulic experimentation and in vitro blood test with the same geometry of the pump. The change of hemolytic and hydrodynamic performance of the pump at different radial clearance gaps is examined using CFD. These results are used to obtain a set of optimal design points for the current design of the pump using MOPSO algorithm. The comparison of CFD and MOPSO results shows that by combining these methods, designers can significantly reduce the design time of RBPs.

7.2 Model

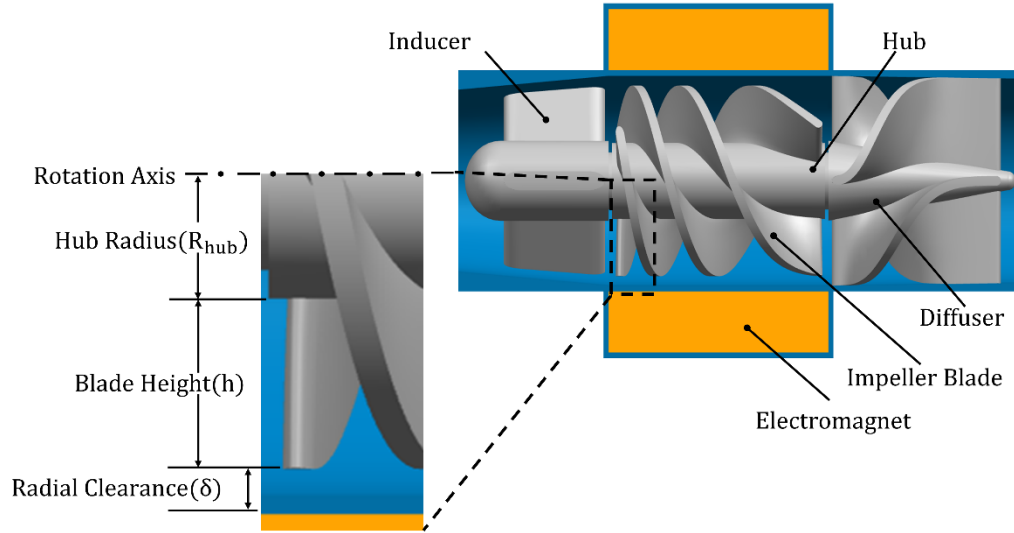


Figure 7.1: Schematic diagram of the inducer, impeller, diffuser, and electromagnet. Magnified view representing nomenclature of the pump.

7.3 MOPSO

MOPSO is an optimization algorithm inspired by the behavior of flocking birds that solve problems with multiple objective functions [103]. It initializes several candidate solutions randomly over the search space, which then iteratively converge to an optimized solution space. The main steps for PSO algorithm are as follows:

- I. Initialize each particle.
- II. Calculate fitness value for each particle. If fitness value is better than the best fitness value (p_{best}) in history, then set the current value as the new best.
- III. Choose particle with best fitness value of all particles as the g_{best} .
- IV. For each particle, calculate velocity and its position according to equations (7.1) and (7.2)

$$v_i(t+1) = \omega v_i(t) + c_1(p_{best} - x_i(t)R_1) + (c_2(g_{best} - x_i(t)R_2) \quad (7.1)$$

$$x_i(t+1) = x_i(t) + v_i(t+1) \quad (7.2)$$

where t and $t+1$ represent to successive iterations, i represents particle index, x is the particle position and v is the particle velocity. R_1 and R_2 are random numbers chosen between 0 and 1. c_1 is the personal learning coefficient and c_2 is the global learning coefficient. The value of these coefficients should be $0 \leq c_1, c_2 \leq 4$ [104]. In

general, by increasing the acceleration coefficients, the particle's frequency of oscillation around the optimum also becomes higher and lower values for these constants produce sinusoidal patterns. Therefore $c_1 = c_2 = 1$ is chosen.

- V. For restricting the particles to move too far from the search space, the particle velocities on each dimension are clamped to a maximum velocity v_{max} , where $v_{max} = kx_{max}$ and $0.1 \leq k \leq 1$. If the sum of acceleration would cause the velocity on that dimension to exceed V_{max} , which is a parameter specified by the user, then the velocity on the dimension is limited to v_{max} .

In our study, the objectives are to maximize efficiency η and minimize NIH, over the possible values of clearance gap. CFD is used to determine expressions relating η and NIH with respect to dimensionless clearance gap. Using these as the objective functions, MOPSO determined the optimized value for clearance gap. The PSO gives excellent performance for inertia weight between 0.4 to 0.9 [105], therefore, inertia weight is chosen as 0.5. The swarm exploration ability and its diversity is increased by selecting higher population size [104], therefore the population size is selected as 200 and the repository size as 100. Further discussion about the application of MOPSO in engineering application is provided by Kulkarni *et. al.* Venketesan and Surekha *et. al* [106-108].

7.4 Shear Stress and NIH

Based on equation (3.15) blood damage in RBPs directly depends upon the level of shear stresses produced in blood during the operation. Figure 7.2 shows the magnitude of average shear stress (ASS) in the impeller, the inducer and the diffuser sections at different radial clearances. In the impeller section for pump model 1, the minimum ASS of 12.44 Pa occurs at 150 μm clearance, while minimum ASS for model 2 occurs at 200 μm clearance with the magnitude of 10.45 Pa. The magnitude of ASS shows no significant change in the stress level at the impeller, diffuser and inducer sections as the tip clearance changes. The magnitude of ASS within the impeller of pump model 1 is 13.07 ± 0.63 Pa which is not significant in contributing blood damage.

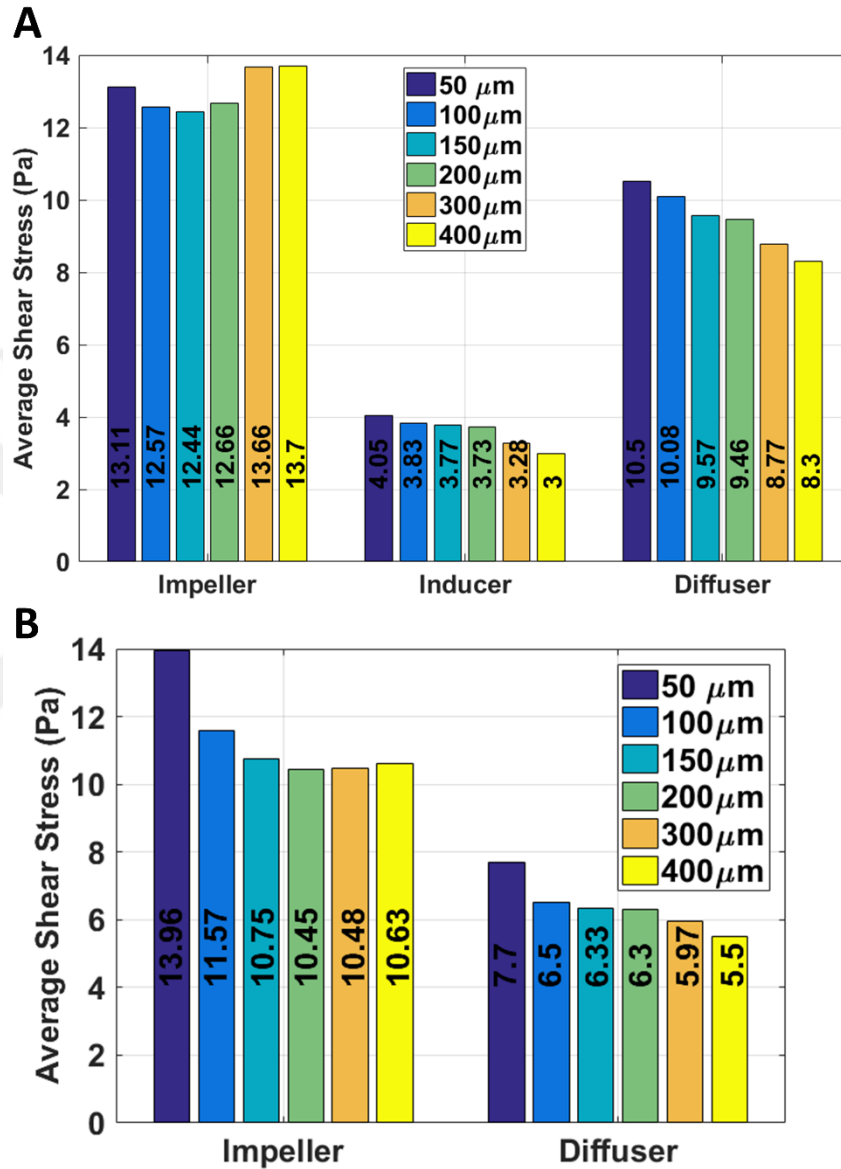


Figure 7.2: Magnitude of average shear stress in impeller, inducer and diffuser sections at different radial clearances.

However, within the tip clearance region, there is a significant amount of change in ASS magnitude as in red curve of Figure 7.3. The maximum ASS for pump model

1 is at 50 μm clearance gap region (144.84 Pa) while the minimum shear stress occurs at 400 μm clearance gap (38.23 Pa). The similar pattern is observed for pump model 2 where maximum ASS of 180 Pa is observed at 50 μm clearance and the minimum ASS of 37 Pa exits for 400 μm clearance gap. There is a significant decrease in ASS with the increase in the tip clearance gap. From this behavior, it is determined that as the δ increases there is a reduction in ASS. In Figure 7.3 ASS in tip clearance region and NIH are plotted against non-dimensional clearance gap. In both models both NIH and ASS in tip clearance region can be curve fitted using first order power law model. Thus, it can be concluded that NIH is directly dependent upon ASS in clearance region.

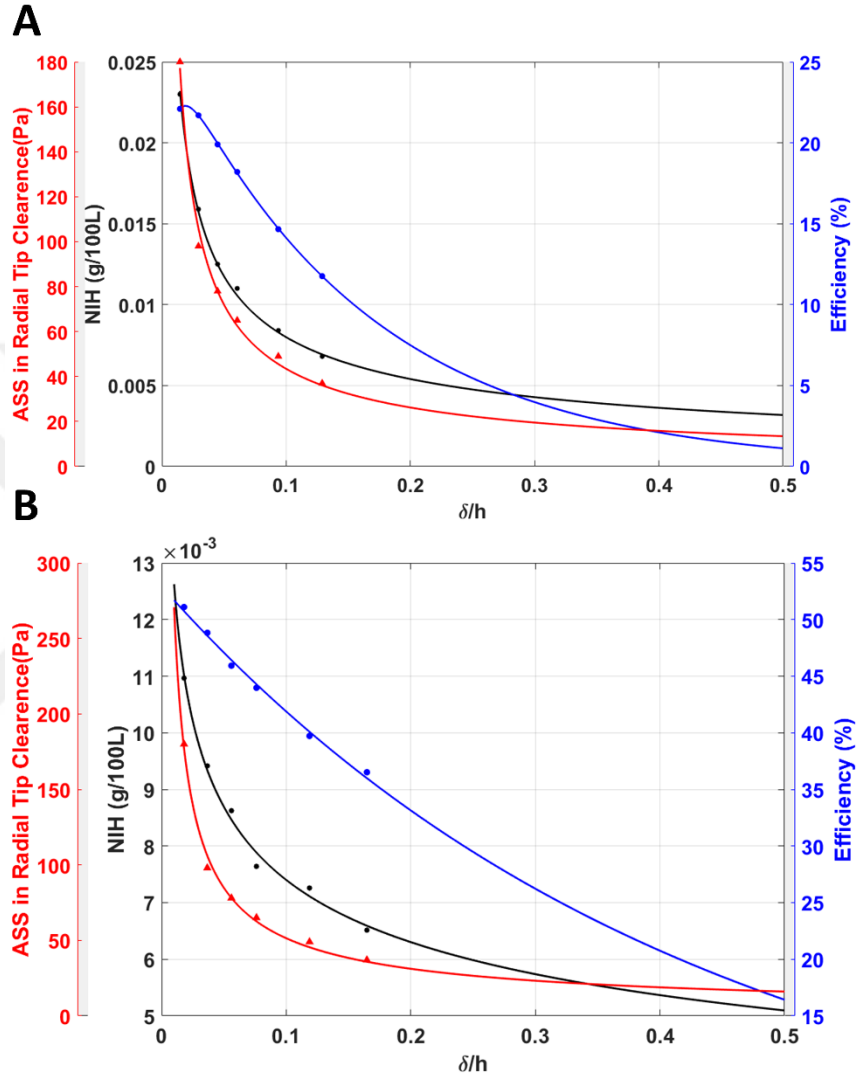


Figure 7.3: Average shear, NIH and hydraulic efficiency stress in different radial clearances regions.

Figure 7.4 shows the ASS magnitude at a different cross-section along the axial length of clearance region. The behavior confirms the trend of decreasing shear stress as the radial clearance gap increases. The cross-sectional area of clearance region is

kept constant. It can be observed from the profile in Figure 7.4 that the average shear stress is minimum in the middle of clearance region (except for 50 μm) and the maximum at the outlet and immediately after inlet region. This attribute is due to the interaction of leading and trailing edges of the impeller. In 50 μm gap region the trend shows an increase in ASS along axial length representing the effect of no-slip occurring at the tip and the surface of the shroud. As the blood flows on impeller the velocity of fluid increases and due to a small gap in the velocity gradient is increasing in clearance region along axial length creating an increase in ASS.

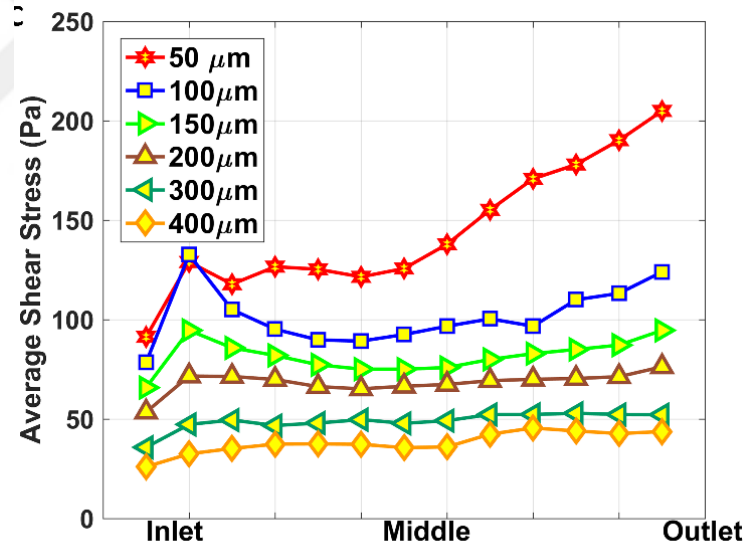


Figure 7.4: Distribution of average shear stress in clearance region along the axial length of the impeller.

Figure 7.5 shows the stress contour at the planes of inducer, impeller, diffuser and clearance gap of pump model 1. Particles experiencing mechanical stress higher than 50 Pa are more prone to hemolysis. Thus, elements in red in Figure 7.5 are more likely

to be damaged. There is a notable decrease in stress levels as the clearance gap increases from 50 μm to 400 μm . In smaller clearances, high-stress particles extend into the diffuser sections.

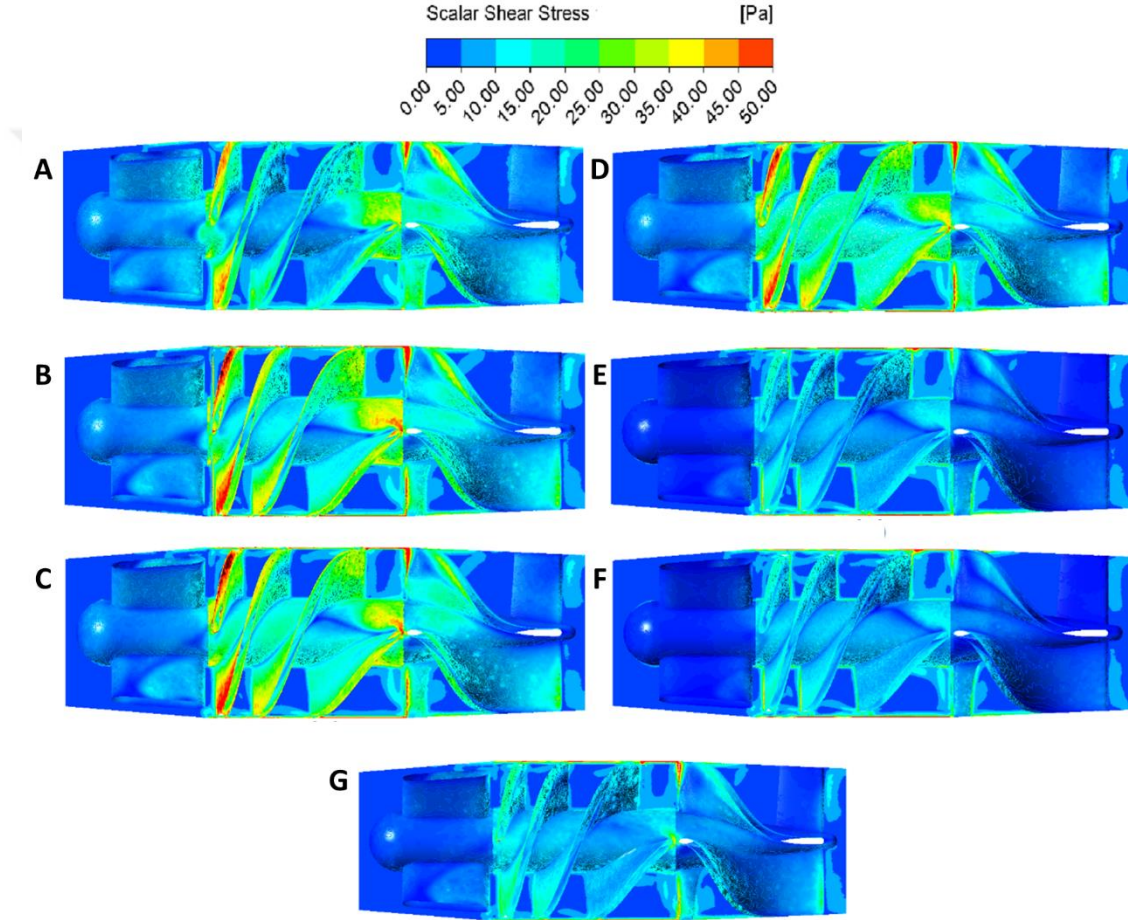


Figure 7.5: The contour of shear stress in (left to right) inducer, impeller, and diffuser for different radial clearances. Elements in red color show shear stress more than 50 Pa. The increase in the radial clearance gap in impeller region shows diminishing of high-stress elements at the blade tip. **A:** 50 μm **B:** 100 μm . **C:** 150 μm . **D:** 200 μm . **E:** 300 μm . **F:** 400 μm . **G:** 220 μm .

7.5 Hydraulic Results

Figure 7.3 shows the variation of hydraulic efficiency with respect to the radial clearance. It is observed that as the clearance increases, the hydraulic efficiency of the pump decreases, thus reducing the performance of the pump. This attribute is due to tip leakage flow. Figure 7.6 shows the relative velocity vectors of a 200 μm clearance model. The arrow is showing the direction of flow of fluid. The velocity vectors in the gap are in reverse direction causing leakage flow. This leakage flow in an axial pump occurs due to the pressure difference between pressure and the suction side of the blade. As the clearance gap increases the annular area between the rotating and the stationary body also increases. The increase in annular area has a negative effect on pressure generated by the pump at same rotational speed and flow rate, thus a decrease in hydraulic efficiency occurs.

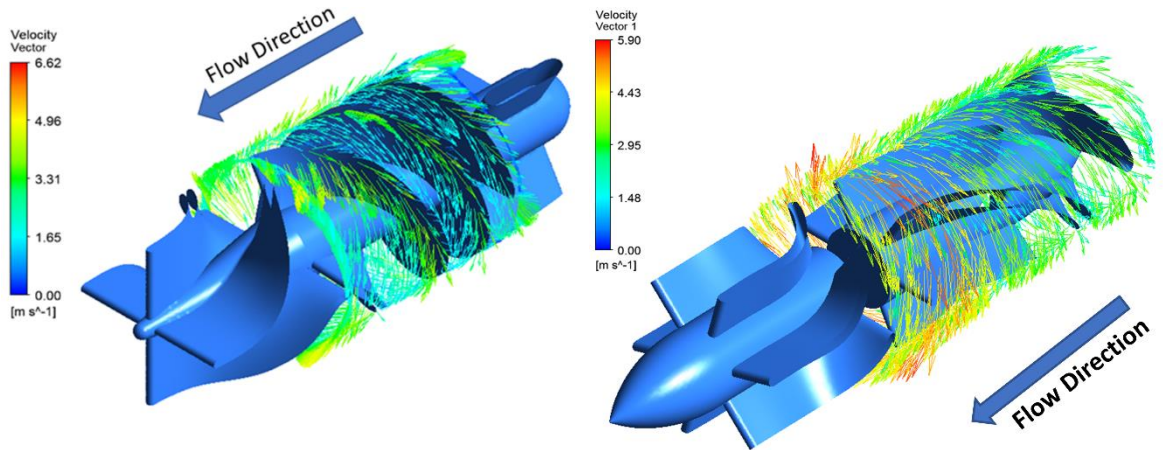


Figure 7.6: Relative velocity vectors in the 200 μm radial clearance gap region. Arrow direction showing the direction of flow of fluid. Velocity vectors showing the tip leakage flow.

7.6 MOPSO results

There is no relation available in the literature which establishes the relation between η and NIH with respect to change in radial clearance. CFD data was used to establish these relations to be used in MOPSO algorithm. Figure 7.3 shows the variation of η with respect to dimensionless clearance and in terms of the exponential terms using CFD results it is represented as:

$$\eta(\delta/h) = \alpha_{\eta} e^{\beta_{\eta}(\delta/h)} - \gamma_{\eta} e^{\sigma_{\eta}(\delta/h)} \quad (7.3)$$

The increase in clearance gap has a non-linear decreasing effect on the NIH estimated and is represented as:

$$NIH(\delta/h) = \alpha_{NIH}(\delta/h)^{\beta_{NIH}} + \gamma_{NIH} \quad (7.4)$$

The constants for pump model 1 in the current study are

$$\alpha_{NIH} = 0.00239, \beta_{NIH} = -0.5399, \gamma_{NIH} = 0.0002977, \alpha_{\eta} = 26.63, \beta_{\eta} = -6.341, \gamma_{\eta} = -11 \text{ and } \sigma_{\eta} = -111.4$$

The constants for pump model 2 in the current study are

$$\alpha_{NIH} = 0.004339, \beta_{NIH} = -0.2319, \gamma_{NIH} = 0, \alpha_{\eta} = 0.5292, \beta_{\eta} = -2.34, \gamma_{\eta} = 0 \text{ and } \sigma_{\eta} = 0$$

The condition on (δ/h) is such that $0 \leq (\delta/h) \leq 0.1$, i.e. the maximum radial clearance gap is 10% of the radius of the impeller. Figure 7.7 shows the optimal solution for the impeller with the MOPSO for pump model 1. The objective function for the NIH is minimized while the objective function for the efficiency is maximized. The highlighted region in Figure 7.7 shows the trend for NIH values less than 0.01 g/100L. In this region, the optimal solution is $(\delta/h) = 0.0672$ (which corresponds to the clearance of 220 μm), while the efficiency is 18.09 % and NIH is 0.01 g/100L. CFD analysis was performed to verify the MOPSO results. The NIH estimated using CFD simulation is 0.00987 g/100L and the hydraulic efficiency is 17.95%, validating the MOPSO results. For pump model 2 the MOPSO results revealed the optimum clearance gap of 258 μm . At this gap, the hydraulic efficiency is 41.93% while NIH is 0.0074 g/100L. The NIH estimated using CFD simulation is 0.00736 g/100L and the hydraulic efficiency is 42.05%.

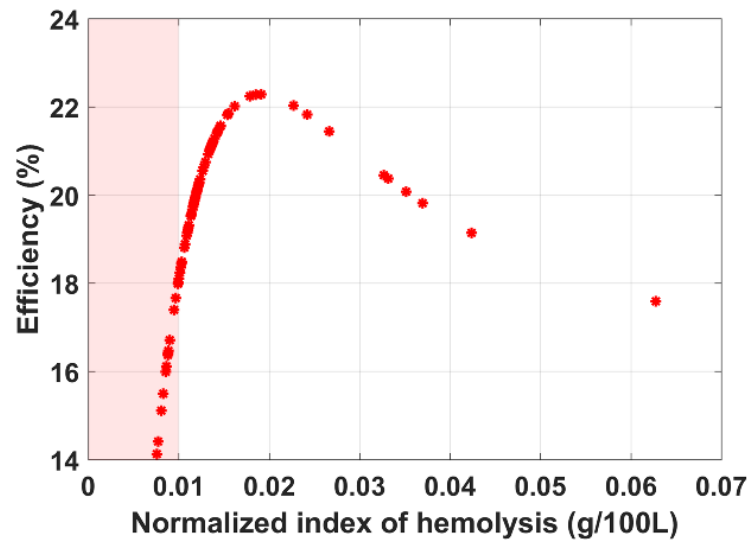


Figure 7.7: Optimized solutions for the NIH and Efficiency.

Figure 7.8 shows the increase in MOPSO simulation time with respect to changes in population size and number of iterations. Currently, we performed six CFD simulations to achieve relation shown in Figure 7.3. Once these functional relationships are established MOPSO is more time efficient.

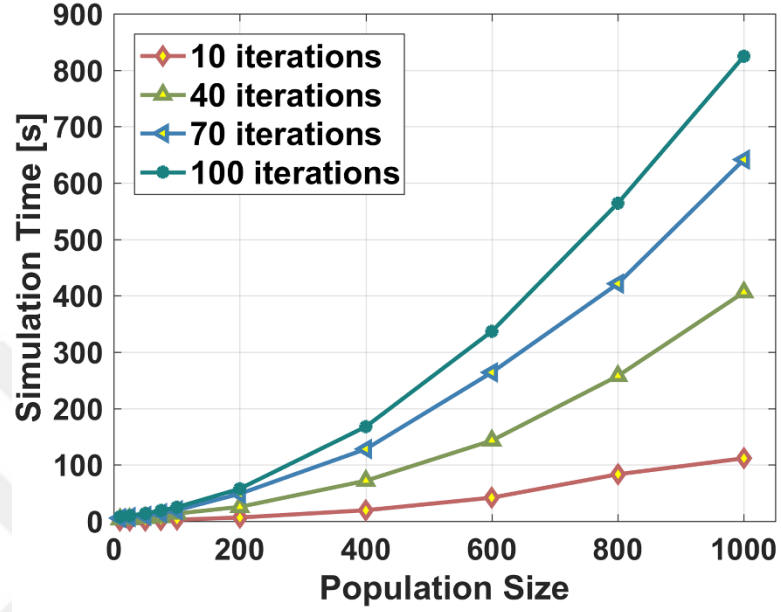


Figure 7.8: Variation of MOPSO simulation time with respect to change in population size and number of iterations.

7.7 Discussion

While designing axial flow blood pumps, there are many parameters which need to be optimized for better hemolytic and hydrodynamic performance. One of the key parameters is radial clearance between the rotor and the casing. This study entails the computational analysis of radial gap clearance in an axial flow pediatric blood pump using computational techniques like CFD and MOPSO. The device under consideration is currently under development in our lab and Table 1 provides its dimensions. Figure 7.1 shows a schematic diagram of the pump showing nomenclature used for the current study. The accuracy of the numerical model was established by comparison of hydraulic and hemolysis test results with same geometry of the pump.

Figure 5.5 shows the results of hydraulic tests with the maximum difference of 6 mmHg between experimental and numerical results. The quantitative analysis of NIH using 5 different power law methods revealed that the constant proposed by Gesehuas *et al.* is best suitable for current study.

According to power law model, blood damage is directly proportional to shear stress levels within the pump. Figure 7.2 shows the ASS in the impeller, diffuser and inducer section of the pump showing no significant change in magnitude. But Figure 7.3 and Figure 7.4 show the effect of radial tip clearance on ASS. It can be observed that the maximum shear stress of 143.84 Pa occurs at a minimum clearance of 50 μm . The trend in Figure 4B also shows a gradual decrease in ASS as the tip clearance increases up to 400 μm . Figure 5 shows the region of high shear stress in the overall pump. The contour in red colors shows the stress more than 50 Pa. As the clearance increases in Figure 7.5, the red color diminishes showing a decrease in overall shear stress. The numerical result shows that maximum shear stress of magnitude in 50 μm model is 1208 Pa while in 400 μm it reduces to 1088 Pa. These trends clearly indicate that in axial flow pumps if the tip clearance increases the chance of blood damage decreases.

The relation between objective functions in terms of a variable is required to implement MOPSO algorithm. In our case, the objective functions are η and NIH while the variable is clearance. In literature, there is no study available which provides this relationship in axial flow blood pumps. Thus, six CFD simulations were performed to obtain discrete data points. Figure 7.3 shows the curve fitting function obtained using CFD simulations. These functions were used in MOPSO algorithm. Figure 7.7

shows the MOPSO solution result showing the search space results with potential optimized points. The threshold for NIH level was set to be less than 0.01 g/100L. Based on this blood damage constraint, the optimal design parameters were selected and analyzed numerically. The MOPSO result shows that the optimum radial clearance is 220 μm . CFD analysis of this clearance provides the validation of MOPSO results.

7.7.1 Limitation

The geometry of pump is based upon the original design of pediatric pump and the current study is valid for this design, however, the procedure is valid for any axial flow pump. Besides this, the functional relationship between efficiency and NIH with respect to tip clearance were obtained using CFD simulations. These relationships should be further verified by performing numerical and experimental simulations in different models of axial flow pumps. The current study is primarily a computational study in which numerical model is verified experimentally with a single model. In numerical studies, an error may arise due to mesh quality and turbulence models. Besides this, in very large clearances the flow regime is fully turbulent which may cause excessive stress causing predicted hemolysis using current power law constants. The current study also does not account for machining inaccuracies like surface finish and eccentricity.

Chapter 8 : CONCLUSION

Mechanical circulatory support has emerged as a life-saving device for people having chronic heart failure. The use of these devices started in adults in 1953 with the introduction of cardiopulmonary bypass. These systems have evolved as assist devices for “bridge to transplantation” and as “destination therapy” solutions for adult patients with chronic heart diseases. Although rapid advancements have been made in the field of adult circulatory support same cannot be said for pediatric patients. Due to physiology and flow conditions, adult MCS cannot be used in pediatric patients. While designing pediatric blood pumps many challenges like the small size, power consumption, less blood damage and no clot formation occurs. Thus, designing such a device is not a simple task and many designs should be evaluated to achieve the optimum geometry.

The main objective of this thesis is to develop a novel pediatric blood pump. The target population of the device is from newborn up to the age of 2 years. During this period a child body is continuously developing, thus, flow rate and pressure requirement changes. The pressure change during this period is from 63 mmHg to 75 mmHg with flow rate requirement changing from 0.25 L/min to 1.5 L/min. One of the biggest challenges arrives while designing such a small device is an increase in shear stress within the pump body. Due to high rotational speeds and small size, the velocity

gradient within the pediatric pump is high. This causes excessive blood damage. Besides this, any stagnant region or rough or uneven surface can cause blood clot formation. Thus, a blood pump should be streamlined in design and have minimum shear stress.

The pediatric LVAD under investigation benefits from the novel enclosed impeller design. CFD analysis allows an extensive performance evaluation of the pump. Pump performance curves and efficiency, along with fluid stresses were estimated using numerical simulation. Besides continuity and momentum equation, turbulence model was used to predict and reduce turbulent flow regions in the pump. In order to validate the CFD model a benchtop prototype was manufactured and hydrodynamic performance evaluation was done. The predicted CFD performance shows good correlation with experimental data, validating the model. There is good agreement between experimental and numerical NIH values, thus validating the numerical model for further design improvements using CFD. The experimental results have validated the design concept and required performance thresholds of the pump.

While designing axial flow blood pumps one of the key parameters is radial clearance between the rotor and the casing. In this study, we employed CFD and MOPSO technique to devise a method for optimization of radial clearance in axial flow pumps. The variation in hydraulic efficiency and NIH with respect to the radial clearance was obtained using CFD simulations. The accuracy of the numerical model was verified by comparing hydraulic performance and in vitro results for a shrouded impeller design. The MOPSO result shows that the optimum radial tip clearance is

220 μm for pump model 1 and 258 μm for pump model 2. CFD analysis of this clearance provides the validation of MOPSO results. The simulation time comparison proves that combination of CFD and MOPSO is a time efficient method while designing rotary blood pumps. The proposed approach provides a gateway towards the optimization of different geometric parameters using combined CFD and MOPSO technique while designing a blood pump. These parameters include impeller, diffuser blade lengths and wrap angles and the axial distance between rotating (impeller) and stationary (inducer and diffuser) parts of the pump.

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