Master Thesis

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Modeling and flow control for a left ventricular assist device

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Date: December 12, 2020

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Abstract

Acute heart failure is one of the most common reasons for hospitalization due to heart diseases. As patients lifes at the final stages of heart failure depend on receiving a suitable donor heart and the numbers of cases does by far exceed the number of available donor organs, acute heart failure often results in patients death. Left ventricular assist devices (LVADs) have become a common treatment option in patients with heart insufficiency. They provide the ability to assist the patients heart in it's functionality of pumping blood through the circulatory system and thus can prolong a patients time span for proper treatment with a donor heart.
The Sputnik VAD is a rotary blood pump that was recently developed by our project partner in Russia. In the course of this work, first a model representation for the Sputnik LVAD will be developed and the parameters of this model will be identified. The model will then be used to design a current and a speed control. Furthermore, a cascaded flow control is to be designed in order to be able to specify arbitrary flow trajectories. Additionally, different Iterative Learning Controls will be implemented and compared. The control algorithms will be implemented using Matlab and Simulink. Finally, the different control approaches will be evaluated on a cardiovascular simulator developed at MedIT.

Contents

List of Symbols

Abbreviations

BTD	Bridging to decision
BTR	Bridging to recovery
BTT	Bridging to transplantation
BVAD	Biventricular Assist Device
CVDs	Cardiovascular Diseases
CVS	Cardiovascular System
DT	Destination therapy
HTx	Heart transplantation
IMACS	International Mechanically Assisted Circulatory Support
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
LVAD	Left Ventricular Assist Device
MCS	Mechanical Circulatory Support
RWTH Aachen	Rheinisch-Westfälische Technische Hochschule Aachen
VADs	Ventricular Assist Devices
WHO	World Health Organization

1 Introduction

1.1 Motivation and goal

1.2 Struture of the thesis

2 Medical Fundamentals

Comprehension of the physiological functionality of the human heart and the cardiovascular system is an important prerequisite to the work addressed in this thesis. Therefore the basics of these topics will be explained in this chapter.

2.1 Cardiovascular System

2.2 Heartinsufficency

3 Technical Fundamentals

Not only the medical background covered in the previous chapter, but also knowledge of the technology of mechanical heart support technologies, such as ventricular assist devices is essential for this work. Since the main part of this thesis addresses the implementation of flow control algorithms for a left ventricular assist device, the basics of system identification and control theory will be presented here as well.

3.1 Ventricular Assist Devices

The World Health Organization (WHO) names cardiovascular diseases (CVDs) as the global number one cause of death. In 2016 about 17.9 million people died from CVDs, which represent 31% of all global death that year.[Wor20] Despite the fact that heart transplantation (HTx) still is the gold standard for treatment of patients with terminal heart failure [Sch10] ventricular assist devices (VADs), as a kind of mechanical circulatory support (MCS) technology, are becoming more and more important in treating patients with CVDs. This is due both to the fact that this disease pattern is becoming more significant due to demographic change and to the increasing shortage of donor organs.[DMH19]

3.1.1 Technology

Since the first artificial blood-pump has been implanted in 1963 [LHH$^+$63] technology of VADs has improved significantly.
The general aim of ventricular assist devices is to provide mechanical support in pumping blood through the human body with the heart remaining inside the patients body. Assistance can be either implemented to support the heart in a counter pulsation approach, working synchronous to the heart cycle, or as an asynchronous support. Despite there being several types of VADs, all of them are working according to the same principle. Blood is taken from the circulatory system through the pumps inlet and ejected at another location via the outlet of the pump.[LW16]
VADs are differentiated by three criteria: the localization of the device inside the human body, the flow profile and the implantation strategy.
Regarding the localization of the assistance there are three types of VADs. With around 93% of all implemented devices the most commonly used ones are the left ventricular assist devices.[DMH19] LVADs are placed inside the left ventricle, from where they are pumping blood into the aorta [GSL$^+$03]. The second localization option is given by placing the device as a support for the right ventricle. These devices are therefore called right ventricular assist devices (RVADs). RVADs are positioned such that blood is taken from the right atrium and ejected into the pulmonary artery. [DMH19] In some cases RVADs in

combination with the aforementioned LVADs are used to build a biventricular assist device (BVAD). This type of heart support is mainly used for more severe heart diseases with a high risk of developing right heart failure. [SH19] An overview of the different localization strategies is presented in GRAFIK!!
The flow profile as the second criterion for VAD distinction is represented through pulsatile and continuous flow devices. The most commonly known type of pulsatile device is a pneumatically driven pump ventricle. [LW16] However, according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) over 95% of all implanted devices are continuous flow devices [KPK+17]. These in their most commonly used form are electrically driven rotational blood pumps. A technological difficulty with these devices is the high probability of blood damage due to small gaps and very high rotational speed. In exchange for this problematic these devices enable a dynamic adaption to the patients physiological needs by being able to quickly adjusting parameters like the motor current. The possibility of keeping track of these signal characteristics furthermore makes it possible to detect malfunctions such like misplacement of the pump. [LW16]
Implantation of the VADs can be performed in one of three ways: paracorporeal, intracorporeal or percutaneous [DMH19]. For VAD systems which follow a paracorporeal approach, only the in- and outflow cannulas are located inside the human body. The cannulas are connecting the pump, which is located outside the body, with the ventricle and the vessels. Due to the pump being placed outside of the patients body, these systems provide the option for pediatric MCS. For most other systems this is not possible due to the device being to big to fit inside a child's body. [SBL19] One example for paracorporeal systems are the aforementioned pneumatically driven pump ventricles [LW16]. As far as the other two criteria for VAD differentiation are concerned, all combinations of localization and flow control are possible [SBL19]. As an example of a percutaneous device, [DMH19] names the Impella 2.5, which is a rotary blood pump with continuous flow used for left ventricular assistance.

3.1.2 Therapeutic objective

Traditionally the therapeutic goals of VAD treatment can be divided into three categories: *bridging to transplantation* (BTT), *bridging to recovery* (BTR) and *destination therapy* (DT). However in some cases also the classification into *bridging to decision* (BTD) and *bridging to transplantability* are mentioned as well. The decision for one of these goals is based on the type of CVD and the condition the patient is in, when receiving the VAD.[KSS+11] An overview on the relation between the INTERMACS Score, the New York Heart Association(NYHA)-classification and the patient's condition is presented in Table 3.1.

The INTERMACS Score, which is based on data from patients which have received VAD treatment, links the need for a VAD and the appropriate time frame in which the devices needs to be implanted. It is of high importance in the decision of the therapeutic objective for VAD treatment. [DMH19]

INTERMACS Score	NYHA	Patient condition	Survival time
1	IV	critical cardiogenic shock	hours
2	IV	increasing catecholamine demand	days
3	IV	stable under inotropics	a week
4	IV	frequent decompensation	weeks-month
5	IV	rest discomfort/ not resilient	weeks-month
6	IV	rest discomfort/ merely resilient	varies
7	IIIb	merely resilient	one year survival rate: 50-70%

Table 3.1: Relation between INTERMACS Score, NYHAc-classification, patient condition and approximate survival time based on [Eif18]

The goal of *bridging to transplantation* has a big relevance with patients in NYHA-IV Stadium which are showing hemodynamical instability. Due to a heart transplantation being the desired final treatment for these patients there must be no contraindication to HTx. In case the patient does show a contraindication, such as malignant tumors or an uncontrollable sepsis, the therapeutic objective changes from BTT to DT. In order for a treatment with a VAD as destination therapy being indicated all conservative treatment options need to be exhausted. Due to the ever-growing shortage of donor organs DT as a therapeutic approach in patients with heart insufficiency will become more relevant in the future even in cases usually suited for an HTx. [DMH19] There may occur some cases, in which at first a contraindication for HTx exists, which later on may dissolve. These indicate a therapy based on a *bridging to transplantability* goal. [KSS$^+$11] HIER NOCH AUS VAD 7 BEISPIEL LISTEN!!
The indication for a *bridging to recovery* approach is twofold. Either the patient shows pump failure as a result of ischemia reperfusion damage or due to infectious genesis. In the first case the myocardium usually is able to recover within a few days, whereas in the second one the potential and the time necessary for recovery depends on how badly the tissue is damaged. In either scenario a weaning from the VAD is an essential part of therapy. [DMH19]
If a patient is admitted in cardiogenic shock and medical treatment is not sufficient, *bridging to decision* becomes a relevant form of therapy. By providing the patient with a VAD, a more accurate assessment of the patient's condition is possible. Based on this, the decision on further treatment can be thought through more thoroughly. [KSS$^+$11] Table 3.2 illustrates the proportions of different VAD types and therapeutic goals using the International Mechanically Assisted Circulatory Support (IMACS) register.

VAD type		Therapeutic objective	
LVAD	93%	DT	40%
BVAD	4%	BTD	30%
TAH	2%	BTT	29%
unknown	0.1%	others (BTR,...)	1%
RVAD	0.05%		

Table 3.2: Percentages of VAD types and thearapeutic objectives in mechanical heart supports based on [DMH19].

3.2 Control Theory

3.2.1 PI Controller

Chien Hrones Reswick

3.2.2 Iterative Learning Control

4 Modeling and Identification

4.1 Sputnik VAD

The Sputnik VAD is an axial-flow blood pump, developed in a cooperative project of the National Research University of Electronic Technology, OJSC Zelenograd Innovation-Technology Center of Medical Equipment, FSBI "Academician V.I. Shumakov Federal Research Center of Transplantology and Artificial Organs", Ministry of Health of Russian Federation, DONA-M LLC and BIOSOFT-M LLC in 2009. [ST15]
This device is used for left ventricular assistance in patients with acute heart failure. The therapeutic objective in implantation of a Sputnik VAD is bridging to transplantation. The VAD is able to pump up to 10 liters of blood per minute with a continuous flow profile. The implantable pump weighs about 200 g, has a length of 81 mm and a maximum diameter of 34 mm. It consists of a moving and a stationary part. The moving part, the impeller, which is a rotor with four blades, contains a permanent NdFeB-magnet which is actuated by a brushless DC motor. The rotor spins clockwise with speed values between 5000-10000 rpm. The stator is located inside a titanium housing with a 16 mm diameter. The stationary part of the pump consists of a flow straightener with three stationary blades and a flow diffusor with three twisted blades. The flow straightener is located in front of the rotor and straightens the incoming blood flow into the rotor. Behind the rotor, the blood is directed into the diffusor. Figure 4.1 depicts a cross-section of the Sputnik VAD and identifies it's individual components. The connection between the pump and the cardiovascular system is performed using in- and outflow cannulas, a felt ferule and vascular prosthesis which is sewed to the aorta. [ST15]

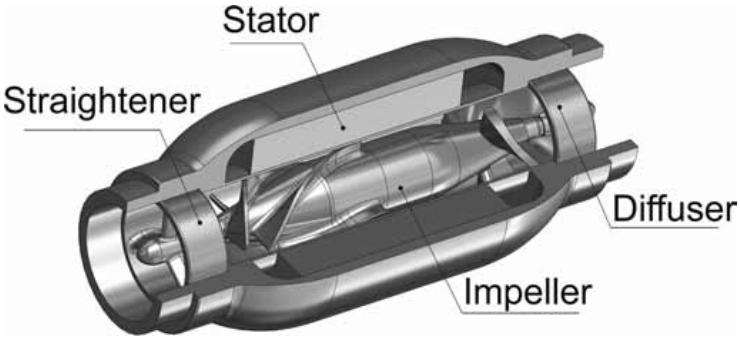

Figure 4.1: Cross-section of the Sputnik VAD from [**?**]

The Sputnik VAD is powered using two lithium-ion batteries, fully loaded providing enough energy for up to eight hours of system support. The maximum charging time for the batteries is less than five hours. During this time the batteries can either be exchanged by another set of batteries or the system can be powered through connection to an AC network. A microprocessor-based driving unit is used to regulate the pump speed, manage

the power supply and store parameter data. It is connected percutaneously to the pump with a up to 170 cm long and 5 cm wide lead. [ST15]

4.2 Hardware in the Loop Test Bench

4.3 System Identification

5 Implementation of Flow Control

5.1 Controller Design

5.1.1 PI Controller

Chien Hrones Reswick

Dynamische Messung nutzen Werte an Sprungstellen Nach Wendetangenten verfahren -> GRAFIK

5.1.2 Iterative Learning Control

5.1.3 Iterative Learning Control with varying iteration length

5.2 Evaluation of Controllers

Kontanten Fluss Ã$\frac{1}{4}$ber verschiedene Druckbereiche?

Herzschlag dazu - Druckverlauf

6 Conclusion and future work

A Appendix

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