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Development of a Pediatric Heart Assist Device Monitoring System

Natalie Hill

Development of a Pediatric Heart Assist Device Monitoring System

by

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Abstract

Development of a Pediatric Heart Assist Device Monitoring System

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Heart failure (HF) is one of the leading causes of deaths for adults worldwide, but has disproportionately significant effects on pediatric patients that are often overshadowed. Treatment options for pediatric patients with HF are extremely limited, resulting in increased mortality rates within hospitals. Patients often depend on ventricular assist device (VAD) support as a bridge to transplant. The Berlin Heart EXCOR is the only FDA approved device for pediatric use in the US. However, many hemodynamic and neurological complications continue to arise; for instance, up to 30% of EXCOR patients suffer from stroke. Currently, there is no effective way to monitor the EXCOR device operation in a clinical setting. If there was a way to monitor the device quickly and efficiently, patient outcomes could be improved. The objective of this thesis is to develop a pediatric heart assist device monitoring system that can be used in a clinical setting to analyze device function. A mock cardiovascular flow loop incorporating dedicated pressure and flow sensors was developed in order to simulate several clinical settings a pediatric patient would experience. A custom EXCOR driving unit (CEDU) was developed and tuned in order to pump a functioning EXCOR device in a programmable and repeatable manner. The monitoring system relies on mobile device video recordings (to mimic a clinical setting) to analyze the function of the EXCOR. These videos, as well as clinical data, are analyzed using an in-house algorithm that quantifies the EXCOR membrane operation for each cardiac cycle. The results of each experiment are compared to those of a fully functional EXCOR device. Using the in-house developed algorithm, it was found that the EXCOR device reacted differently to different types of hemodynamic stimuli introduced to the flow loop, and this difference in EXCOR operation could be quantified and compared to ideal operating characteristics. In summary, this project

provides a unique platform to rigorously analyze EXCOR membrane operation towards developing quantitative analytics that can be used in the clinic to improve patient monitoring and overall patient outcomes.

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I would like to thank my advisor, Dr. Venkat Keshav Chivukula, for always having my back these past three years at Florida Tech. I wouldn't be here today without him, and greatly appreciate all the opportunities he has given me. Additionally, I would like to thank Rachel Hillner and Marcello Mattei for being some of the best people to bounce ideas off of, and for making the lab a brighter place. I would also like to thank the entirety of the MCFL lab for their constant support. Finally, I would like to thank all my professors at Florida Tech for providing me the knowledge and skills that have allowed me to succeed up to this point.

Chapter 1
Introduction

1.1 Pediatric Heart Failure

Pediatric HF is generally characterized by an impairment of ventricular function that causes insufficient cardiac output, and can take many forms.[1–4] More than 14,000 children are hospitalized and diagnosed with HF annually in the United States.[1,5,6] This leads to either death or transplantation in 46% of pediatric patients within five years after diagnosis.[6] Pediatric patients with heart failure have a higher mortality rate (6.7%) than those hospitalized without heart failure (0.4%).[5] This is an extremely stark difference in survival rate and highlights a significant need to address the treatment of pediatric heart failure. Additionally, the mortality rate for infants with HF is 11%.[5] Nearly 40-50% of pediatric patients with HF do not survive 2 years after diagnosis. Even with a heart transplant, the median survival age is 18 years, shown in Figure 1.[5] These devastating outcomes can be attributed, in part, to the lack of clinical research specific to pediatric cases. Generally, pediatric treatment mirrors treatment for adult HF. This includes using the same medications used to treat adults, such as ACE inhibitors, beta-receptor & aldosterone antagonists, and diuretics.[7] These treatment options are adjusted according to experts, and then applied to the pediatric patient. However, this is often not an effective way to treat pediatric heart failure due to the vast differences between a pediatric heart and a fully developed adult heart. This is supported by recent studies that suggest mechanisms associated with pediatric heart failure vary from those associated with adult HF.[7] Often times the pediatric patient will often need mechanical circulatory support, which can take form as a ventricular assist device (VAD). These devices are often used as a bridge to transplant. However, the mortality rate for pediatric patients on VAD support is around 35%, shown in Figure 2.[8]

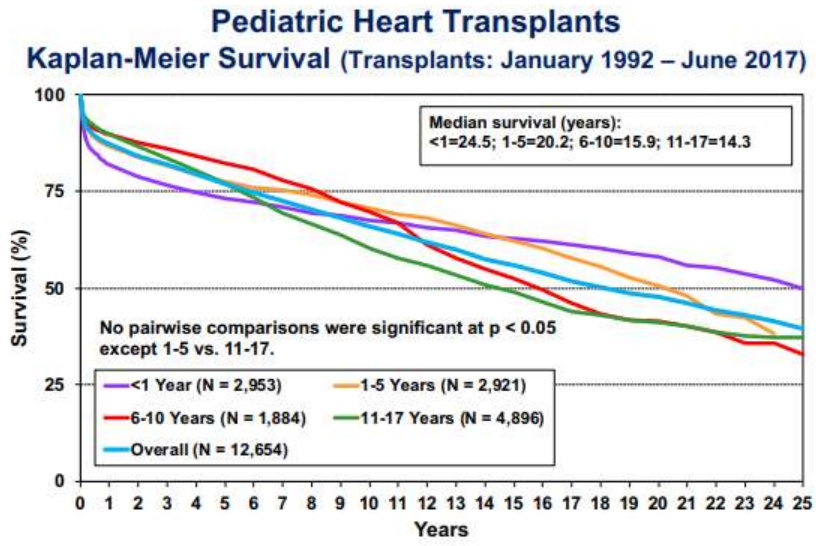

Figure 1: The decrease in survival rate for different age groups over time. The median survival age for each group after transplant is shown in the top left corner.[1,5]

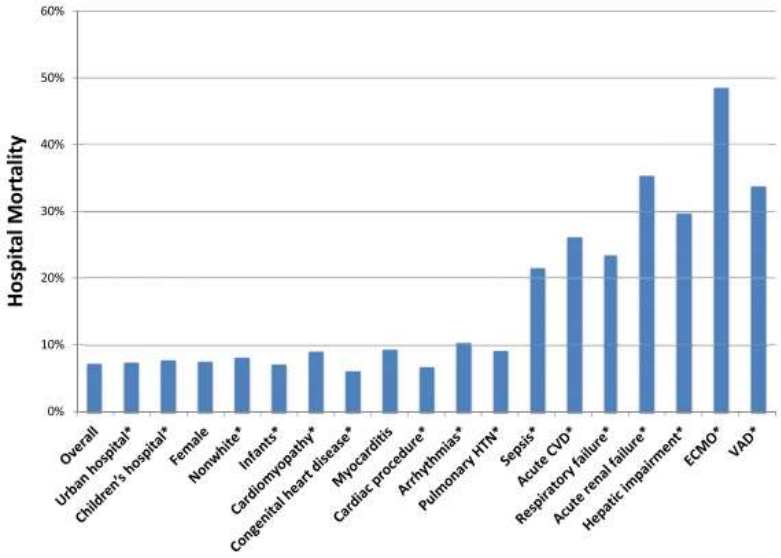

Figure 2: The mortality rate of pediatric patients with different diseases/treatments. Note the disparity between the mortality rate of ECMO and VAD devices.[1,8]

1.2 Ventricle Assist Devices (VADs)

VADs were first used to treat a pediatric patient in a clinical setting in the 1960's.[8] Currently, VADs are a commonly used option in the management of end-stage heart failure.[9] They are

most commonly used as a bridge to transplant across all patient demographics.[10–12] Before VADS became clinically available to pediatric patients, Extracorporeal Membrane Oxygenation (ECMO) was the primary treatment used.[13] However, pediatric mortality rate for patients on ECMO is devastatingly high (almost 50%) (shown in Figure 2).[8] Generally, VADs take over the pumping function of the impaired heart to supply the rest of the body with sufficient blood flow. For treatment of left heart failure, the inlet cannula is typically inserted at the left atrium or apex of the left ventricle, with the outlet cannula emptying into the aorta.[14] Patients suffering from both left and right heart failure may have two VADs (BiVAD) as well. Studies have shown that pediatric patients who used a VAD device as a bridge to transplant reported a 91% survival rate after transplant.[15] The median length of time on VAD support for this study was 27 days.[15] VADs also act as the only treatment choice for patients under 5kg, which limits the success of patient outcomes for very young patients.[15] Additionally, VAD are mainly designed to provide short-term support for patients. However, if a patient is using the device as a bridge to transplant, it may take an extended period of time for a transplant to become available. For longer-term treatment, VADs are often paired with ECMO to attempt to improve patient outcomes, yet are generally unsuccessful.[13] Currently, in the US, the Berlin Heart ® EXCOR device is the only FDA-approved VAD for pediatric use, and it has been shown to result in improved patient outcomes over a longer period of time compared to other VADs.[16,17]

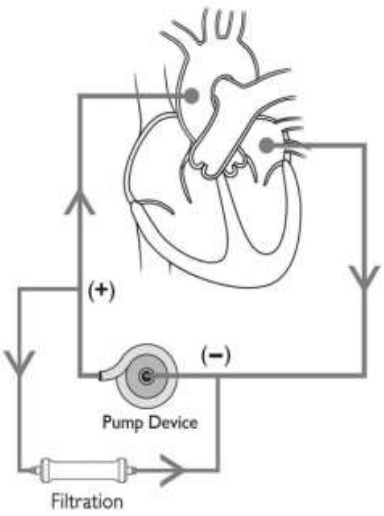

Figure 3: A VAD flow loop diagram. The inlet cannula of the VAD is connected to the left atrium, and the outlet cannula is connected to the aorta.[8]

1.3 Berlin Heart EXCOR

The Berlin Heart EXCOR is the only FDA-approved VAD for pediatric patients. The EXCOR is a mechanical circulatory support system designed to restore proper hemodynamics for severe to life-threatening heart failure patients.[16,17] There are six different sizes of the device, ranging from 10 mL to 60 mL shown in Figure 3 below.[18] These sizes are correlated to the stroke volume it provides to the patient. The necessary cardiac output for each patient varies due to size and age, shown by Figure 4.[18] Patients under 10 kg generally need a cardiac output of around 1 L/min, but larger patients may need up to 6 L/min, which is provided by the larger EXCOR devices.[18,19] The EXCOR acts as a paracorporeal pulsatile membrane pump that is powered by the Ikus Stationary Driving Unit. This driving unit allows clinicians to control the heart rate and driving pressures of the EXCOR. The driving pressures can create a heart rate range from 30 to 150 bpm. The systolic pressure ranges from 60 to 350 mmHg, and the diastolic pressure ranges from -100 to 0 mmHg.[18] Clinicians can alter and monitor these parameters based on the patients' needs. The driving unit is designed to be stationary, but can be deployed as a mobile unit for a maximum of 30 min before the battery is exhausted. The driving unit applies a negative and positive pressure to the EXCOR membrane, which expands and retracts it.[18] This inner membrane

separates the air chamber from the blood chamber. When the membrane is retracted during diastole, blood is suctioned into the EXCOR blood chamber via the inlet. When the membrane is expanded during systole, blood is then forced out of the EXCOR outlet, and travels to the aorta. Trifold valves prevent backflow in both the inlet and outlet.[18]

Figure 4: The different sized EXCORS, ranging from 10 mL (left) to 60 mL (right). The patient is assigned an appropriate EXCOR size based off patient size and cardiac output needs.

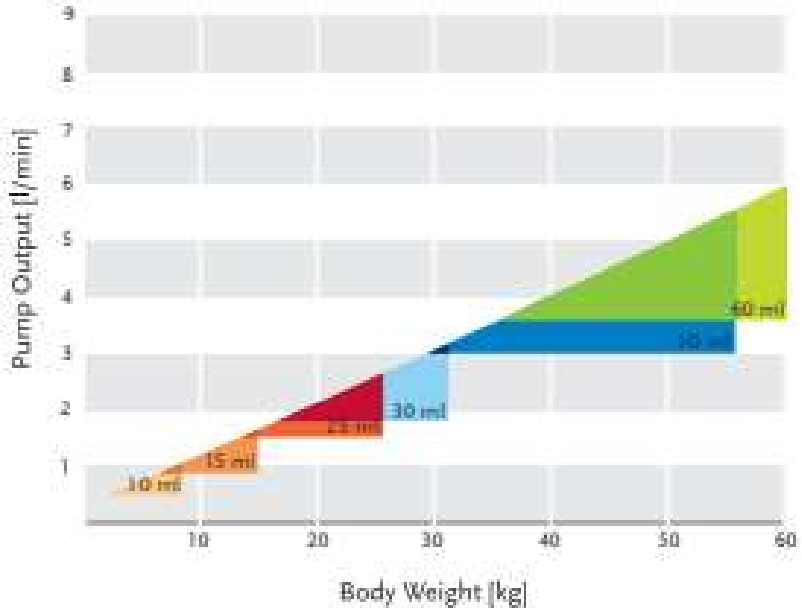

Figure 5: A chart highlighting how pump sizes are assigned to patients based on body weight and pump output.[18]

Figure 6: The IKUS Driving Unit.[18]

1.4 Clinical Challenges

While using the EXCOR as a bridge to transplant can be successful for some patients, many challenges still arise in the clinical setting.[13,20–22] The survival rate for patients on the EXCOR is 56%, and decreases drastically for young children (30%).[23,24] Recent studies have shown that neurological events occur in 29% of EXCOR patients.[25,26] Neurological events, such as stroke, are associated with a higher mortality rate of 42%.[26] These complications can stem from patient-pump mismatch, different hemodynamic situations, or pump malfunction. Though it is unknown how each of these complications individually affect the EXCOR operation, clinicians have resorted to manually checking the EXCOR membrane motion in order to determine if the pump is functioning properly. Since the membrane moves at speeds up to 150 bpm, it is impossible to assess the functionality of the pump with the naked eye. Currently, some clinicians record the membrane motion using a slow-motion camera on their mobile device in order to assess if the pump is operating correctly.[16,27] The functionality of

the pump is determined by the behavior of the membrane. If the membrane fully expands and retracts diastole and systole, then it is assumed to be functioning properly. This means that the membrane has to be completely smooth at the end of diastole, and fully smooth at the end of systole. Clinicians simply assess this membrane behavior frame-by-frame from their slow motion video.[27] If the membrane does not fully extend or retract (i.e. wrinkly), then it is noted that the pump is not functioning correctly. This method of checking patient health is very tedious, qualitative and inefficient, yet this is the only clinical method of checking EXCOR function.[16,27] Additionally, if the pump is not properly functioning, there is no method to determine why the membrane is not behaving correctly. The membrane can be affected by different hemodynamic conditions in different ways, which makes it difficult for the clinicians to determine the next steps in treatment. Due to these complications, it is crucial to develop a monitoring system that can more effectively identify a malfunctioning EXCOR and characterize the membrane behavior under different hemodynamic conditions.

1.5 Objectives

In order to optimize the process of checking the functionality of the EXCOR, it is important to determine how the EXCOR membrane responds to non-normal stimulus. We introduce a custom designed solution called EXCOR Membrane Motion Analyzer (EMMA), an in-house design algorithm, to quantitatively analyze the EXCOR membrane motion from a video recording. My objectives for this thesis are:

1. Develop an experimental setup to subject a EXCOR device to several clinically-relevant hemodynamic scenarios
2. Quantify the hemodynamic parameters of interest for the above clinical scenarios
3. Utilize the in-house developed EMMA algorithm to quantitatively analyze the membrane motion for assessment of EXCOR performance

Extensive testing of the EXCOR under different hemodynamic conditions is performed, , and videos of the membrane are analyzed by EMMA to characterize the membrane motion. Ideally, with enough data, correlations between different blood flow patterns and certain membrane behavior can be determined, which allows clinicians to treat patients much more

effectively. However, before any videos can be analyzed using EMMA, a method to actually run the EXCOR device in a clinically relevant setting must be developed. This involves building a mock-cardiovascular flow loop and a custom EXCOR driving unit (CEDU). For this thesis, EMMA will be used in conjunction with a custom-developed mock cardiovascular flow loop to test an EXCOR device under different clinically-relevant conditions.

Chapter 2
Methods

This chapter explains how the mock cardiovascular flow loop and CEDU were designed and built. There are many different components that were involved in this process, such as designing an actuator driver to power the CEDU, calibrating flowmeter equipment used in the flow loop, and determining which parameters were feasible to vary for each experiment. An overview of the EMMA algorithm is also provided. It was necessary to build this setup in order to obtain the video data that would be analyzed by EMMA. The completion of this setup allows for future experiments to be ran on the EXCOR device under different clinically relevant scenarios.

2.1 Mock cardiovascular flow loop

An in-house mock cardiovascular flow loop was designed to complete these experiments. This flow loop consisted of a custom-built EXCOR driving unit (CEDU), the EXCOR device, nylon tubing, flowmeters, pressure transducers, and a reservoir. Two 10 mL EXCOR devices were obtained from our clinical collaborator Dr. Michael Ma at Stanford University. One was fully functional, while the other seemed to be damaged. The fully functional device was used for all experiments.

2.1.1 Custom EXCOR Driving Unit

While the EXCOR is supported by the Ikus Driving Unit in a clinical setting, it was not possible to attain an official Ikus Driving Unit. Therefore, a Custom EXCOR Driving Unit (CEDU) was built and developed to support the EXCOR device. A high-speed linear actuator was purchased from Progressive Automations (Arlington, WA, USA). The actuator could reach speeds of 9.05’’/sec and push a maximum load of 11lbs.[28] The actuator is comprised of a cylindrical body and a hexagonal-faced piston head. These design specifications made this linear actuator the most ideal candidate for this project because it’s extension and retraction speed could match the high heart rates of pediatric patients. The actuator was mounted on a base, and an extension of the piston head was built in order to

customize the face diameter based on our needs. A wooden rod was used to extended the actuator and act as the base for the reciprocating pneumatic piston. Three circular acrylic disks were laser cut to form the piston head. One with a diameter of 1.2'', and two with a diameter of 1.4''. The smaller disk was glued in between the two larger disks, creating a groove to place an O-ring. The piston head was equipped with O-rings, so that it would be flush inside tubing with an inner diameter of 1.5''. This inner diameter was reduced via plastic connectors to 1'', 1/2'', then finally 5/16'' that connected to the inlet of the EXCOR air chamber. This initial tubing size of 1.5'' was chosen because it would allow the piston head to travel the minimal distance in order to push enough volume of air to pump the EXCOR membrane. Initial calculations used the equation below, where V is the volume of air pushed, D is the diameter of the tubing, and L is the length the piston head needs to travel. The assumption that air is incompressible was made for simplicity. Using this calculation with V=10 mL and D = 1.5'', it was calculated that the theoretical distance the piston head would have to extend and retract was 0.69''. However, since this equation assumed air was incompressible, it was found that this distance would not push enough volume of air into the EXCOR to extend and retract the membrane completely. After initial testing of the device using the Actuator Driver described in the next section, the piston head needed to extend and retract 1.35'' to push enough air into the EXCOR for moving the membrane. Using the same equation as before, it was calculated that the piston head was pushing 39 mL of air in order to completely extend and retract the EXCOR membrane at 90 bpm. This greatly exceeded the initial estimation of 10 mL of air based off of the EXCOR air chamber size, due to the compressibility of air.

$$V = \frac{\pi}{4} D^2 L$$

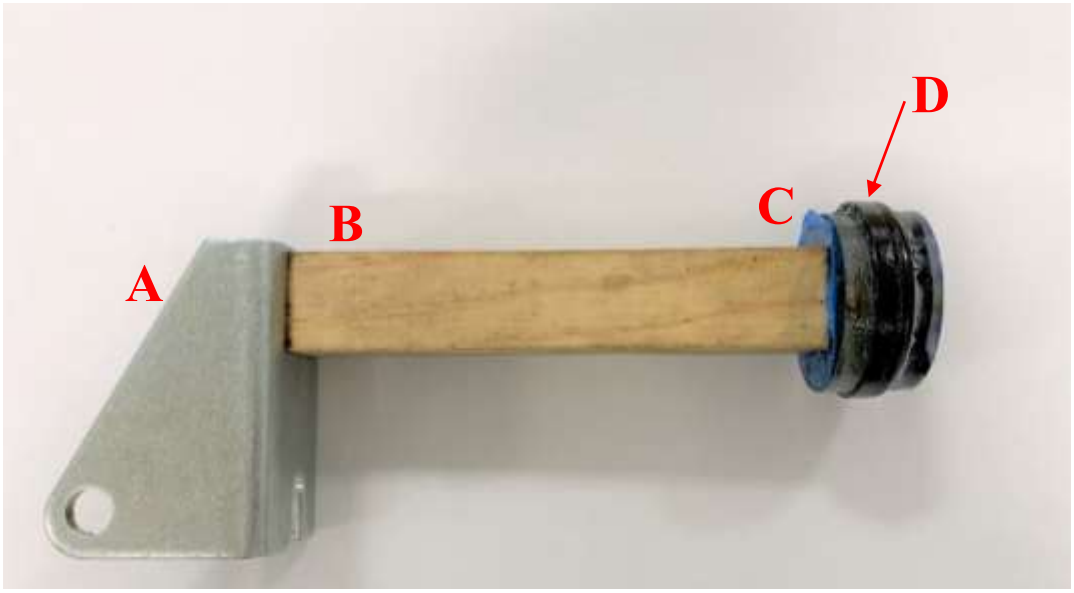

Figure 7: The piston head extension. Metal bracket (A) connects the rod to the original piston head. (B) is then connected to the acrylic disks (C), the new piston head. The O-rings (D) can be seen in the middle of the head to provide for an air-tight fit inside of the tubing that will still allow for the piston head to move smoothly inside of it.

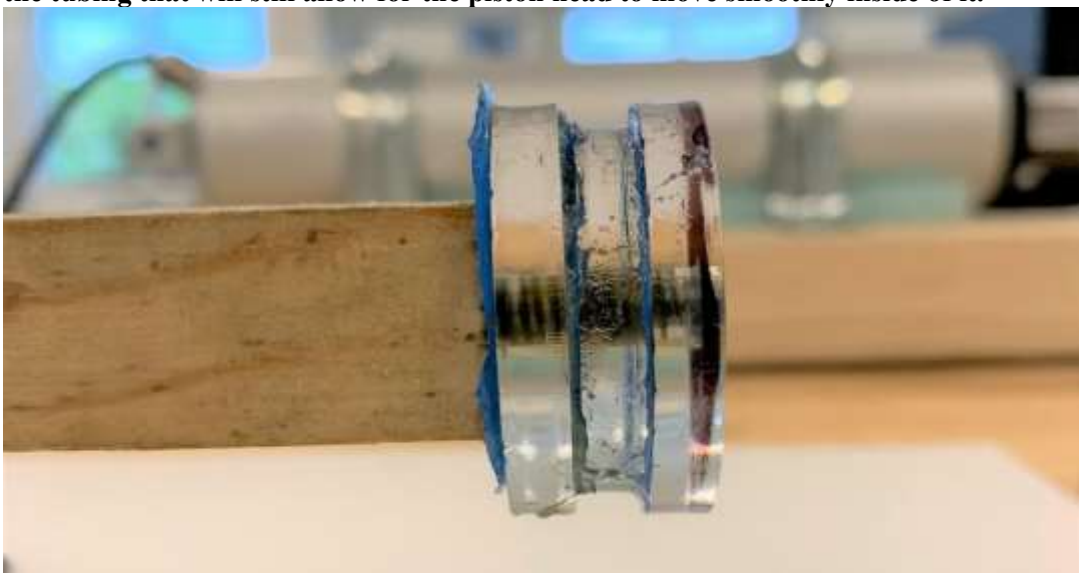

Figure 8: A close up of the acrylic disks that compose the custom-built piston head. The three individual disks can be seen, with the smaller disk in the middle. This creates a groove that allows the O-ring to fit snugly in between the larger disks.

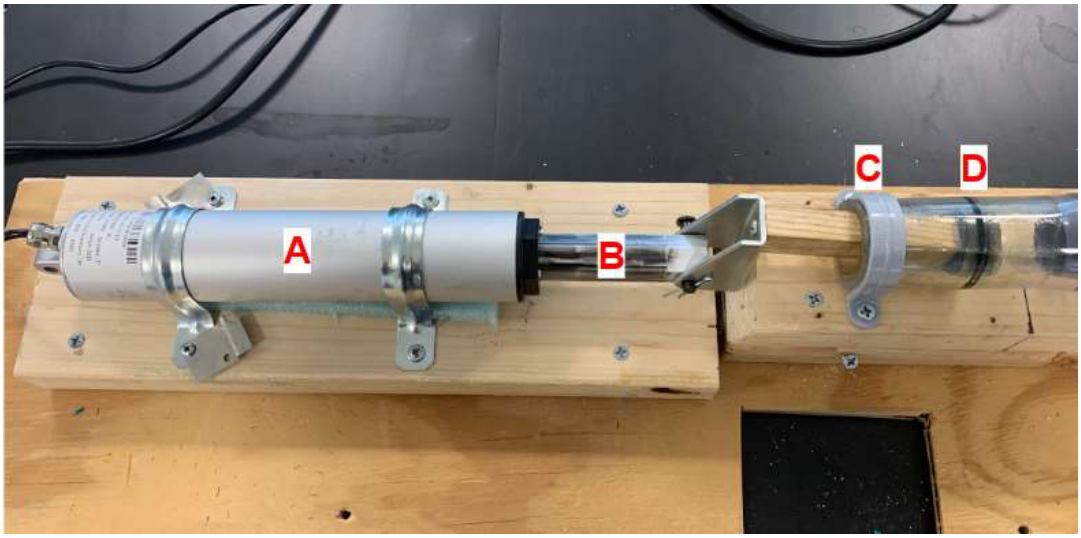

Figure 9: A- The body of the linear actuator. B- A clamp used to secure the actuator piston head and tubing. C- the custom-built piston head extension. D- the tubing that connects to the EXCOR device.

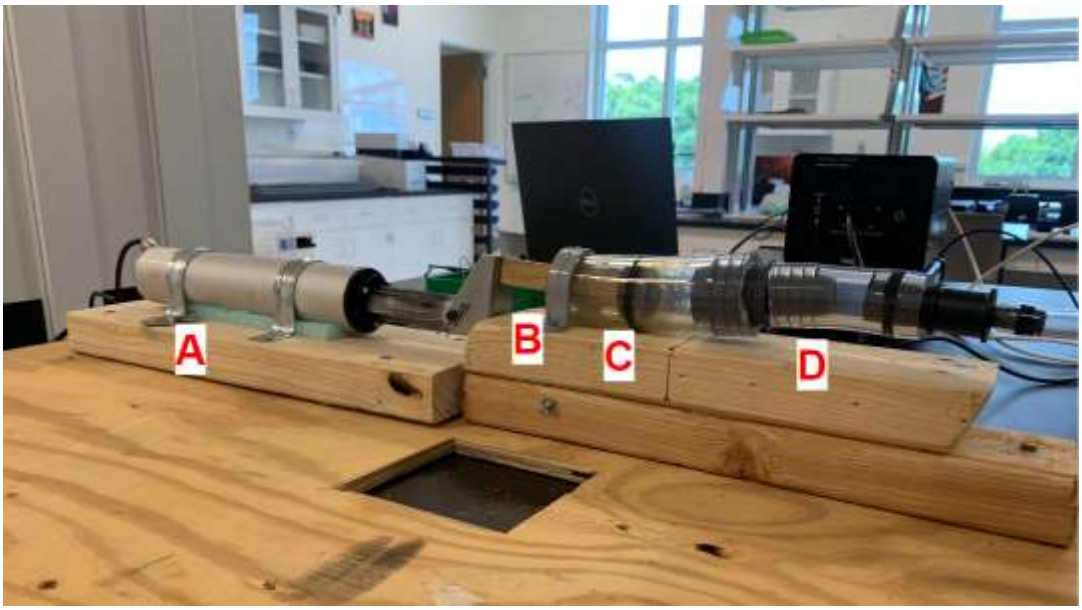

Figure 10: A- The body of the linear actuator. B- A clamp used to secure the actuator piston head and tubing. C- the custom-built piston head extension. D- the tubing that connects to the EXCOR device.

2.1.2 Actuator Driver

The CEDU is controlled via an actuator driver. The actuator driver consists of an Arduino Uno and a L298N motor driver module (Amazon.com). The speed and distance at which the actuator moves is controlled via the Arduino, which is explained below. The L298N Motor Driver then converts the Arduino code into a readable signal for the actuator. The L298N Motor Driver Module is used to drive DC and stepper motors.[29] Its ability to control the speed of the motor via a signal from a microcontroller makes it optimal for use in the CEDU. A switch is also used to turn the actuator on and off.

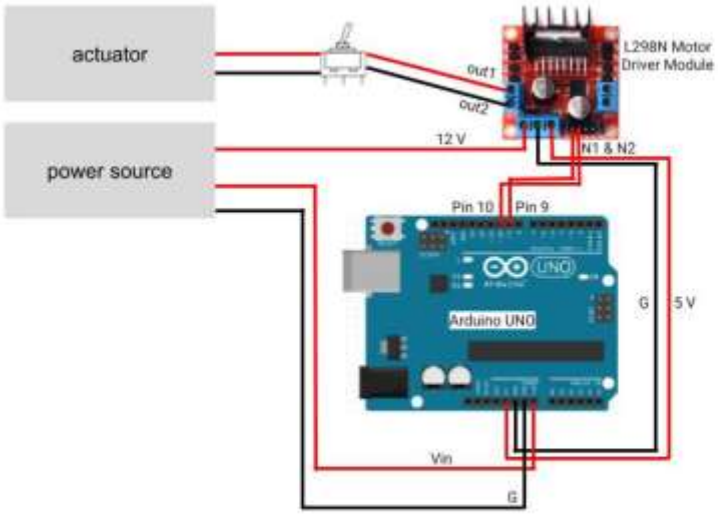

Figure 11: The actuator connects to pins out1 and out2 of the L298N Motor Driver Module. The 5V and ground pin of the L298n Motor Driver Module is connected to the respective pins on the Arduino UNO. The 12V pin is connected to the power supply. Pin 9 and pin 10 of the Arduino are connected to the N1 and N2 pins of the L298N Motor Driver Module. These pins relay the speed and distance that the actuator is coded to travel.

2.1.3 Actuator Driver Code

The code controls the speed at which the CEDU moves, and how long, in seconds, it extends and retracts for. It can be found in Appendix A.1. In order for this to occur, five

variables are initialized: distanceTime, stopTime, timeNow, timePrev, and InperSec. The variable distanceTime controls for how long the piston head extends and retracts. For example, it is set to 0.3 if the piston head is supposed to extend for 0.3 seconds, then retract at 0.3 seconds. The variable stopTime is the period of time between extension and retraction, and is set to 0.1 seconds. The variables timeNow and timePrev act as timesteps that indicate when the actuator should extend and retract based on the time that has passed. The variable InperSec controls the speed at which the piston head moves. The main concern while using this code is making sure that the variables InperSec and distanceTime allow the piston head to move the necessary length to push enough volume of air. This can be calculated by the equation: distanceTime*InperSec = L, with L being the distance the piston head travels. For a distanceTime of 0.3s, and a InperSec of 9.05in/sec, the value of L was equal to 1.35'' – this was the minimum distance the piston head needed to extend and retract in order to completely push the EXCOR membrane smoothly. The heart rate the CEDU produced was then calculated by counting the number of extension/retraction cycles in 10 seconds, and multiplying it by 6 to get the bpm. For the above values of each variable, shown in Table X, the heart rate was calculated to be 90 bpm. This is the maximum heart rate the CEDU can currently achieve because it is traveling at the maximum retraction and extension speed of the actuator. In order to increase the heart rate, the distance the piston head travels would have to be reduced, but that would result in incomplete extension and retraction of the EXCOR membrane due to insufficient volume of air being pushed through the tubing. This can be modified by adjusting the diameter of the pneumatic tubing and actuator settings in the future (see future work). The code specifies when the actuator should begin extending, when it should stop extending, when it should begin retracting, and when the cycle should start over again. The code is slightly modified to create unequal systolic and diastolic ratios by introducing two different distanceTime and InperSec variables. This allows for the piston head to extend and retract at different speeds, thereby providing the ability to vary the systole: diastole ratio for experimental runs.

Table 1: The variables used to create a heart rate of 90 bpm.

	distanceTime	InperSec	BPM
Value	0.3 s	9.05 in/sec	90 bpm

2.1.4 Flowmeters

A flowmeter (Atrato Titan 760, Titan Industries, Dorset, UK) was placed at the inlet of the EXCOR. This flowmeter can detect flows in the range of 0.1 L/min to 20 L/min, and has a manufacturer-specified accuracy of +/- 1%.[30] The Atrato is an ultrasonic flowmeter and measures the time of flight of particles in the water.[30] Before running any experiments, it was necessary to conduct extensive calibration of the flowmeter. The flowmeter had to be calibrated manually via a scale factor incorporated into the affiliated software. Each flowmeter was connected in series with a pre-calibrated peristaltic pump. The pump would run different flow rates, ranging from 200 ml/min to 1500ml/min. At each flow rate, data was obtained using the flowmeter for one minute. The flow rate at each sample was exported as a .csv file. The average flow rate was calculated and compared to the actual flow rate created by the peristaltic pump. Per manufacturer's recommendations, the scale factor was manually adjusted based on the margin of error between the flowmeter and peristaltic pump. This procedure was repeated for different flow rates until an appropriate scale factor was found, and the flowmeter reflected the same average flow rate as the flow rate displayed by the peristaltic pump. It was found that it is necessary to run the flowmeters for 2-3 minutes to obtain an accurate and repeatable flow rate.

Figure 12: The Atrato Titan 760 flowmeter.

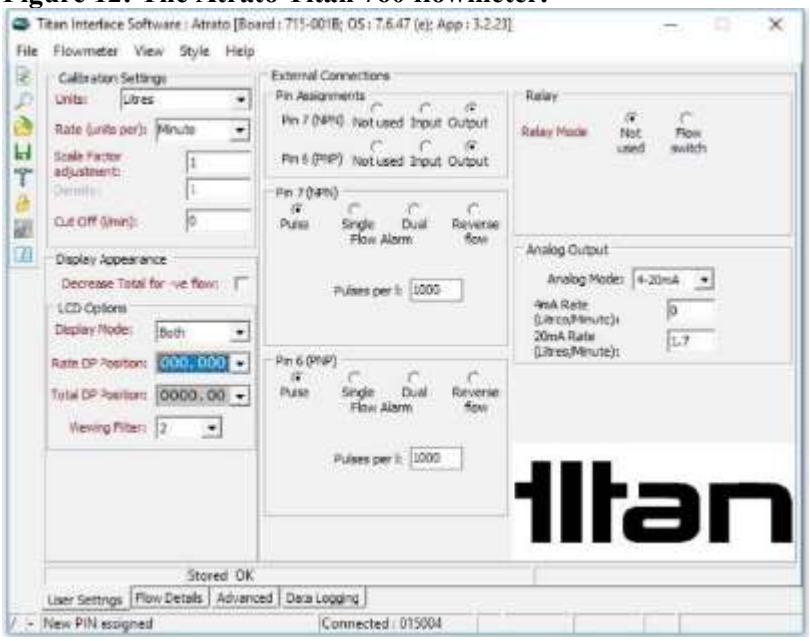

Figure 13: The Titan Interface Software used to collect the flowmeter data.

2.1.5 Pressure Transducers

The pressure transducers (Utah Medical 6069, Utah Medical Inc., Midvale, UT, USA) were previously calibrated by the manufacturer.[31] No further calibration was performed due to lack of calibration equipment, rather, the functionality of the pressure transducers was tested. When connected in series, all three transducers reported similar pressures, and when connected before and after the flowmeter, an appropriate pressure drop was recorded. The pressure waveforms were collected using the specialized Vivitest software provided by ViVitro (ViVitro Inc., Victoria, BC, Canada). The Vivitest software only collects one pressure waveform cycle per trial, which is about 10 seconds long.[31] After repeated tests, this was deemed sufficient as the pressure waveforms do not vary significantly within each individual experiment. The software also displays the waveforms in real time, and then allows for the data to be exported to a .csv file.

Figure 14: A snapshot of the Vivitest Software Interface. The yellow waveform is the inlet pressure, and the blue waveform is the outlet pressure.

2.1.6 Final Setup

The final mock cardiovascular flow-loop setup consisted of several different components. The CEDU was connected to the EXCOR. The EXCOR was connected in the

middle of the flow loop via 5/16'' tubing. Pressure transducers were connected immediately adjacent to the inlets and outlets of the EXCOR. A singular flowmeter was connected to the flow loop upstream of the EXCOR. An outlet flowmeter was not used because it introduced too much resistance to the flow-loop, causing issues with proper EXCOR function. It was assumed that the inlet flowrate is equivalent to the outlet flowrate (i.e., conservation of mass). The outlet tubing dispensed the fluid into a reservoir, which is where the inlet tubing was also connected to. The pressure transducers were connected to the Vivitro I/O module, which is then connected to a laptop. The Vivitro software Vivitest was used to collect the pressure readings. The flowmeter was connected to a different computer, and data collection was performed by its respective software. A tripod was set up by the EXCOR to allow for a mobile device to record video of the EXCOR membrane.

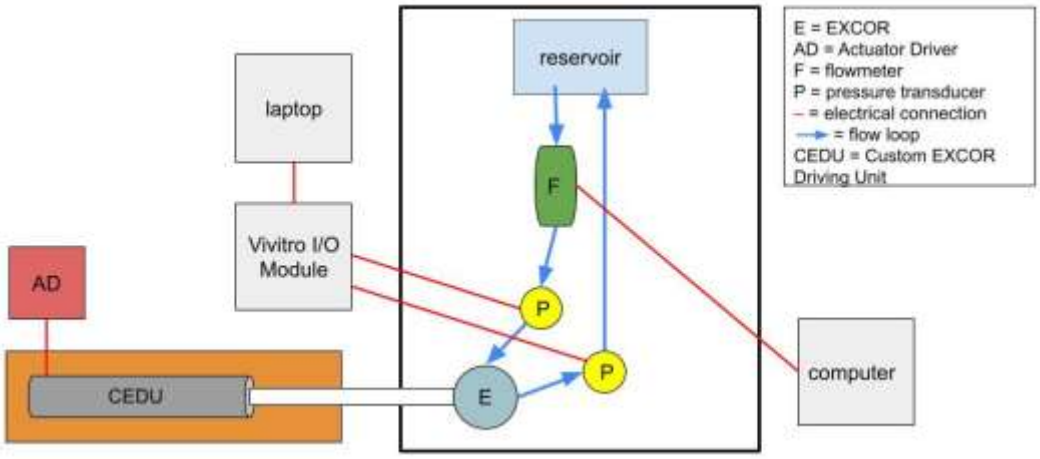

Figure 15: The mock cardiovascular flow-loop. A- EXCOR device. B- inlet pressure transducer. C- outlet pressure transducer. D- outlet tubing. E – flowmeter.

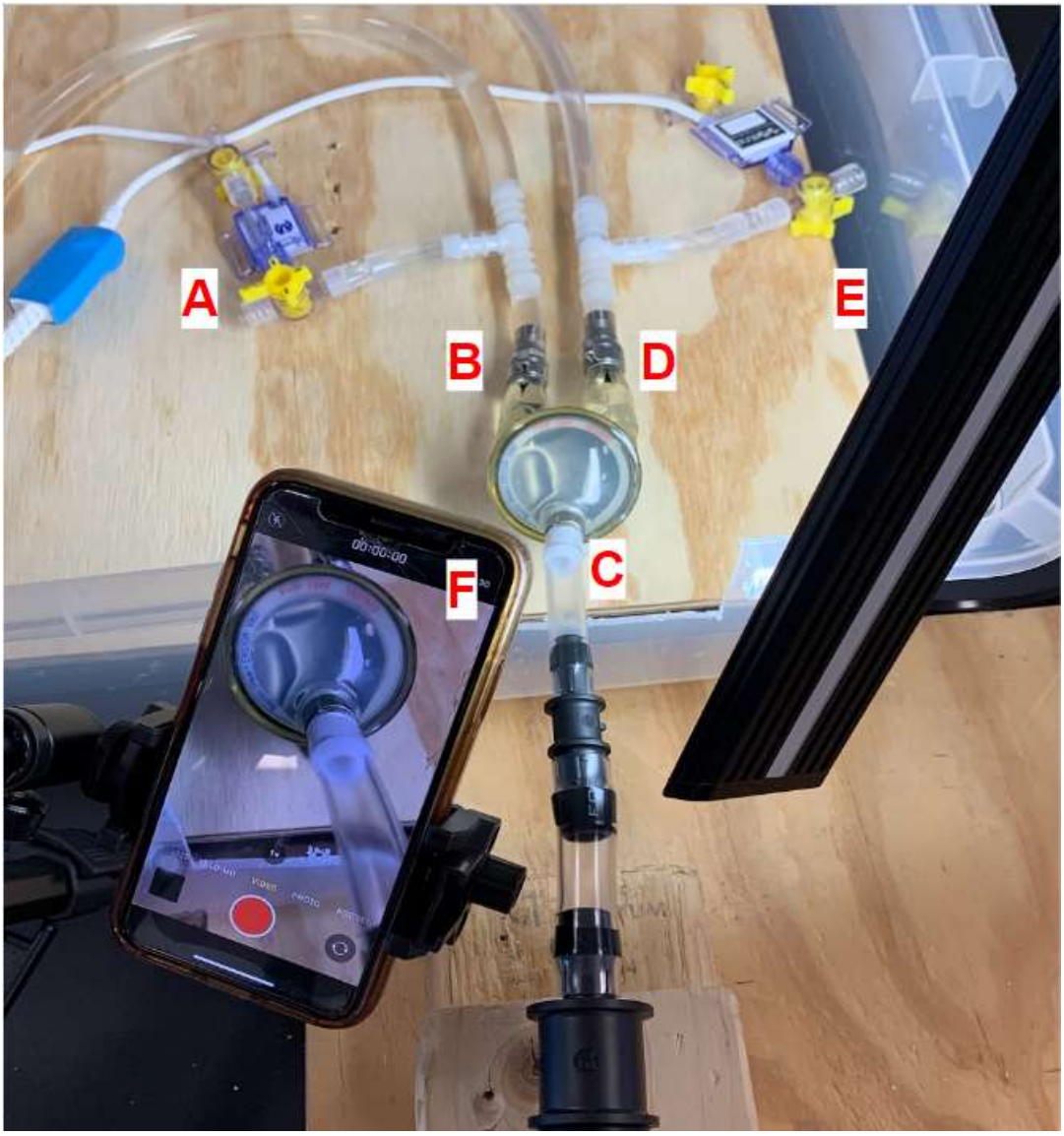

Figure 16: A close-up of the EXCOR device. A- inlet pressure transducer. B- EXCOR inlet. C- Inlet/outlet of EXCOR air chamber, connected to the CEDU. D - EXCOR outlet. E- outlet pressure transducer. F- mobile device used to collect video data of EXCOR membrane movement.

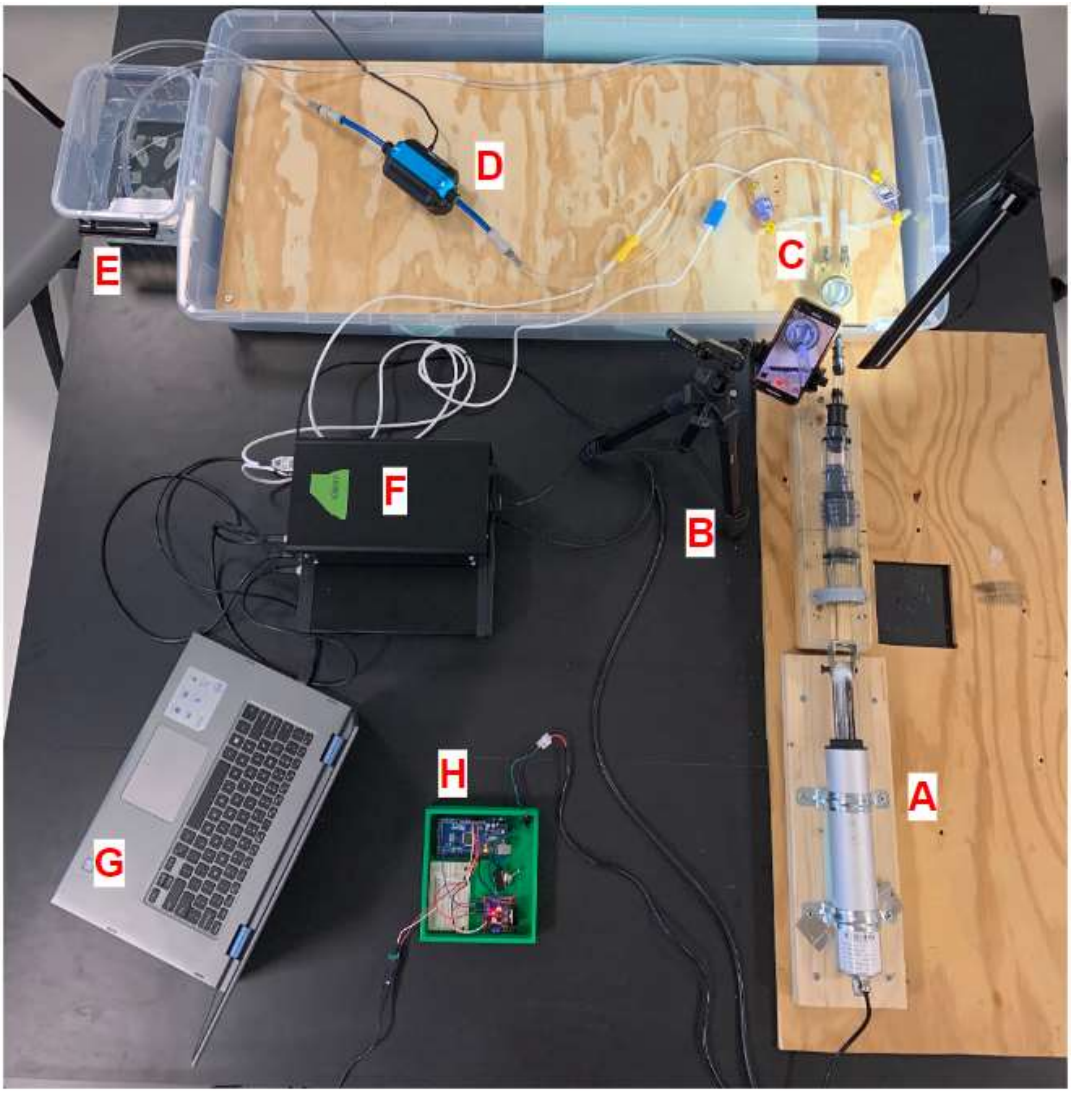

Figure 17: The entire mock cardiovascular flow-loop. A- CEDU. B- tripod used with mobile device to collect video. C- EXCOR with pressure transducers. D- flowmeter. E- reservoir. F- Vivitro I/O Module. G- laptop. H- Actuator driver

2.2 Planned Experiments

Due to the limitations of the CEDU, experiments were completed based off of what we could achieve with the current equipment. The CEDU performs optimally at a heart rate of 90 bpm, which is comparable to that of a pediatric HF patient. The CEDU code was

designed to create heart beats with an equal ratio of systole and diastole, as well as systole= ⅓ diastole. Under these two parameters, the resistance of the cardiovascular flow loop was also altered. Tubing of size 1/2'' was used for the R0 case. The case R1 introduced increased resistance to the flow loop by using 5/16'' tubing. Two more cases were created, R2 and R3, where the resistance was increased by decreasing the tubing size (5/16'') at a singular point in the flow loop. The inlet diameter was also reduced, creating the $R_{in}2$ case. By varying both the systolic and diastolic ratio, as well as the resistance to blood flow, it was made possible to model a dynamic cardiovascular system that models clinically relevant situations. Two different heart rates, 120 bpm and 80 bpm, were also tested under two different conditions, R1 and R2.

Table 2: Planned experiments.

Planned Experiments			
Systole = Diastole			Systole = 1/3 Diastole
120 bpm	80 bpm	90 bpm	90 bpm
R1	R1	R0	R0
R2	R2	R1	R1
		R2	R2
		R3	R3
		$R_{in}2$	$R_{in}2$

Figure 18: The method of increasing resistance for R2.
Method of increasing resistance to R2

Figure 19: Method of increasing resistance for R3.
Method of increasing resistance to R3.

2.2.1 Experimental Procedure

Before running the final experiments, the mock cardiovascular flow loop had to be set up appropriately. The correct tubing was put into place, and it was ensured that there were no bubbles within the flow loop. If a resistance was being used, the clamp was also adjusted appropriately. Connection of the flowmeter to the computer was ensured. Then the CEDU was turned on for at least 2 minutes to ensure proper calibration of the flowmeter and pressure transducers. After the EXCOR had been running for this time, the CEDU was turned off before official trials were ran. A mobile device was then placed into proper position via a tripod, ready to take a video of the EXCOR membrane. The experimental procedure reads as follows:

1. Turn on CEDU
2. Start mobile device video

3. Start collecting flowmeter data
4. Start collecting pressure waveform data
5. After 45 seconds, stop mobile device video
6. After 1 minute, stop flowmeter data collection
7. Turn off CEDU

The video is started with a Bluetooth button that is connected to the mobile device. The flowmeter data is collected for 1 minute so that there is enough data for each trial to create an accurate average. The Vivitest software only collects one pressure waveform cycle per trial, which is about 10 seconds long. This is deemed sufficient as the pressure waveforms do not vary significantly within each individual experiment.

2.2.2 Video Recording

The EXCOR membrane was recorded for each experiment using an iPhone XS and a mobile device tripod. The videos were taken in real-time at a frame rate of 30 frames/second. The video was taken for a total length of 45 seconds. The video was exported from the mobile device to a computer, and edited with the free software Wondershare Filmora. Here, the video was cropped to an approximately 10 second clip and the video speed was reduced to 0.25, resulting in a 40 second slow motion video. The background of the video was also removed using this software, so that only the EXCOR membrane appeared in the video, shown in Figure 21. This video was then provided to the custom EMMA algorithm that analyzed the membrane motion.

2.3 EMMA

An in-house designed algorithm, EMMA, was used to analyze the membrane motion of the EXCOR for each experiment. This algorithm was initially developed by a BME senior design team in 2022.[32] EMMA is based off the core principle that the EXCOR is functioning properly when the membrane fully extends and retracts with each beat. The software uses computer vision to track the membrane movement, and detect whether this phenomenon

occurs or not.[32,33] This software was built in Python, and uses a feature extraction process called Histogram of Oriented Gradients (HOG) to quantify the membrane smoothness. HOG is commonly used for computer vision applications, such as Face Recognition and Traffic Sign Detection.[34–36] HOG identifies and compares the intensity of each pixel to the other pixels surrounding it, creating a gradient.[36] If the EXCOR membrane is not smooth, then a larger gradient is detected. A smooth membrane results in a much smaller gradient. This feature extraction process is applied to each EXCOR video frame-by-frame to identify if the membrane is completely smooth between beats. Each EXCOR video has been cropped, so that only the EXCOR membrane appears in the video. EMMA functions by converting a .mov file to individual PNG files with resized frames. HOG is applied to each frame, which creates a separate HOG image that shows the gradients. The frames are then converted back into a video, so that the gradients can be seen changing in real-time. While watching the HOG video, each time the EXCOR completes a heartbeat, the membrane analysis should ideally be completely blank (smooth, i.e., no gradients) during full extension and retraction. If there are still white pixels at this moment, then the membrane is not fully extending or retracting. The pixels allow for the identification of the specific area of the membrane that may be wrinkly. However, it is not feasible to individually watch every video to determine these points. An algorithm takes an array of the magnitudes of each gradient value at each pixel in an image frame and averages them. This creates a numerical representation of membrane smoothness for each frame. It is important to note that any noise, such as glare, is filtered out of the signal so it does not significantly affect the representation. This gradient is inversely proportional to percent smoothness of the EXCOR membrane – in other words, a smooth membrane will have a very low value (ideally 0) and a deformed or wrinkled membrane will have a high value (i.e., low smoothness). The smoothness is plotted with respect to time to represent the frame-by-frame evolution of membrane smoothness. The smooth points of the membrane are represented by the plot maximums and are identified with a peak detector. The prominence of this peak represents how smooth the membrane is. The time between detected peaks is also plotted in the same time frame. This is an important criterion that allows for identification of a consistent functional EXCOR heart rate.

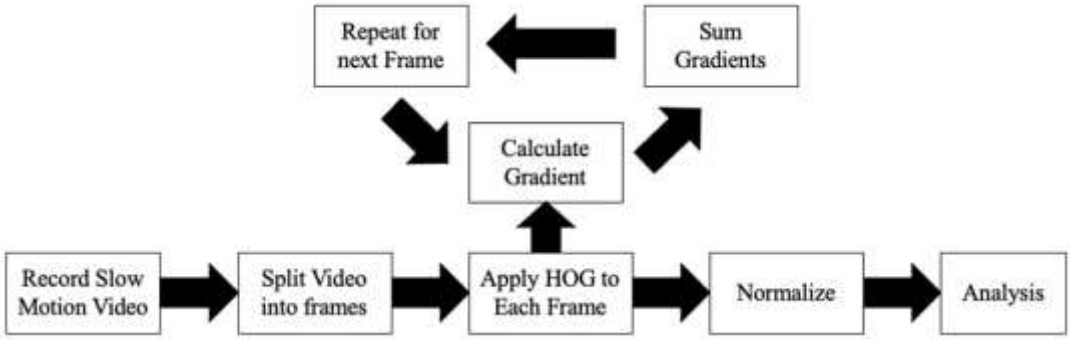

Figure 20: A flowchart showing the process of applying the HOG software during EMMA.

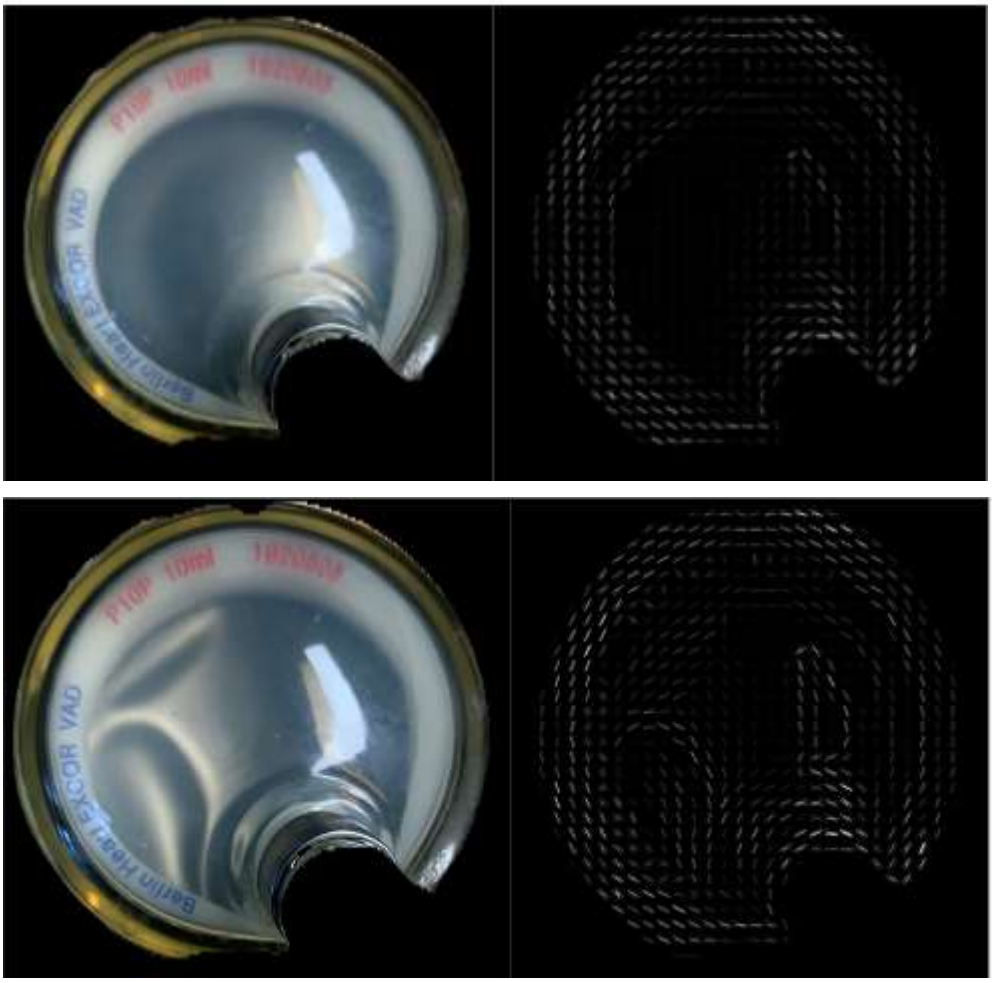

Figure 21: Side-by-side comparison of the normal video to the HOG video. The larger the gradient of pixel intensity, the more white the pixels display in the HOG video.

2.4 Data Analysis

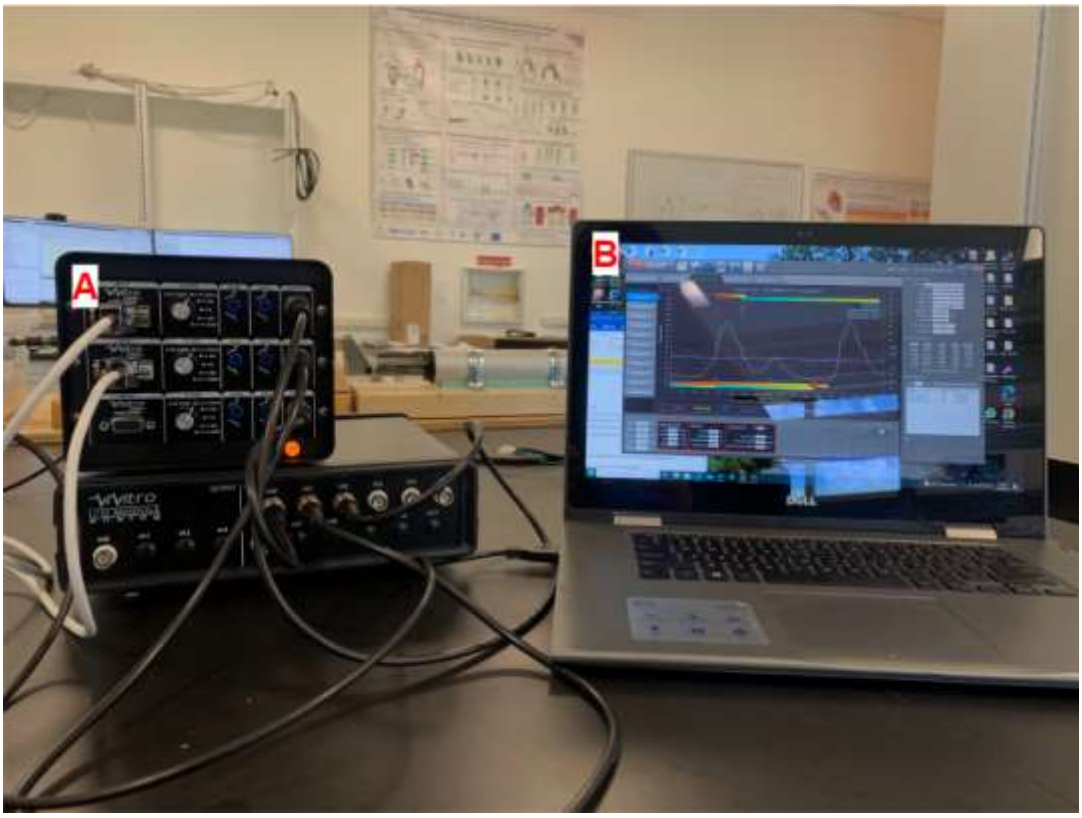

Figure 22: A- The Vivitro I/O Module used to collect the pressure sensor data. B- The Vivitro Vivitest Software displaying pressure waveforms.

In-house code was also developed in Python to analyze the flowmeter and pressure data collected from each experiment. Both the flow rates and pressure waveforms were collected as .csv files. The flow rate file was read into Python, and NumPy was used to calculate the average flow rate of all three trials for each experiment. Since the flow rate is pulsatile, it is also plotted with respect to the number of samples. The sampling rate of the flowmeter is 17 samples/second. The pressure waveforms were collected with the Vivitro software Vivitest. This software collects the pressure signal for 10 cardiac cycles for each trial. The relevant sections of the pressure .csv file were read into Python. The outlet and inlet pressures of the EXCOR were then plotted. It was determined that calculating the maximum, minimum, and average pressures was misleading and did not accurately reflect

the behavior of the EXCOR. The sampling rate of the pressure transducers is 293 samples/second.

The flow rates and pressure waveforms were also plotted together on the same graph to show the correlation between the blood flow and pressures. In order to accurately reflect the EXCOR behavior, the signals were both resampled so that they would align correctly in the time-domain. Furthermore, the average flow rate and pressure drop were used to determine the resistance of the flow-loop for each experiment. The area under the curve of the flow rate is also taken to calculate the total flow for each trial.

Chapter 3
Results

This chapter will describe the results obtained from EMMA and the mock cardiovascular flow loop. The results for the Systole = Diastole cases, Systole = 1/3 Diastole cases, varying heart rates, and clinical videos are described in detail.

3.1 Systole = Diastole

3.1.1 Flow Rates and Pressure Waveforms

The total flow is calculated by taking the area under the curve of the temporal flow rate for each experiment and is shown in Figure 23. As the resistance is increased, the total flow decreases, which is expected since the pressure is increased. The total flow for R0 is greater than the rest of the experiments because it experiences the least resistance.

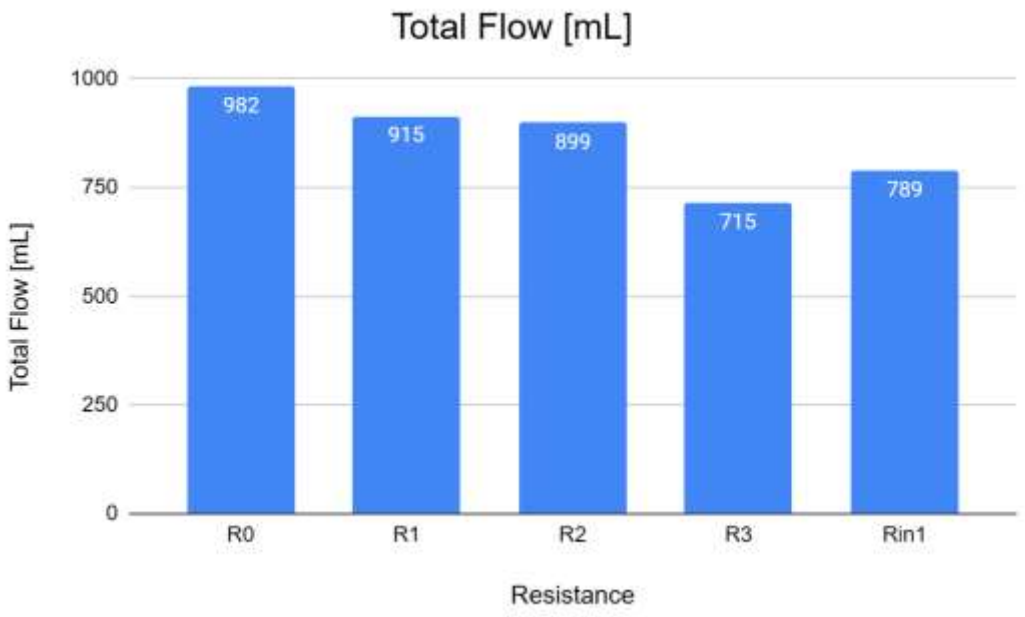

Figure 23: Showing the total flow for each case. The flow decreases as the resistance is increased.

The pressure waveforms below are plotted for each experiment and compared to the R0 case as a baseline. The label e indicates the peak inlet pressure, which occurs at the beginning of diastole (i.e., pump filling). The label f indicates the peak of the outlet pressure at the start of systole (i.e., pump emptying). The inlet pressures drop to 0 (sometimes it drops below 0) during pump systole, since the pump is in the emptying phase, and there is a unidirectional valve preventing backflow through the inlet during this phase. As expected, the EXCOR outlet pressures were higher for the increased resistance cases in Figure 24 (A and B). The negative pressures could be the result of extra suction provided by the motion of the membrane as the EXCOR fills, or due to possible calibration issues with the pressure transducer (which were calibrated by the manufacturer using specialized equipment).

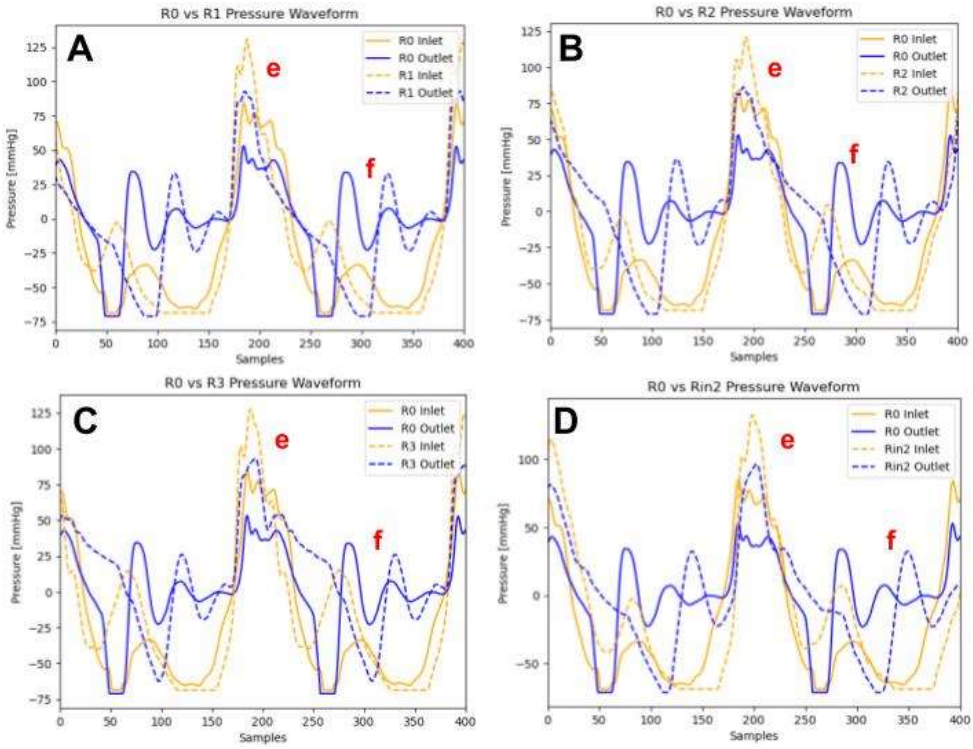

Figure 24: Showing the pressure waveforms for each experiment with respect to the R0 case. It is observed that all the pressures are higher than the R0 case.

The flow rates are also plotted with the pressure waveforms below for each experiment. As expected, the flow rate increases while the outlet pressure peaks during systole. This pattern is consistent across all five experiments performed. However, differences in the flow rates between each experiment are observed. The peak in flow rate corresponds to the second peak in the outlet pressure. At this point in time, since the outlet pressure is greater than the inlet pressure, the EXCOR membrane is extended, pushing the fluid out of the chamber and into the flow loop. The flow rate decreases as the inlet pressure peaks, which represents the filling of the EXCOR device, and a retracted membrane.

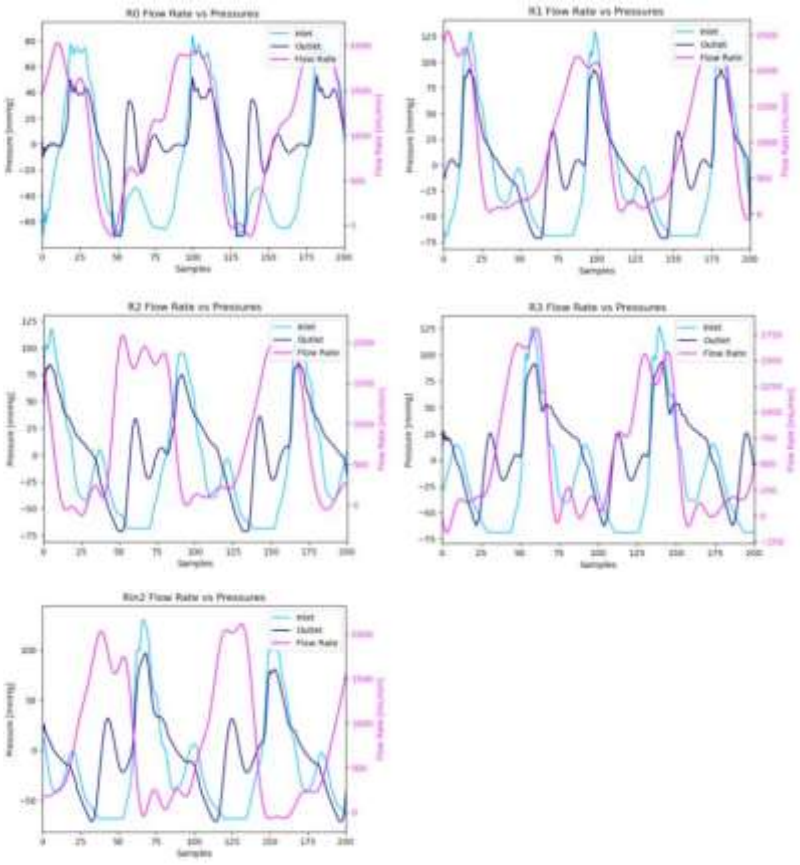

Figure 25: The flow rate curve is overlayed with the pressure waveforms for each case to show how the flow rate increases when the outlet pressure during systole peaks.

3.1.2 Membrane Motion Analysis

For Figures 26-30 below, the EXCOR membrane at peak A should be fully retracted due to complete filling during diastole. The membrane at peak B should be fully extended due to completion of systole. This is indicative of a properly functioning EXCOR device, which is demonstrated during the R0 case. However, due to the different parameters introduced, this does not occur for each experiment. The green rectangle represents diastole, and the blue rectangle represents systole.

For R0, the EXCOR membrane fully extends and retracts for almost every cardiac cycle, representing complete filling and emptying. This is shown in Figure 26 below, with three peaks representing one cardiac cycle. The first peak occurs at the beginning of diastole, the second peak occurs at the beginning of systole, and the third peak signifies the beginning of diastole of the following cycle. The dip between each peak represents the mid-way point between diastole and systole because the membrane is considered "wrinkled" and generates the lowest smoothness value from the HOG algorithm. Additionally, the time between peaks (TBP) demonstrates how the EXCOR is performing properly. The slight triangle pattern seen in the R0 case indicates that diastole is taking longer than systole. For the R1 case, the EXCOR membrane is not fully extending, as can be seen in Figure 27. EMMA is picking up the smoothness of the membrane while it is retracted; however, the smaller peaks around 40% smoothness, shown by point B, indicate that the membrane is not fully extending during systole. This pattern is consistent throughout the experiment. The TBP is fairly consistent as well, but displays the time between diastolic peaks because the systolic peak is not smooth enough to be recognized. For the R2 case, the EXCOR membrane is not completely extending during systole as well. However, some of the systolic beats are classified as smooth enough to be a peak, and are picked up by EMMA. This is characterized by point B, showing the point that is classified as a smooth point at around 40%-50% smoothness. However, because EMMA does not recognize every systolic beat as a smooth peak, it causes the TBP to be inconsistent. For R3, EMMA does not recognize any systolic peaks. The TBP values represent the time between diastolic peak, which stays constant around 3 seconds. This is due to the EXCOR membrane not completely smoothing during systole. For Rin2, the EXCOR membrane does not fully extend during systole. EMMA only recognizes a smooth peak during diastole, shown by point A. The patterns for R3 and Rin2 are very

similar due to the imposed resistance on the system.

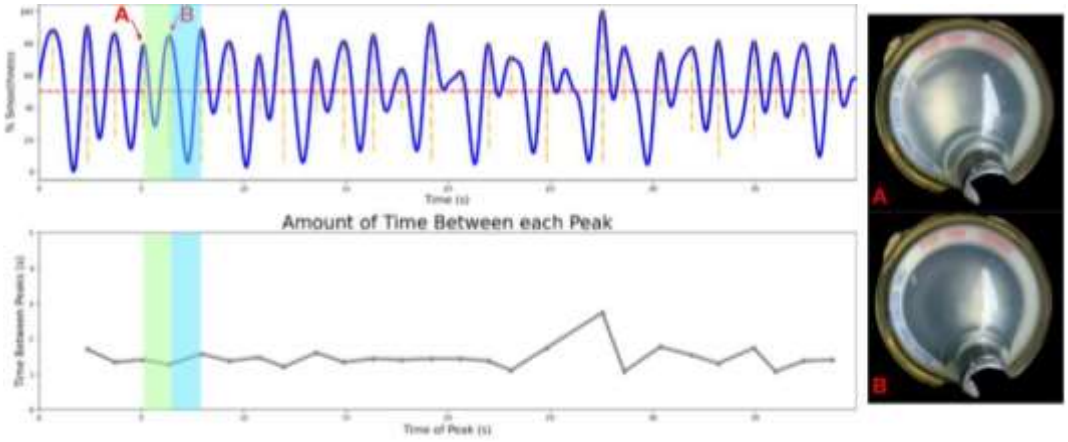

Figure 26: EMMA results for the R0 case. Both the diastolic and systolic peak are recognized.

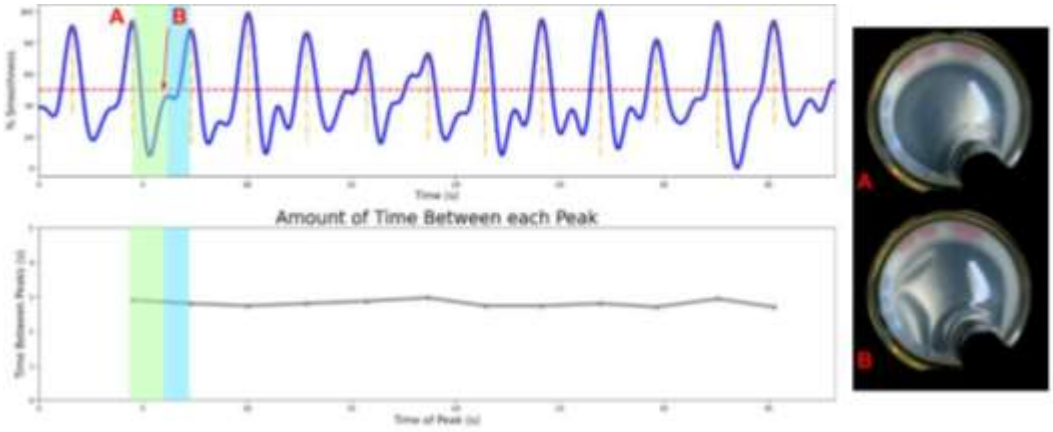

Figure 27: The EMMA results for the R1 case. Only the diastolic peak is recognized.

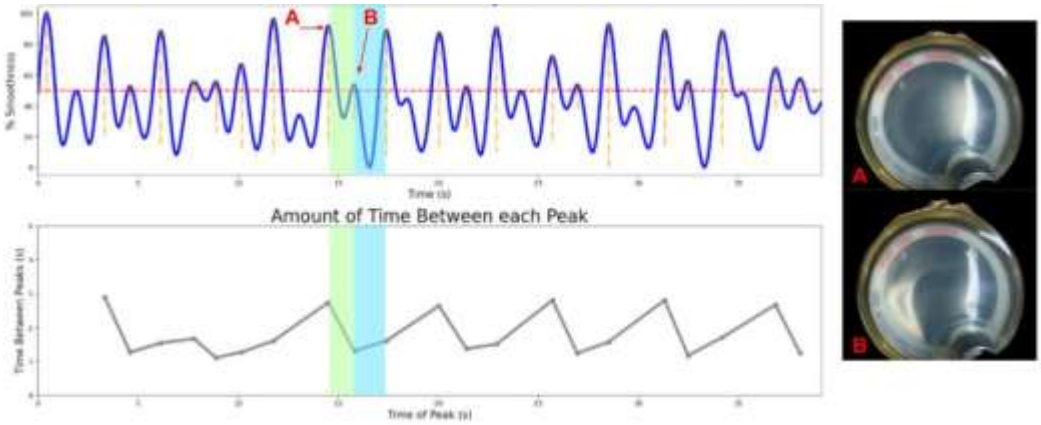

Figure 28: The EMMA results for the R2 case. Only the diastolic peak is recognized.

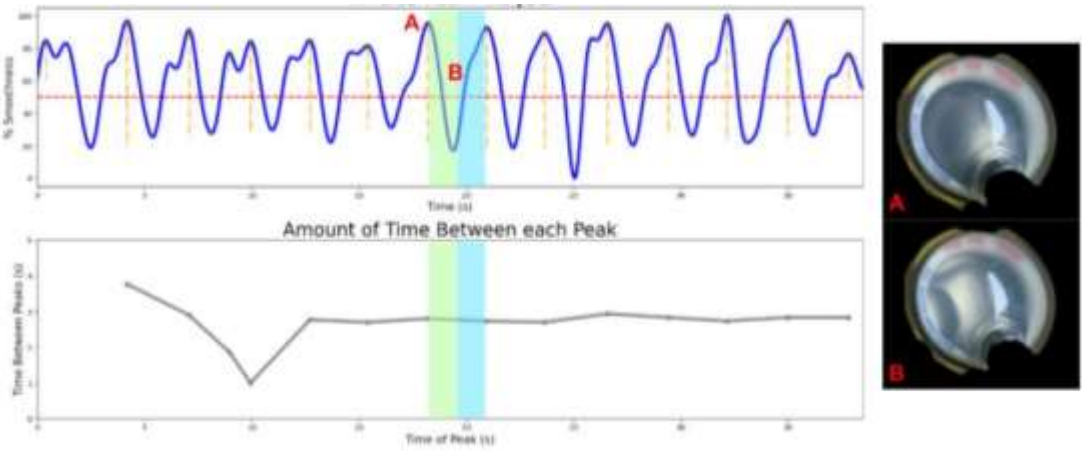

Figure 29: The EMMA results for the R3 case. Only the diastolic peak is recognized.

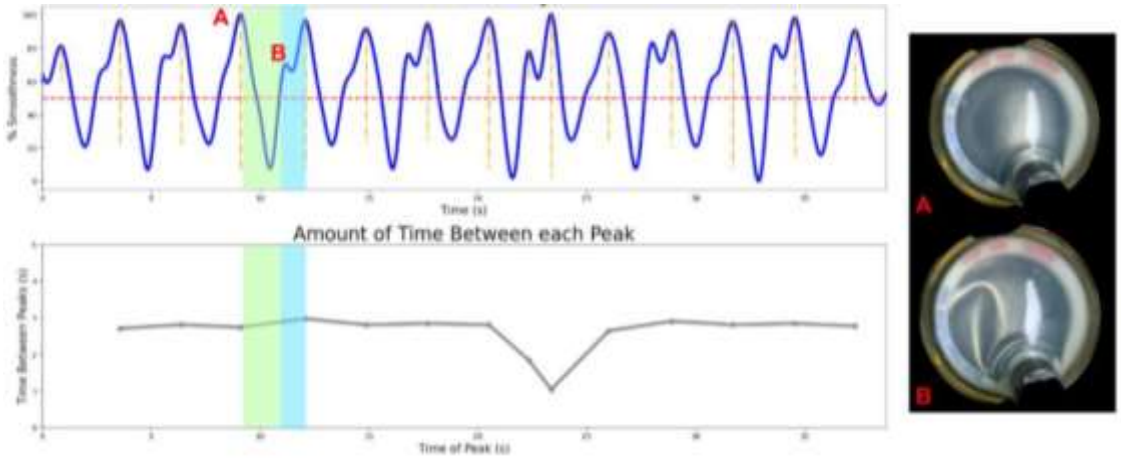

Figure 30: The EMMA results for the R2 case. Only the diastolic peak is recognized.

3.2 Systole = 1/3 Diastole

3.2.1 Flow Rates and Pressure Waveforms

The total flow for each experiment is shown below in Figure 31. As expected, the largest flow occurs for R0, while the least flow occurs for R3.

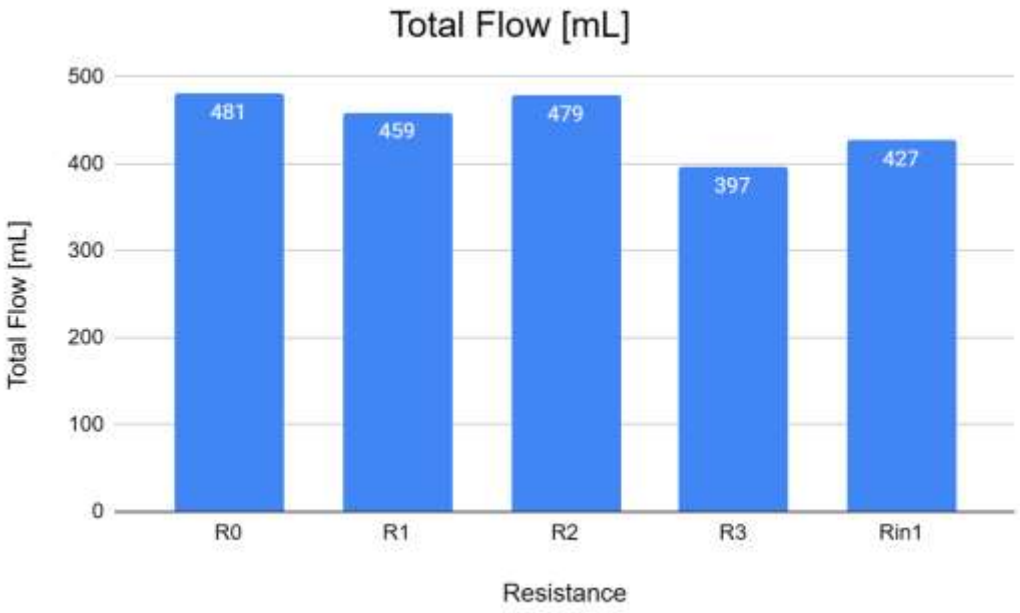

Figure 31: The total flow [mL] for the systole = 1/3 diastole cases. The total flow decreases as the resistance increases.

The inlet and outlet pressures of each experiment are compared to R0 in Figure 32. Label e represents the beginning of diastole (i.e., filling). Label f represents the beginning of systole (i.e., emptying). As expected, the inlet and outlet pressures increase as the resistance is increased. Similar to the systole = diastole cases, the inlet pressures drop to 0 (sometimes it drops below 0) during pump systole due to emptying and unidirectional valves preventing backflow. The negative pressures could be the result of extra suction provided by the motion of the membrane as the EXCOR fills, or due to possible calibration issues with the pressure transducer (which were calibrated by the manufacturer using specialized equipment).

However, the overall pressures are decreased when compared to the systole = diastole cases. This is due to the longer diastole, which requires less pressure to suction the fluid into the chamber during diastole.

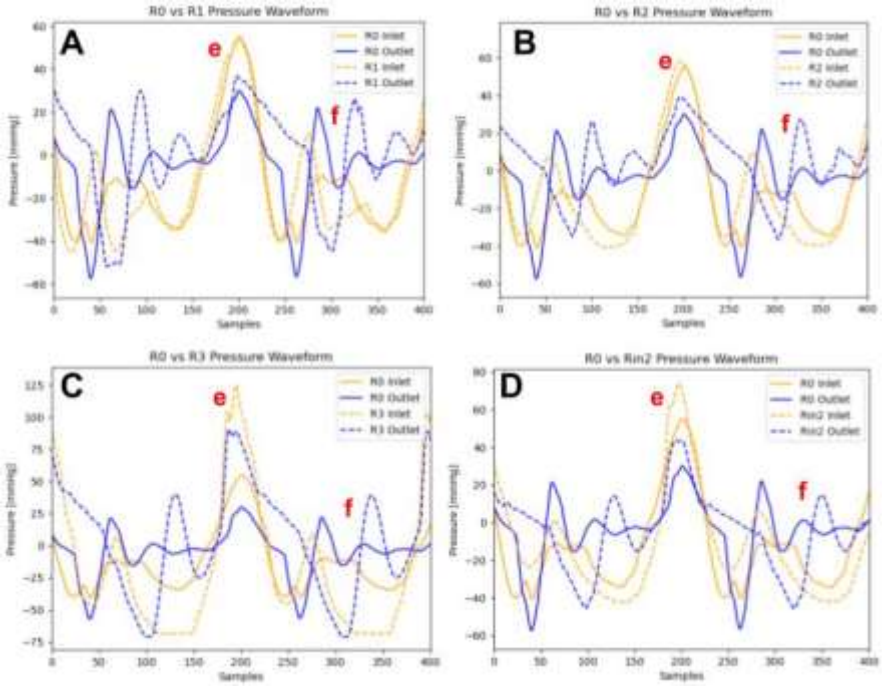

Figure 32: The pressure waveforms for each case are plotted with respect to the R0 case.

The flow rates for each experiment are plotted with respect to the pressure waveforms below, Figure 33. The flow rate increases at the same time as systole occurs, which is when the outlet pressure is greater than the inlet pressure. The flowrates are also lower than those of the systole=diastole cases, which corresponds to the decreased total flow as well.

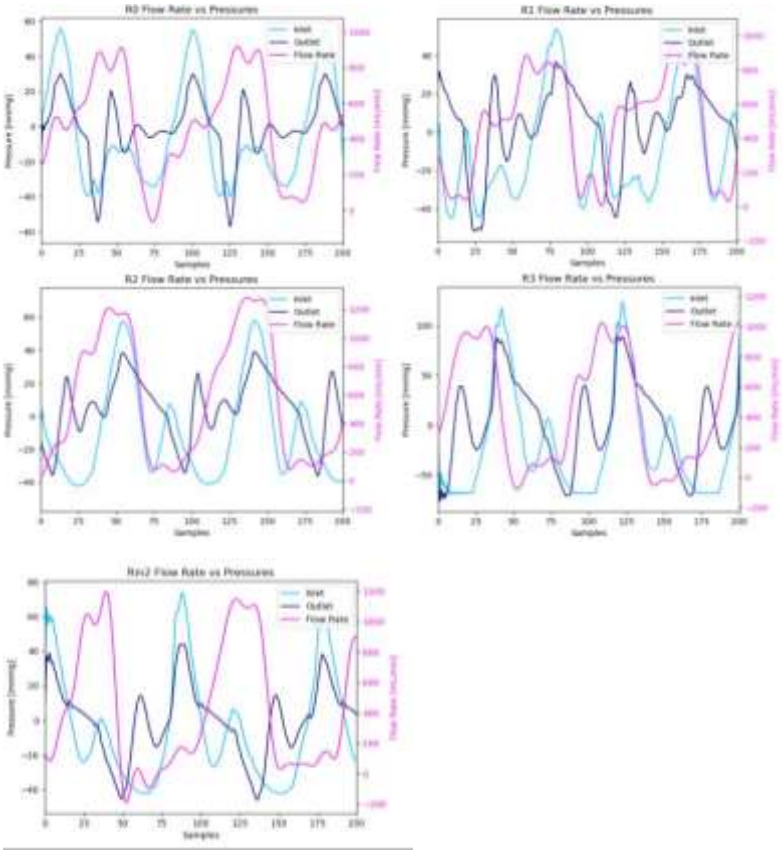

Figure 33: The flow rates of each experiment plotted with respect to the pressure waveforms. This shows how the flow rate increases as the outlet pressure increases during systole.
:

3.2.2 Motion Membrane Analysis

For R0, the EXCOR membrane did not fully retract during diastole but fully extended during systole. This is shown by peak A and B in Figure 34. Peak B represents the complete extension of the membrane during diastole. As expected, systole is much shorter than diastole, which is demonstrated by the green and blue boxes. The TBP shows the time between systolic peaks, which stays constant around 3 seconds. For R1, EMMA identifies both the diastolic peak and systolic peak, even though neither of the beats are completely smooth. Because both peaks are identified, the TBP is characterized a triangle pattern. This signifies that it takes two seconds for diastole to be completed, and one second for systole to

be completed. While the initial settings of the CEDU set systole = 1/3 diastole, the resistance introduced in the flow loop may have impeded EXCOR membrane function, altering the systolic/diastolic ratio. While EMMA successfully identified both the diastolic and systolic peaks as smooth for this R1 case, the results are slightly misleading since the membrane does not fully extend and retract, shown in Figure 35 (A and B). For R2, the diastolic peaks are recognized and the systolic peaks are not. Since the membrane does not fully extend during systole, EMMA does not identify the systolic peak, shown by point B. However, the time between the diastolic peaks is fairly constant, and systole is much shorter than diastole. R3 is very similar to R2; EMMA does not identify the membrane extension during systole because it does not fully smooth out, shown by point B. However, complete filling occurs during diastole because the membrane is completely smooth in retraction, shown by point A. The time between diastolic peaks is also still consistent, and it is seen that systole is much shorter than diastole. These cases are very similar to each other due to the increased resistance introduced into the flow loops for these cases. For $R_{in}1$, the EXCOR does not completely extend during systole. The membrane slightly extends, which is shown by the point B. Point A shows the complete retraction during diastole. The TBP also stays fairly consistent.

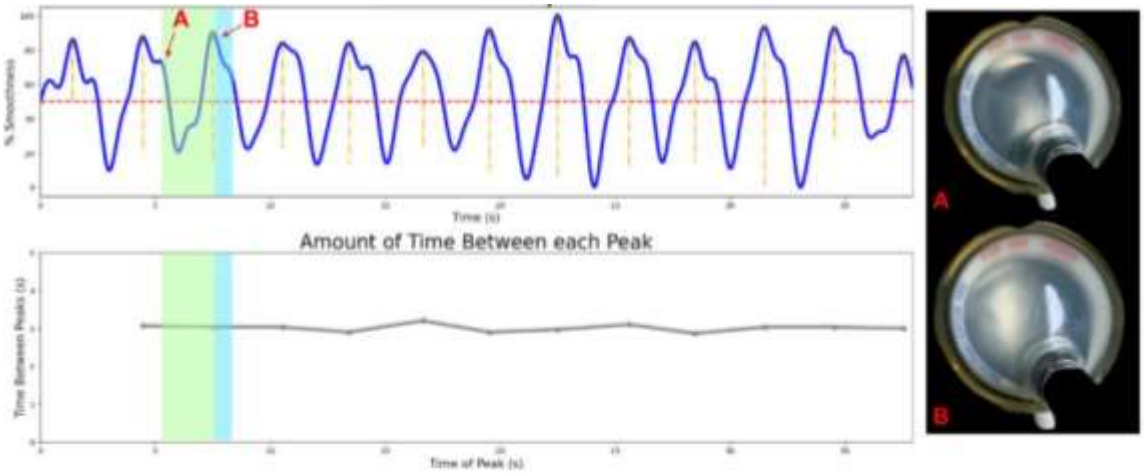

Figure 34: The EMMA results for the R0 case (systole = 1/3 diastole). Only the systolic peak is recognized.

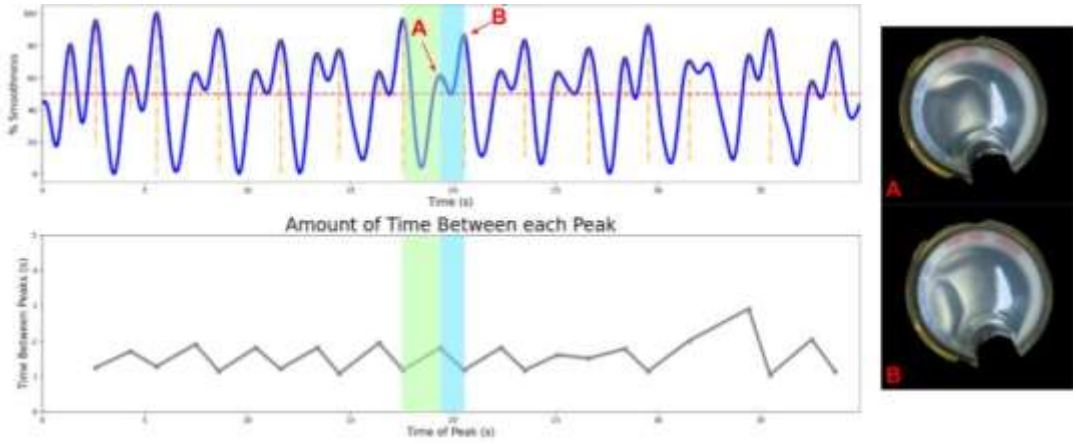

Figure 35: The EMMA results for the R1 case (systole = 1/3 diastole). Both peaks are recognized, but the systolic peak is more prominent.

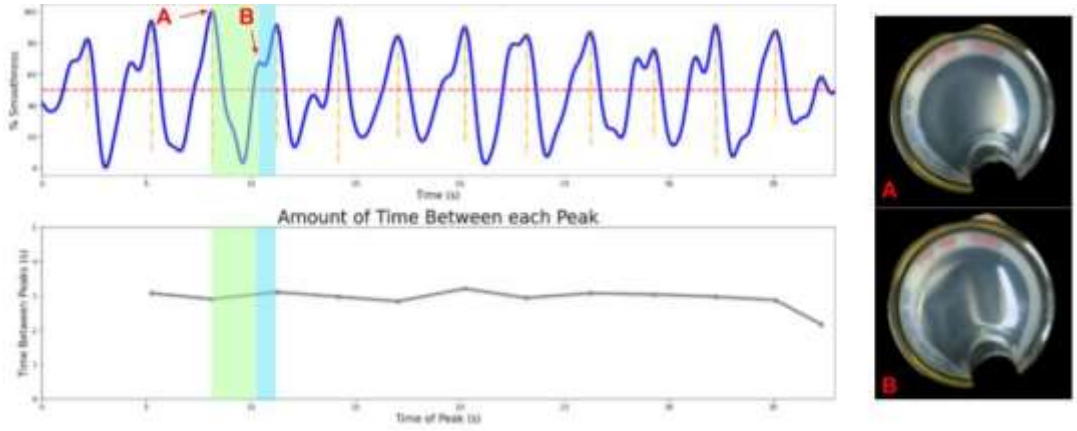

Figure 36: The EMMA results for the R2 case (systole = 1/3 diastole). Only the diastolic peak is recognized.

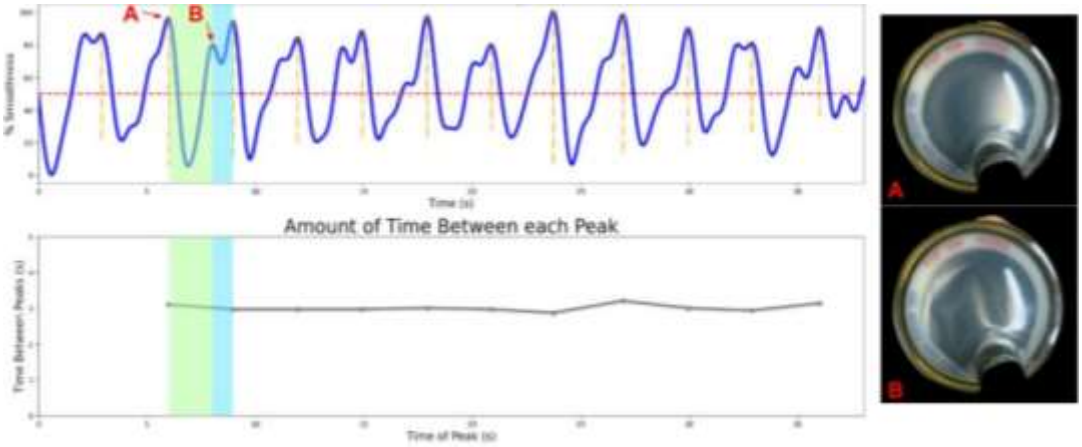

Figure 37: The EMMA results for the R3 case (systole = 1/3 diastole). Only the diastolic peak is recognized.

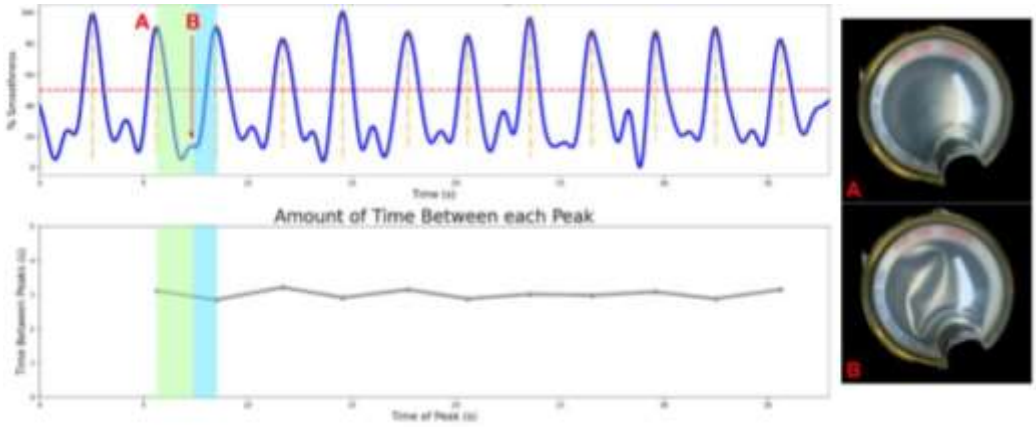

Figure 38: Th EMMA results for the $R_{in}2$ case (systole = 1/3 diastole). Only the diastolic peak is recognized.

3.3 Characterizing EXCOR Behavior

The purpose of this project is to develop a system of identifying when the EXCOR membrane motion under different hemodynamic conditions so that clinicians can have a better understanding of when the EXCOR is malfunctioning. Table 3 below summarizes how the EXCOR membrane reacted to the different hemodynamic conditions introduced in each case based off the results from EMMA.

Table 3: The characteristics of the EXCOR membrane motion for each case.

Membrane Motion Characterization				
	Systole = Diastole		**Systole = ⅓ Diastole**	
	% Smoothness	**TBP**	**% Smoothness**	**TBP**
R0	Both diastolic and systolic peaks	Inconsistent triangular pattern	Wide systolic peak	Constant
R1	Systolic peak only. Small diastolic peak below threshold.	Constant	Lower diastolic peak, full systolic peak	Triangular pattern
R2	Diastolic peaks with small systolic peak	Triangular pattern	Diastolic peak, small systolic fluctuations	Constant

	below threshold			
R3	Wide systolic peaks	Constant	Wide diastolic peak, systolic fluctuations	Constant
Rin2	Slight wide diastolic peak with small systolic peak below threshold	Constant	Diastolic peak with low systolic peak below threshold	Constant

3.4 Calculating Resistances

The experimental resistances were also calculated for each experiment, shown in Table 5. The equation used to calculate this value is shown below. The total flow was divided into the pressure drop for each experiment to yield the calculated resistance. As expected, the calculated resistance increases for the respective experimental cases. It is interesting to note that these resistances are very close to physiological resistance values calculated for a pediatric patient in a clinical setting. The values used to create an estimation of pediatric vascular resistance is shown in Table 4. The resistances of each experiment with respect to the systolic and diastolic ratios are very similar, except for the R3 case. When systole = 1/3 diastole, the resistance is much higher, around 14 mmHg*s/mL. This is because the EXCOR membrane barely extended during systole, reducing the total flow significantly.

$R_{vascular} = V/I$ V= pressure drop [mmHg]; I = flow rate [mL/s]

Table 4: Estimation of pediatric vascular resistance.

Estimation of Pediatric Vascular Resistance			
	V [mmHg]	I [mL/s]	R [mmHg*s/mL]
Lower Range	70	16.6	4.2
Upper Range	90	16.6	5.42

Table 5: Experimental resistance values.

Experimental Resistance Values
Systole = Diastole

	R0	R1	R2	R3	$R_{in}2$
Resistance [mmHg*s/ml]	3.245	5.972	6.375	9.0819	6.061
Systole = ⅓ Diastole					
	R0	R1	R2	R3	$R_{in}2$
Resistance [mmHg*s/ml]	3.663	5.385	6.086	14.934	6.114

3.5 Varying Heart Rate

3.5.1 Flow Rates and Pressure Waveforms

The total flow for both the 120-bpm case and 80 bpm case is shown below. The total flow for 120 bpm is much less than that of 80 bpm because the EXCOR membrane did not fully extend and retract during the cardiac cycle. The total flow for 80 bpm mimic closely that of the systole = diastole cases; however, it is slightly lower due to the slower heart rate.

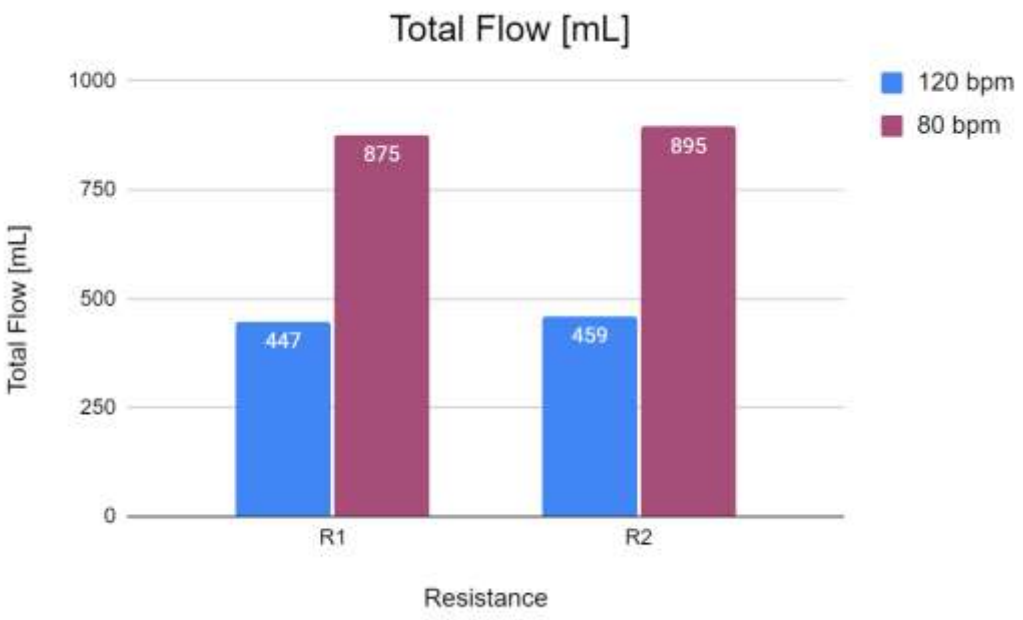

Figure 39: The total flow for both the 80 bpm and 120 bpm cases.

The pressure waveforms for 120 bpm and 80 bpm are shown below. As expected, when the resistance is increased, the inlet and outlet pressures decrease for both 120 bpm and 80 bpm. The pressures for 120 bpm are lower than that of 80 bpm due to pressure transducer placement; however, the trends in pressure with respect to each heart rate is of more importance than comparing the pressure values of each heart rate to each other.

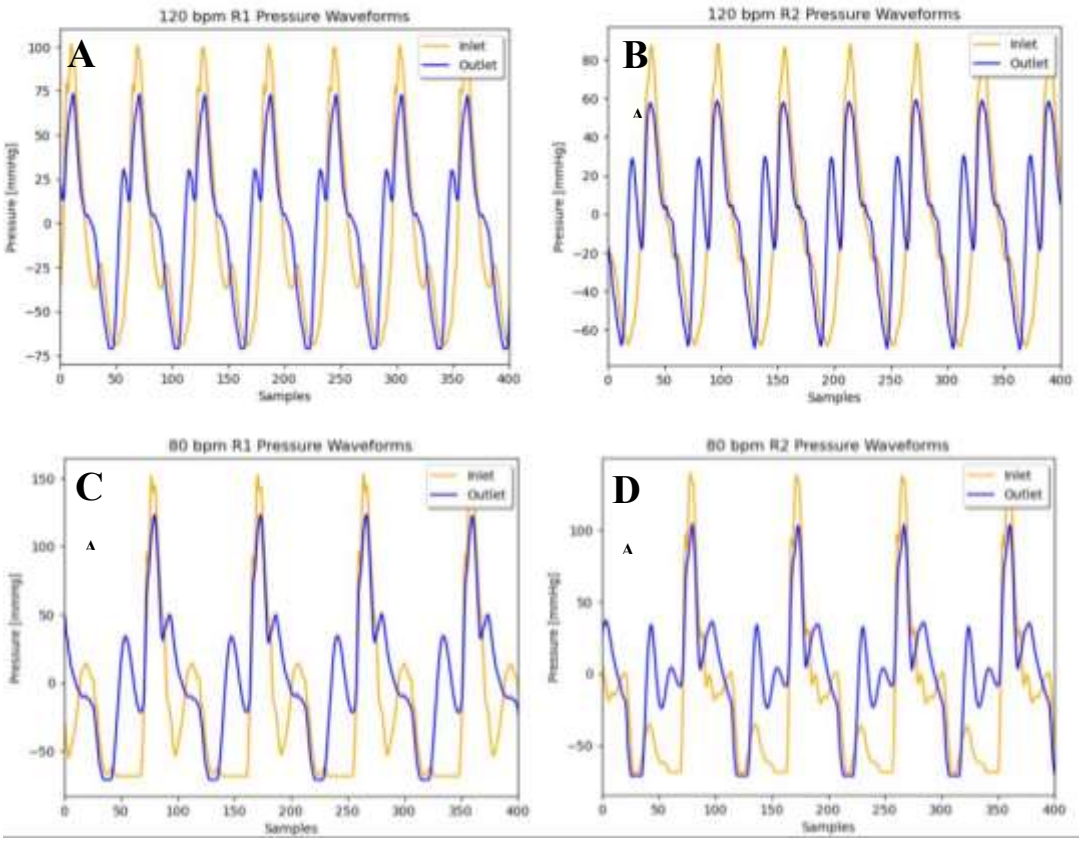

Figure 40: The pressure waveforms for the 120 bpm (A-B) and 80 bpm (C-D) cases.

The flow rates are plotted with respect to the pressure waverforms, showing that the flow increases during systole. The flow rate for 80 bpm is greater than the flow rate for 120 bpm, but they do not vary significantly between the R1 and R2 cases.

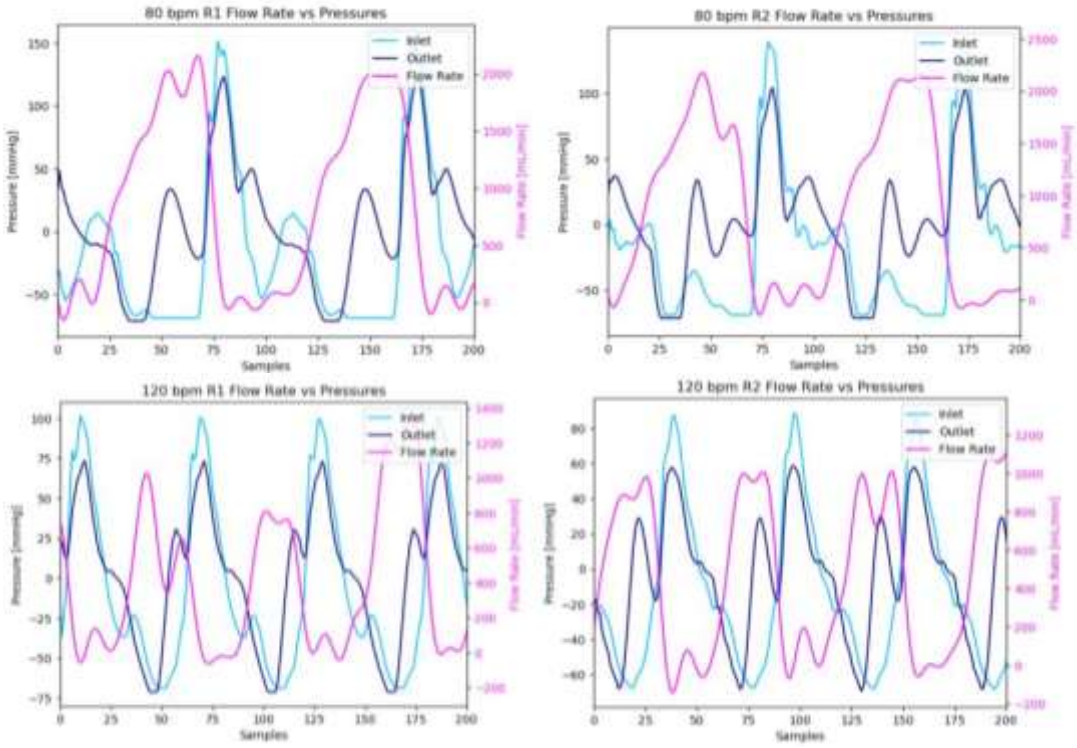

Figure 41: The flow rates plotted with respect to the pressure waveforms for each case.

3.5.2 Membrane Motion Analysis

When the CEDU settings are adjusted to reach 120 bpm, the EXCOR membrane does not fully extend during systole. This is shown in the EMMA analysis as peak B in Figure 42 and 43. Only the diastolic peak was identified as a smooth point (peak A). Varying the resistance from R1 to R2 did not affect this outcome, as it is seen in Figure 42 (B) and Figure 43 (B), the membrane looks exactly the same. The time between the diastolic peaks is fairly consistent for both cases as well.

The EXCOR membrane fully extends and retracts at 80 bpm for both the R1 and R2 cases. EMMA identifies both the diastolic and systolic peaks (peak A and peak B). The TBP fairly constant for the R1 case, around 1.5 seconds, because the diastolic/systolic ratio is set to be equal by the CEDU. For the R2 case, the TBP shows that it takes approximately 1

second for diastole to be completed and 2 seconds for systole to be completed.

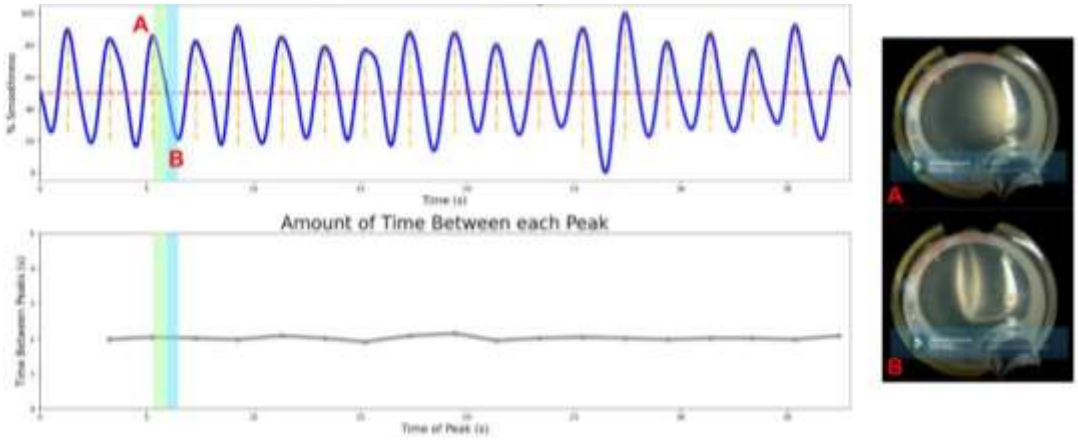

Figure 42: The EMMA results for the R1 case for 120 bpm. Only the diastolic peak is recognized

.

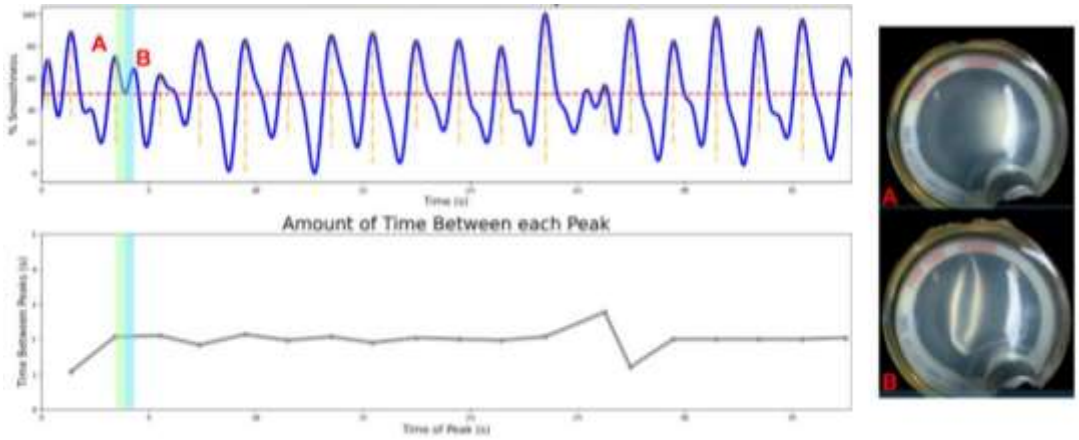

Figure 43: The EMMA results for the R2 case for 120 bpm. Only the diastolic peak is recognized.

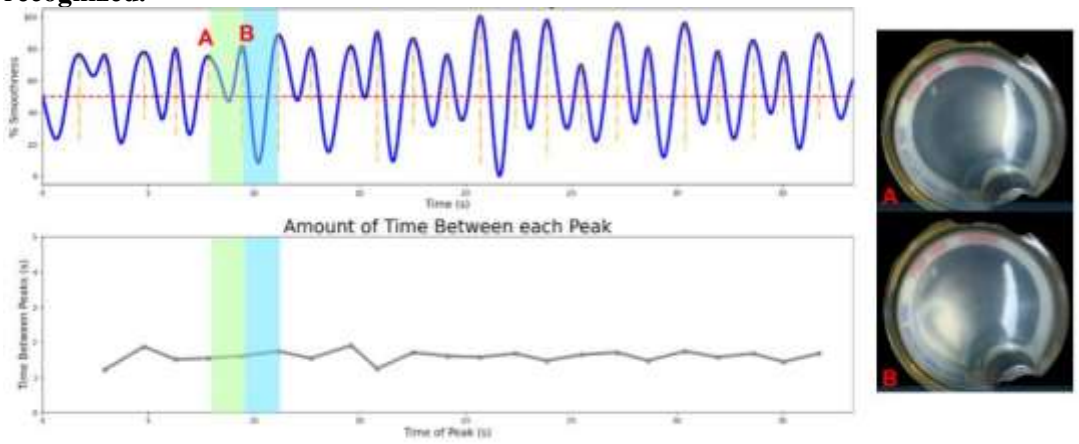

Figure 44: The EMMA results for the R1 case for 80 bpm. Both the diastolic and systolic peaks are recognized.

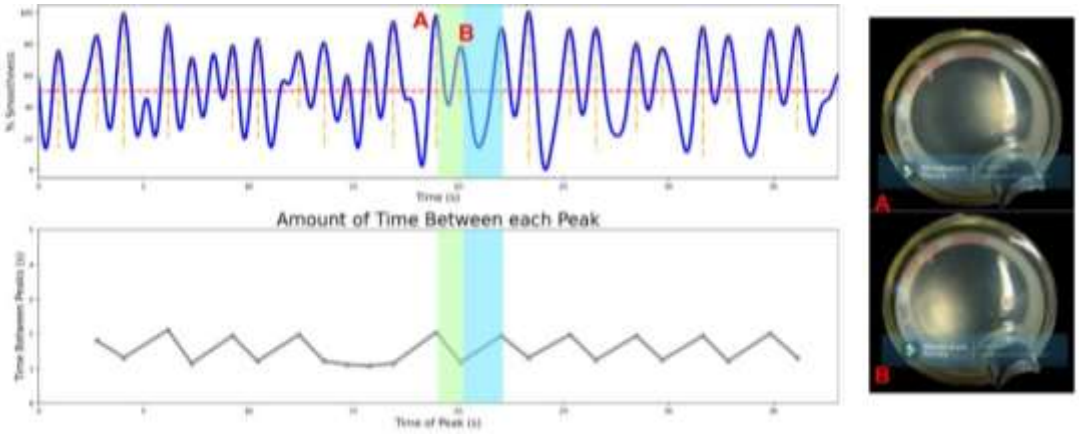

Figure 45: The EMMA results for the R2 case for 80 bpm. Both the diastolic and systolic peaks are recognized.

3.6 Clinical Data

Clinical data from our clinical collaborator Dr. Aditya Badheka (Pediatric Critical Care, University of Iowa, Iowa City, IA, USA) was analyzed with EMMA. Three videos were obtained, each one recording a different type of EXCOR malfunction at a heart rate of 80-90 bpm. One video had a fully functioning EXCOR with complete filling and emptying, one had incomplete filling and complete emptying, and one had complete retraction and incomplete emptying. These videos were taken with a mobile device at a frame rate of 30 frames per second, the same as the videos collected in the experiments above. Figure 46 shows the EMMA analysis of the fully functioning EXCOR case. It is seen that EMMA does not recognize the systolic peak during emptying, even though the membrane is completely smooth. This may be due to the provided videos containing more noise than the videos taken in lab, along with blurring of the EXCOR device due to it being out of focus. It is hypothesized that EMMA would display more accurate and representative results if (i) the EXCOR is in focus and (ii) the signal processing filters in the algorithm were adjusted for these specific videos. Figure 47 shows the EMMA analysis of incomplete filling and complete emptying. As expected, the diastolic peak is not recognized during incomplete filling, but the systolic peak is. The EMMA analysis for complete filling and incomplete emptying is also as expected, with EMMA only recognizing the diastolic peak during filling.

Figure 49 and 50 displays the results from EMMA when tested on initial clinical data received in 2021 from Dr. Badheka. Point A represents adequate smoothing of the EXCOR during diastole, indicated by the high percent smoothness value. As diastole continues, the membrane deforms and "wrinkles", leading to a minimum smoothness value at point B. In Figure 49, systole occurs at point C, where the membrane is smooth again. The TBP oscillates between 2.5 seconds and 1.5 seconds, respective to diastole and systole. When the membrane does not adequately smooth, there is a large increase in TBP, ~4 seconds, confirming the absence of membrane smoothing, which can be seen qualitatively from the video frames. In Figure 50, the membrane forms an odd star shape during systole, rather than completely smooth.

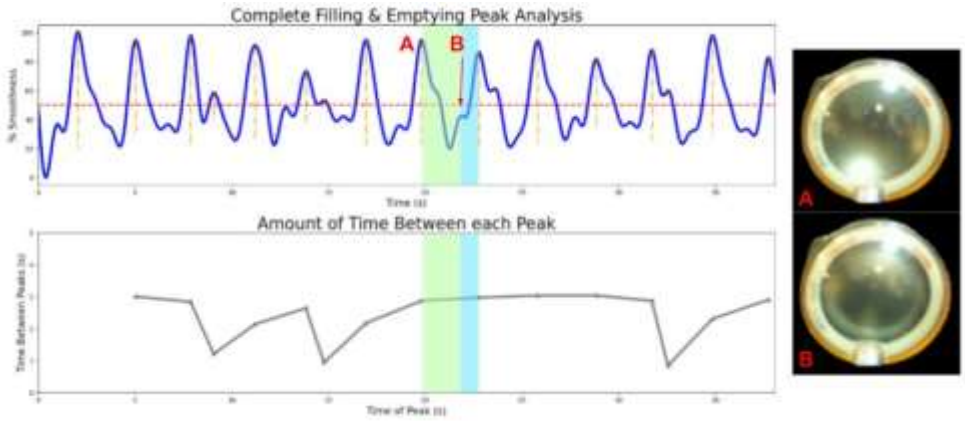

Figure 46: The EMMA analysis for the clinical video data of complete filling and emptying. Only the diastolic peak is recognized.

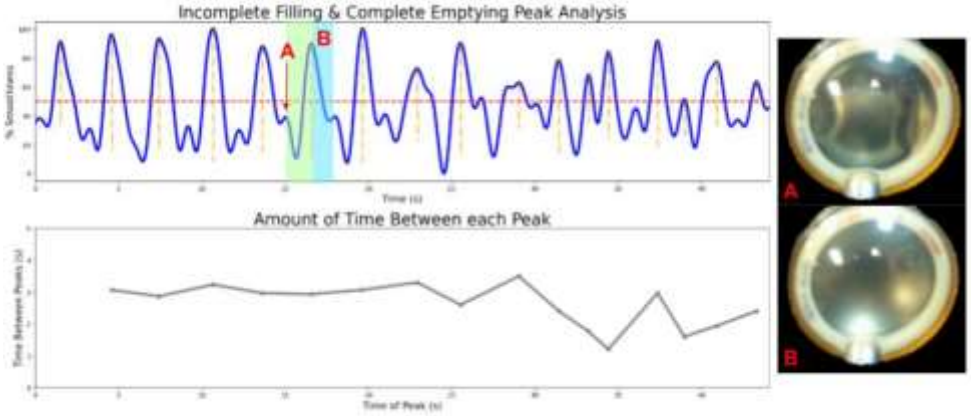

Figure 47: The EMMA results for incomplete filling, complete emptying. As expected, only the systolic peak is recognized.

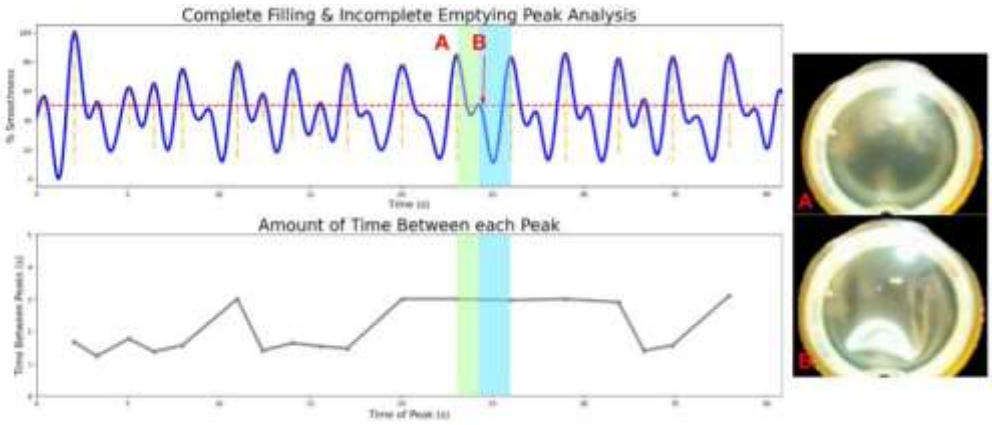

Figure 48: The EMMA results for complete filling, incomplete emptying. As expected, only the diastolic peak is recognized.

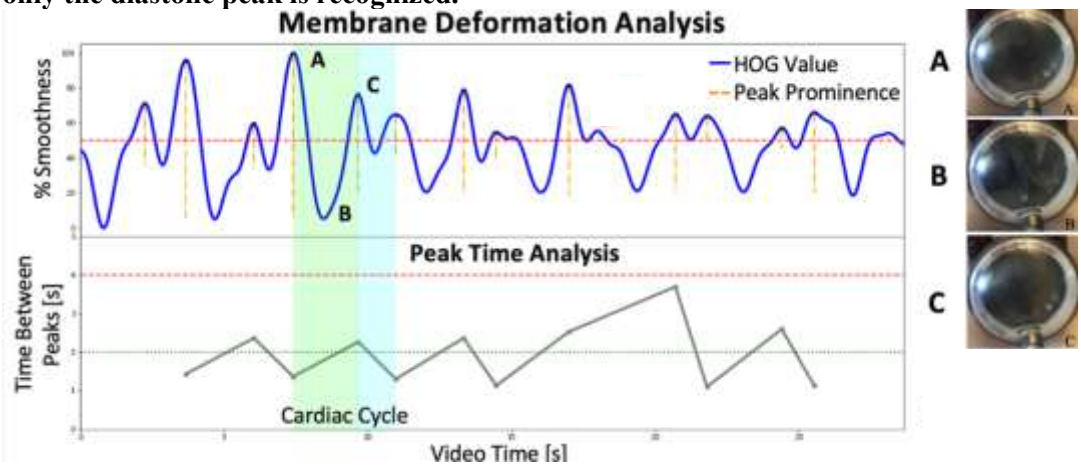

Figure 49: The EMMA results for initial clinical data used to test and train EMMA. Both the diastolic and systolic peaks are recognized.

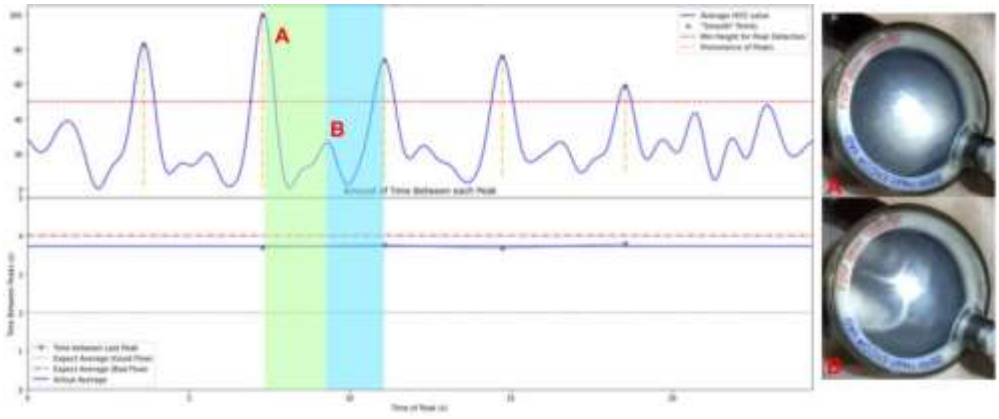

Figure 50: The EMMA results for initial clinical data used to test and train EMMA. Note that only the diastolic peak is recognized, and the membrane forms a wrinkly star-shape during systole.

Chapter 4
Conclusions

In this chapter the overall conclusions of this thesis will be discussed, as well as the significance of the obtained results. This chapter will also cover the future work that can be done using the groundwork that has been created during this thesis project.

4.1 Conclusions

The objective of this thesis was to lay the groundwork for the continuous development of a pediatric heart assist device monitoring system. Currently, the survival rate for patients on the EXCOR can be as low as 30%.[37,38] Clinicians have no way to monitor this device in real time in order to ensure its functionality.[16,27] If there was a way to monitor this device quickly and efficiently, patient outcomes could be improved. The monitoring system that is currently being developed is based off of how clinicians are currently attempting to monitor the device, by using a mobile device video recording.[27] A mock cardiovascular flow loop was built in order to simulate the clinical setting a pediatric patient would experience. A custom EXCOR driving unit (CEDU) was also built in order to pump the EXCOR device. These two steps were necessary to even begin collecting video data from a functioning EXCOR device. Once the CEDU and flow loop were appropriately tuned, official data collection was able to begin. A total of 42 individual trials were performed for 14 different clinical scenarios. Each experimental scenario had different parameters adjusted, such as resistance, heart rate, or systolic to diastolic ratio. Flow rate, pressure, and video data were collected for each experiment and underwent extensive post-processing. The in-house developed software EMMA was used to analyze the EXCOR membrane motion from the recorded videos. As expected, it was found that the EXCOR membrane reacted differently to different stimuli. Generally, increasing the resistance of the flow loop caused incomplete emptying of the EXCOR, which was successfully detected by EMMA. Overall, the data obtained in this project lays a solid foundation for future work to be completed using this monitoring device system.

4.2 Future Work

While this project generated impactful results as the first iteration of a pediatric heart assist device monitoring system, there is much work to be done in order to optimize the process. Because the original IKUS Driving Unit is not available outside of a clinical setting, the CEDU was built in order to pump the EXCOR. The current iteration of the CEDU could only generate enough pressure to pump the EXCOR membrane fully at a heart rate of 90 bpm. If more clinical situations are to be tested in the future, the CEDU will need to be able to successfully pump the EXCOR (i.e., fully extend and retract the membrane) at heart rates up to 120 bpm or higher.[16] There are several ways in which this could be achieved. First, the diameter of the piston head can be increased. Because the diameter would be larger, the piston head would be able to travel a smaller distance in order to pump the same amount of air into the EXCOR air chamber. This would allow for systole and diastole to take up less time, creating a faster heart rate. Additionally, the length of the tubing between the piston head and the EXCOR air chamber can be minimized, reducing the effect of air being compressible within the tubing itself. If the tubing length is longer, there is more room in the tubing for the air to be 'compressed' and not be pushed into the EXCOR air chamber. This is something that should be reduced in the future.

Synchronizing the multiple data acquisition methods would also allow for easier post-processing. Currently, the flow meter data acquisition, pressure waveform acquisition, and video recording are all started at different periods of time because they all have different "start" buttons. If these three start buttons were to combined into one, then the data processing would be much simpler because the flow rate data, pressure waveforms, and video data would already be in sync. Currently, the time-domain of these different types of data are manually adjusted to analyze the pressure and flow data, which should be optimized and synchronized in the future.

The mock-cardiovascular flow loop can also be improved upon as well. While this system lays down the groundwork for future projects, it can be made more clinically relevant

in several ways. The tubing size can be adjusted to more closely match the size of pediatric arteries for various vascular resistances. During the experiments in this project, the resistance for each case was just increased at a single point, almost simulating a stenosis-like scenario. In the future, multiple points of increased resistance can be introduced, or the entire tubing size can be reduced to introduce increased resistance throughout the flow loop. The EXCOR currently suctions fluid from a reservoir, which basically simulates a pediatric patient with a heart that is completely non-functioning. This does not simulate the environment a patient with a partially-functioning heart experiences. In order to introduce this factor, a peristaltic pump can be used to introduce a very slight pulsatile flow into the flow loop. A Vivitro Superpump, which is a programmable cardiovascular simulator pump, can also be used to create pulsatile flow based off of different user-defined waveforms.[31] This allows for even greater variability of the type of patient cases that can be simulated in the future. Additionally, only one flowmeter is currently used in the flow loop, and it is placed at the inlet of the EXCOR. A flowmeter was not placed at the outlet because it caused too high of a resistance that impeded EXCOR function. While the assumption that the outlet flow would mimic the same behavior as the inlet flow was deemed appropriate, it would still be beneficial to introduce a flowmeter at the outlet in order to have exact data to represent the outlet flow. Further, the existing mock flow loop setup does not account for the vascular compliance – this can be improved in future iterations by including compliance chambers.

The future work above mostly involves the set-up of future experiments. However, the data analysis can also be improved. The EMMA software is an extremely novel technology that was recently developed on a limited amount of training data.[32] Therefore, the method it used to generate positive results on the training data may not be the most optimal when applied to different types of videos of the EXCOR membrane. This algorithm should be tested and trained on a wide variety of EXCOR videos now that the CEDU is available and allows for creation of this data. For example, the signal processing that EMMA employs can be tuned to filter out irrelevant data for EXCOR videos taken at different angles, lighting, quality, framerates, and heart rates. Currently, it is found that EMMA does not provide results representative of the EXCOR behavior if the angle or lighting varies greatly from the data it is trained on. This should be a major objective of a future project, as it is

necessary to tune EMMA in order to develop an accurate pediatric heart assist device monitoring system. There is also no way to quantify the predicted error of each result EMMA puts out.

Additionally, while the CEDU and EXCOR can be made as clinically relevant as possible, the most relevant data still comes from a clinical setting. Currently, there are only a handful of clinical videos available for testing with EMMA. Future work should include obtaining more clinical videos in order to train and test EMMA on as well. This type of data is most relevant because it is actually collected in a clinical setting, and it is even more relevant if the EXCOR is connected to a patient.

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Appendix

A.1 CEDU Code

Systole = Diastole

```
byte Speed = 0;
int extend = 10;   //connected to motor board N1
int retract = 9;   //connected to motor board N2
//int Speed;
int distanceTime;
int stopTime;
int timeNow;
int timePrev = 0;
int InperSec;
void setup() {
  pinMode(extend, OUTPUT);
  pinMode(retract, OUTPUT);
}
void loop() {                                                    //delay for 84 bpm is 300, 100,
300
  if(digitalRead(2)==HIGH){
    timeNow = millis();
    InperSec = 9.05;

    Speed = 255*InperSec/9.05;                    //choose any speed in the range [0,255]
    distanceTime =  300 ; // 160 is theoretical value 2*1000/InperSec;
//choose the time extended
    stopTime = 100;                                                  //adjust if needed
       if (!(timeNow - timePrev >= distanceTime)) {   //extend at given speed for given time
    //if given time hasn't passed, extend
    //hence, if given time has passed, stop extending
      digitalWrite(retract, 0);
      digitalWrite(extend, Speed);
    }
    else if (timeNow - timePrev >= distanceTime && timeNow - timePrev <= distanceTime
+ stopTime) {  //stop for 1/10 a second
    //if given time has passed, stop
    //if given stop time has passed, stop stopping
      digitalWrite(retract, 0);
      digitalWrite(extend, 0);
```

```
    }
    else if (timeNow - timePrev >= distanceTime + stopTime && timeNow - timePrev <=
distanceTime + stopTime + distanceTime) {  //retract at given speed for 3/10 second
    //if done stopping, retract
    //if given time has passed, stop retracting
      digitalWrite(retract, Speed);
      digitalWrite(extend, 0);
    }
    else {
      timePrev = timeNow;  //reset time for next loop
    }
  }
}
```

Systole = 1/3 Diastole

```
float Speed1 = 0;
float Speed2 = 0;
int extend = 10;   //connected to motor board N1
int retract = 9;   //connected to motor board N2
int distanceTime1;
int distanceTime2;
int stopTime;
int timeNow;
int timePrev = 0;
float InperSec;
void setup() {
  pinMode(extend, OUTPUT);
  pinMode(retract, OUTPUT);
}
void loop() {       //delay for 90 bpm is 300, 100, 300


  if(digitalRead(2)==HIGH){
    timeNow = millis();
    InperSec = 9.05;
     Speed1 = 187*InperSec/9.05;    //choose any speed in the range [0,255]
    Speed2 = 140*InperSec/9.05;
```

```
   distanceTime1 =  300 ; // retract time //
   distanceTime2 = 400;  //extend time  //
   stopTime = 50;                //adjust if needed
      if (!(timeNow - timePrev >= distanceTime2)) {   //extend at given speed for given
time
   //if given time hasn't passed, extend
   //hence, if given time has passed, stop extending
     digitalWrite(retract, 0);
     analogWrite(extend, Speed1);
   }
   else if (timeNow - timePrev >= distanceTime2 && timeNow - timePrev <=
distanceTime1 + stopTime) {  //stop for 1/10 a second
   //if given time has passed, stop
   //if given stop time has passed, stop stopping
     digitalWrite(retract, 0);
     digitalWrite(extend, 0);
   }
   else if (timeNow - timePrev >= distanceTime1 + stopTime && timeNow - timePrev <=
distanceTime2 + stopTime + distanceTime1) {  //retract at given speed for 3/10 second
   //if done stopping, retract
   //if given time has passed, stop retracting
     analogWrite(retract, Speed2);
     digitalWrite(extend, 0);
   }
   else {
     timePrev = timeNow;  //reset time for next loop
   }
  }
}
```

A.2 Flowmeter and Pressure Analysis Code

```
import pandas as pd
import numpy as np
import matplotlib.pyplot as plt
from scipy.signal import welch
from scipy import signal
from sklearn import preprocessing
import matplotlib.gridspec as gridspec
import warnings
warnings.filterwarnings("ignore")
import csv
from itertools import islice
# import graph_objects from plotly package
import plotly.graph_objects as go

# import make_subplots function from plotly.subplots
# to make grid of plots
from plotly.subplots import make_subplots
from matplotlib.patches import Patch
from matplotlib.lines import Line2D
from sklearn.model_selection import train_test_split
from sklearn.linear_model import LogisticRegression
from sklearn import metrics

## MASTER CODE- does everything
## DONT RUN UNLESS SAVING IMAGES TO FOLDERS

readdata1 =
csv.reader(open(r'C:\Users\nhill2018\Desktop\Flowmeter_Data\120normal\inlet1.c
sv', 'r'))
data1 = []
readdata2 =
csv.reader(open(r'C:\Users\nhill2018\Desktop\Flowmeter_Data\120normal\inlet2.c
sv', 'r'))
data2 = []
readdata3 =
csv.reader(open(r'C:\Users\nhill2018\Desktop\Flowmeter_Data\120normal\inlet3.c
sv', 'r'))
data3 = []
skiprows = range(0, 18)
```

```
readdata =
pd.read_csv(r'C:\Users\nhill2018\Desktop\Pressures\120normal\120normal1.csv',
'r', skiprows =skiprows, encoding = 'latin')

#####################################################################
#####################################################################

for row in readdata1:
  data1.append(row)

for row in readdata2:
  data2.append(row)

for row in readdata3:
  data3.append(row)

data1.pop(0)              #get rid of header in first row apparently
data2.pop(0)
data3.pop(0)


q1 = []
q2 = []
q3 = []

for i in range(len(data1)):
  q1.append(int(float(data1[i][0])))

for i in range(len(data2)):
  q2.append(int(float(data2[i][0])))

for i in range(len(data3)):
  q3.append(int(float(data3[i][0])))

#print(q1)
#print ('Average Flow Rate 1 :          ', (np.nanmean(q1)))
#print ('Average Flow Rate 2 :          ', (np.nanmean(q2)))
#print ('Average Flow Rate 3 :          ', (np.nanmean(q3)))

avg1 = np.nanmean(q1)
avg2 = np.nanmean(q2)
avg3 = np.nanmean(q3)
```

```
Average = (avg1+avg2+avg3)/3

print(avg1, avg2, avg3)

print('Average Flow Rate : ', Average)

auc = np.trapz(q1)
print('Total Flow [ml]=', auc)

#########################################################################
#####################################################
#resampling flow rate
flowrate = q1
sample_rate = 0.06
samples = len(q1)
t = int(sample_rate*samples)

b = q1[1:143]

flow = signal.resample(b, 1000)

#plt.plot(flow, color = 'fuchsia')
#plt.xlim(0,1500)
#plt.xlabel('Samples')
#plt.ylabel('Flow Rate [ml/min]')
#plt.title('Flow Rate')

#########################################################################
#####################################################
#Pressures only
j=0
k=0
all_chunks=np.zeros((2550, 8))

while j < len(readdata):

    for i in range(j, j+255):
        all_chunks[k]=np.array(readdata.loc[i][0].split(',')[2:]).astype('float32')
        k+=1
    j=i +3
```

```
pressures = all_chunks[:, 2:4]
#Pwav = signal.resample(pressures, 1000)

ip = all_chunks[1:2560, 2:3]
op = all_chunks[1:2560, 3:4]

Pwav1 = signal.resample(ip, 1000)
Pwav2 = signal.resample(op, 1000)


#fig, ax = plt.subplots(facecolor= 'white')
ax.set_title('Pressure Waveforms')
ax.set_xlabel('Samples')
ax.set_ylabel('Pressure [mmHg]', color='black')
l0, = ax.plot(Pwav1, 'deepskyblue')
l1, = ax.plot(Pwav2, color='navy')
ax.legend((l0,l1),('Inlet', 'Outlet'), loc='upper right', shadow=True)
#plt.savefig(r'C:\Users\nhill2018\Documents\Images\SdneDhighR\bigP.jpg')
plt.show()


#########################################################################
#######################################################
#Pressures only, cropped
fig, ax = plt.subplots(facecolor= 'white')
ax.set_title('120 bpm R1 Pressure Waveforms')
ax.set_xlabel('Samples')
ax.set_ylabel('Pressure [mmHg]', color='black')
l0, = ax.plot(Pwav1, 'orange')
l1, = ax.plot(Pwav2, color='blue')
ax.legend((l0,l1),('Inlet', 'Outlet'), loc='upper right', shadow=True)
plt.xlim(0,400)
#plt.savefig(r'C:\Users\nhill2018\Documents\Images\SdneDhighR\smallP.jpg')
plt.show()



#########################################################################
#######################################################
#big pressure vs flow
legend_elements = [Line2D([0], [0], color='deepskyblue', label='Inlet'),
```

```
                Line2D([0], [0], color='navy', label='Outlet'),
                Line2D([0], [0], color = 'fuchsia', label='Flow Rate')]

#fig, ax1 = plt.subplots()
ax1.set_xlabel('Samples')
ax1.set_ylabel('Pressure [mmHg]')
l2 = ax1.plot(Pwav1, color = 'deepskyblue')
l3 = ax1.plot(Pwav2, color = 'navy')
w = ax1.legend((l2,l3),('Inlet', 'Outlet'))
ax1.tick_params(axis ='y', labelcolor = 'black')

ax2 = ax1.twinx()

ax2.set_ylabel('Flow Rate [mL/min]', color = 'fuchsia')
l4 = ax2.plot(flow, color = 'fuchsia')
w = ax2.legend((l4), ('Flow Rate'))
ax2.tick_params(axis ='y', labelcolor = 'fuchsia')
plt.xlim(0,1000)
ax2.legend(handles=legend_elements, loc='upper right')
plt.title('Flow Rate vs Pressures')
#plt.savefig(r'C:\Users\nhill2018\Documents\Images\SdneDhighR\PvFbig.jpg')


#########################################################################
#########################################################
#small pressure vs flow
legend_elements = [Line2D([0], [0], color='deepskyblue', label='Inlet'),
                Line2D([0], [0], color='navy', label='Outlet'),
                Line2D([0], [0], color = 'fuchsia', label='Flow Rate')]


fig, ax1 = plt.subplots()
ax1.set_xlabel('Samples')
ax1.set_ylabel('Pressure [mmHg]')
ax1.plot(Pwav1, color = 'deepskyblue')
ax1.plot(Pwav2, color = 'navy')
ax1.tick_params(axis ='y', labelcolor = 'black')

ax2 = ax1.twinx()

ax2.set_ylabel('Flow Rate [mL/min]', color = 'fuchsia')
ax2.plot(flow, color = 'fuchsia')
```

```
ax2.tick_params(axis ='y', labelcolor = 'fuchsia')
ax2.legend(handles=legend_elements, loc='upper right')

plt.xlim(0,200)
plt.title('80 bpm R2 Flow Rate vs Pressures')
#plt.savefig(r'C:\Users\nhill2018\Documents\Images\SdneDhighR\PvFsmall.jpg')
```

A.3 EMMA Code

```
#importing required libraries
import glob
import os
import pandas as pd
import cv2
import matplotlib.pyplot as plt
import moviepy.editor as mpy
import moviepy.video.io.ImageSequenceClip as ISC
import natsort
import numpy as np
from matplotlib import pyplot as plt
from skimage.feature import hog
from skimage.transform import resize
"""User Prompts"""
#Ask what video to convert
videoFileName = input("What is the file name of the video you would like to analyze? ")
#Ask whether to save the resized video
ifResizedSave = input("Would you like to save a resized video for comparison (y or n)? ")
if_min_remvoed = input("Would you like to save a resized video for comparison (y or n)?
")
ifPrintFileNumber = input("Would you like the current photo number continuously printed
(y or n)? ")
#Ask for file names to save as
if ifResizedSave == 'y' or ifResizedSave == 'Y':
    resizedVideoName = input("What would you like the Resized Video to be saved as? ")
hogVideoName = input("What would you like the HOG Video to be saved as? ")
#Asking for fps of video on playback
fps_success = False
while fps_success == False:
    try:
        fps = int(input("What would you like the playback FPS to be? "))
        fps_success = True
    except:
        print("Please input a integer")
```

```
#Deleting previous saved photos in folders
files = glob.glob('video_data/*.png')
for f in files:
    try:
        os.remove(f)
    except OSError as e:
        print("Error: %s : %s" % (f, e.strerror))
files = glob.glob('hog_video_data/*.png')
for f in files:
    try:
        os.remove(f)
    except OSError as e:
        print("Error: %s : %s" % (f, e.strerror))
files = glob.glob('hog_video_data/*.csv')
for f in files:
    try:
        os.remove(f)
    except OSError as e:
        print("Error: %s : %s" % (f, e.strerror))
#Reading First Frame of Video
vidcap = cv2.VideoCapture(videoFileName)
success, image = vidcap.read() #first frame saved
count = 1 #Count to be print if user says yes
  while success:
    """Creating HOG image"""
    # resizing image
    resized_img = resize(image, (128*4, 64*4))
    if ifResizedSave == 'y' or ifResizedSave == 'Y':
        #Saving original image
        plt.imsave("video_data/image_%d.png" % count, resized_img)
    #creating hog features
    fd, hog_image = hog(resized_img, orientations=9, pixels_per_cell=(8, 8),
                        cells_per_block=(2, 2), visualize=True, multichannel=True)
    if if_min_remvoed == 'y' or if_min_remvoed == 'Y':
        np.savetxt(f'hog_video_data/{count}_fd.csv', fd, delimiter=',')
    if count == 1:
        FD_array = np.array(np.average(fd))
        print(f'FD_array = {FD_array}')
    else:
        FD_array = np.append(FD_array, np.average(fd))
        print(f'np.average(fd) = {np.average(fd)}')
    plt.imsave("hog_video_data/image_%d.png" % count, hog_image, cmap="gray")
    #read next frame
    success, image = vidcap.read()
    if ifPrintFileNumber == 'y' or ifPrintFileNumber == 'Y':
        print('Saved image ', count)
```

```
    count += 1
"""Creating Videos"""
if ifResizedSave == 'y' or ifResizedSave == 'Y':
    #Resize Video creation
    image_folder='video_data'
    image_files = [image_folder+'/'+img for img in os.listdir(image_folder) if
img.endswith(".png")]
    image_files = natsort.natsorted(image_files)
    clip = ISC(image_files, fps=fps)
    clip.write_videofile(f'{resizedVideoName}.mp4')
#HOG Video creation
image_folder='hog_video_data'
image_files = [image_folder+'/'+img for img in os.listdir(image_folder) if
img.endswith(".png")]
image_files = natsort.natsorted(image_files)
#clip = ISC(image_files, fps=fps)
clip = mpy.ImageSequenceClip(image_files, fps=fps)
clip.write_videofile(f'{hogVideoName}.mp4')
#Saving HOG Gradient array
np.savetxt(f'{videoFileName}_FD_array.csv', FD_array, delimiter=',')
if if_min_remvoed == 'y' or if_min_remvoed == 'Y':
    """This is an optional process where
    the minimum HOG values are removed from each frame's HOG array
    Currently considered unnecessary since value is normalize anyways
    and this requires a considerate amount of time and processing power"""
    files = glob.glob ("hog_video_data/*.csv")
    array_made = False
    for my_file in files:
        if array_made == False:
            new_fd = pd.read_csv(my_file).to_numpy()
            min_fd = np.array(new_fd)
            array_made = True
        else:
            new_fd = pd.read_csv(my_file).to_numpy()
            new_fd = np.array(new_fd)
            min_fd = np.minimum(new_fd, min_fd)
            print('new fd')
    array_made = False
    for my_file in files:
        new_fd = pd.read_csv(my_file).to_numpy()
        new_fd = np.array(new_fd)
        new_fd = new_fd - min_fd
        print('min removed')
        if array_made == False:
            FD_array = np.array(np.average(new_fd))
            array_made = True
```

```
    else:
        FD_array = np.append(FD_array, np.average(new_fd))
np.savetxt(f'{videoFileName}_min_fd.csv', min_fd, delimiter=',')
np.savetxt(f'{videoFileName}_new_FD_array.csv', FD_array, delimiter=',')
```