Iterative Design and Proof of Concept Prototypes – Emergency Safety Valve for Portable Hemodialysis System

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Abstract

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The purpose of this project is to design and develop an emergency safety valve prototype for the University of Washington Center for Dialysis Innovation (CDI). This valve needs to work in conjunction with already marketed central venous catheters and the CDI's portable artificial kidney. When activated by a sudden tensile force, the emergency safety valve will undergo disconnection causing deployment of the crushing mechanism and thus, stop blood flow within the dialysis system.

This thesis followed a product development process that the product meets the objectives for intended use. The project began with a kickoff meeting to solidify the device goals. Next, the planning phase included literature review on the dialysis process, blood access types and designs. Then, failure mode analysis was performed. The outcome of this phase was identification of the design inputs: Compatible with central venous catheters, external to the catheter placed in subclavian artery, connects to a standard luer lock, failure occurs from a tensile force, and activates from disconnection. The design of the valve went through an iterative process that included designing, testing and analyzing. Three designs were created: The plug mechanism, the crushing mechanism via pin, and the crushing mechanism via flat spring. The crushing mechanism via flat spring showed an achievable outcome of stopping water flow, which was observed during characterization testing of the disconnection force and a simulated use test. This prototype will be handed off to CDI for further development and integration into the portable artificial kidney system.

1. Introduction

1.1. Objective

The goal of this research was to design and fabricate a prototype of an emergency safety valve for the University of Washington Center for Dialysis Innovation. The team at CDI has developed an artificial kidney system that functions to make dialysis a portable and ultimately wearable system. This system includes three separate devices, one of which is patented and two of which are pending patents. This thesis project will closely involve the pending patent AKTIV connection *(1)*, an acronym for Ambulatory Kidney to Increase Vitality. The safety valve will be used in conjunction with the AKTIV device and central venous catheters (CVC) that are on the market. The valve design had to meet the determined design inputs and consider manufacturing feasibility. A series of designs were formed through a three-step iterative process: Design, fabrication and analysis of function.

The process was repeated until a final concept showed high potential for stopping blood flow.

1.2. Format of Project

This project used aspects of the Product Development Process (PDP) as a pathway for taking an idea to a prototype. The PDP is defined as “the sequence of steps or activities that an enterprise employs to conceive, design, and commercialize a product. Many of these steps and activities are intellectual and organization rather than physical” *(2)*. This process comprises six total phases: Planning, concept development, system-level design, detail design, testing and refinement, and product ramp up. This project implements the planning and concept development phases.

The project kick-off began by the CDI team stating their wants, needs, and previous designs of the device. These factors were then assessed for achievability in the planning phase, which led to determination of required design inputs. The design inputs were the starting points of the concept development phase. Fabrication of the concept was completed using 3D printing, and proof of concept was assessed. This occurred as an iterative process until final modifications demonstrated an achievable solution. The design will be handed off to the Center for Dialysis Innovation to carry out the last four phases of the PDP.

1.3. Outcome

After the literature review, finalization of design inputs and completion of the iteration process, a final design was chosen. This design met all the required inputs and fabrication was relatively easy and straightforward. The prototype was characterized based on a disconnection and simulated use test, where it was assembled into a system closely resembling the intended application. Water was pumped through the interior of the system and the valve was subjected to disconnection to observe the mechanism of action. This

valve prototype successfully stopped water flow through the system without leakage or rupture to the tubing.

Figure 1. Final thesis design for the emergency safety valve.

2. Background/Motivation

2.1. Dialysis

As of 2022, approximately 37 million people in the United States are affected by chronic kidney disease (CKD) according to the National Kidney Foundation *(3)*. CKD is characterized by one or both of the kidneys not properly functioning. The function of the kidneys is to eliminate excess fluid and waste products from the blood by ultrafiltration. While the blood is within the kidney, other solutes are adjusted to maintain homeostasis, and then sent back to the rest of the body. CKD is often associated with poor quality of life due to the inability to perform removal of toxins from the blood *(4)*. Renal transplant is the ideal treatment choice, but the shortage of donor kidneys places those suffering from kidney disease on a long waiting list *(5)*. Transplants give patients a higher quality of life, but the next best option for these individuals is dialysis *(4)*. Dialysis is described as the "passage of molecules in solution by diffusion across a semipermeable membrane" *(6)*. This passage through the membrane mimics the ultrafiltration process to remove the excess fluid and waste products.

Dialysis was invented at the University of Washington in the 1960's by Belding Scribner *(4)*. Scribner's process used teflon-coated tubing for blood access to perform urea filtration *(4)*. Advances over the years transformed the design of the teflon-coated tubing to the current day arteriovenous fistulas and grafts for connection to the machine that performs filtration *(4)*. While many areas of medicine have progressed from advancements in diagnostics and new pharmaceuticals, the dialysis process has remained nearly the same.

The process typically takes place in a dialysis clinic, where the patients overall toxin levels are assessed by a nephrologist, who then determines how much urea to remove and how much solute to be put back into the body, this is referred to as the dialysis dose *(4)*. The patient's blood is accessed by connection to the dialysis machine via an arteriovenous

graft, arteriovenous fistula or central venous catheter *(4)*. The dialysis machine has several pumps that function to pump blood through the system. The blood flows through a semipermeable membrane, removing toxins and sending clean blood back to the body *(6)*. A simplified schematic for the dialysis process is shown in **Fig. 2**. While dialysis mimics the filtration of toxins from the blood, it does not replace the full function of the kidney because it cannot perform adequate homeostasis by replacing functional renal specific cells *(8)*. Dialysis has been treating individuals affected by CKD for over 50 years with little change to the overall process. This suggests that the process is efficient because it has mostly remained the same since its invention, but there are many implications of this treatment that negatively affect the environment and dialysis patient's quality of life.

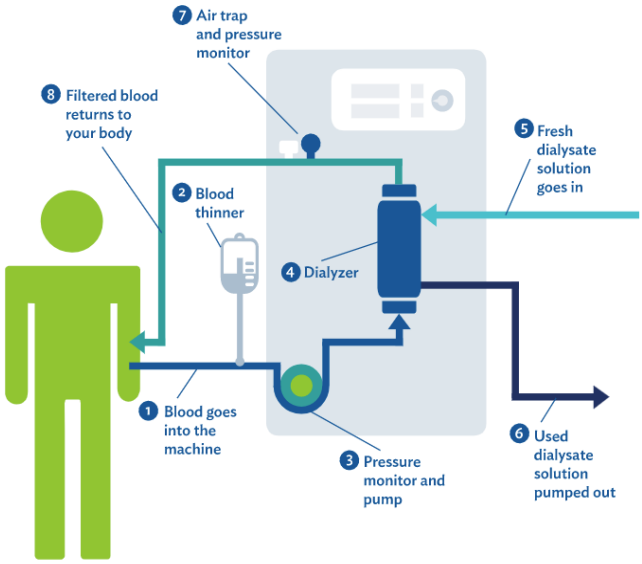


Figure 2. Schematic of blood flow during dialysis treatment *(7)*.

The first limitation of the current dialysis process is patient immobility during the treatment due to connection to heavy machinery *(4)*. The machines that perform the removal of toxins from blood are located at dialysis clinics. Hemodialysis equipment used to

Figure 3. Patient undergoing dialysis treatment. The dialysis equipment spatially required the entirety of the room *(9)*.

take up an entire room, as shown in **Fig. 3**, but now it is approximately the size of a "three to four drawer filing cabinet" *(6)*. Patients are connected to these machines from the chosen blood access device. This means that they are required to remain in one spot because it is impractical to move around while attached to a heavy piece of machinery. The size and weight of hemodialysis equipment can be attributed to it being a single-pass system. Single-pass dialysis machines prepare the dialysate by continuous mixing of a liquid concentration with the proportionate amount of purified water and then dispose of the excess later on *(6)*.

The second limitation is quality and amount of water. The current dialysis process requires approximately 120L of purified water for the dialysate *(8)*, *(10)*. The quality of water used during the process is essential to avoid introducing harmful substances into the patient's blood, as additional electrolytes, minerals and nutrients are required for each session *(6)*. Up to 25% of it is disposed of down the drain *(11)*, *(12)*. This leads to disposal of over 18,000L of water each week *(10)*.

The third limitation is time and frequency of treatment. On average, the entire process of filtering and returning blood from start to finish takes around four hours *(6)*. It is recommended that patients perform dialysis three times a week, for a total of up to 12 hours at the dialysis center, not counting travel time to and from *(6)*. Treatment time and frequency are just as important as determining the dialysis dose *(6)*. Filtration of toxins out of the blood is a time dependent process that obeys the laws of kinetics *(6)*. Shorter duration sessions may not allow for efficient removal of toxins, or to compensate would require an increase in filtration rate *(6)*. Not removing all of the toxins leaves patients with negative side effects, while high filtration rates pose the risk of dizziness as blood is moving at a higher speed throughout the body *(6)*. Frequent Hemodialysis Network (FHN) daily trial which is sponsored by the National Institutes of Health (NIH) compared longer treatment times to the standard practice *(4)*, *(13)*. The outcomes showed that patients had

improved blood control, toxin removal and increase in health-related quality of life when dialysis occurs eight to 12 hours a session, rather than the standard four hours *(4)*. If longer dialysis treatments were to become the standard, it would require patients to sit still for approximately eight hours a time, which is unrealistic and unpleasant.

The idea of allowing patients to dialyze at home is a proposed solution to these limitations. But factors like physician calculation of dialysis dose, performing the connection to and from a heavy machine, and large amount of clean water required are factors that make it an unlikely possibility without adjustments to the process. Due to the large market of individuals requiring dialysis, ongoing development is occurring to find a solution to increase health related quality of life for those with kidney disease. Exploration is occurring in the fields of tissue engineering, cell therapy and wearables. Each with the goal to enhance the function of the kidney along with their own technical obstacles to overcome *(14)*. For the remainder of this thesis, only the challenges of the wearable approach will be considered.

2.2. Need for Wearable Devices

A wearable dialysis device would allow patients to experience constant dialyzing without the need to visit dialysis centers for roughly 12 hours a week. However, there are many technical challenges that need to be addressed, like reduction in the amount of water required, reduction in weight of the filtration machine, and removal of manual calculation of the dialysis dose. A team at the University of Washington's Center for Dialysis Innovation has begun preliminary development activities to solve these technical obstacles. They have developed a patented urea removal technology, referred to as the POUR technology, an acronym for photo-oxidation urea removal. This will enable portable/wearable dialysis by continually running two liters of dialysate through a panel that uses UV light to convert urea into nitrogen, carbon dioxide and water *(15)*. This eliminates the single pass system and requirement for water all while greatly reducing the

size of the equipment (**Fig. 4**). This idea has spun off into a portfolio of intellectual property covering areas of solute separation, blood access, blood compatibility and device integration. CDI is taking a holistic approach to dialysis meaning the entire circuit of dialysis must be considered. The POUR technology will be used with the CDI's pending patents the AKTIV connection and portable hemodialysis system *(1), (16)*. The AKTIV connection is a needleless, touchless and automated vascular access, which will assist in making dialysis a portable, and ultimately wearable treatment *(1), (16)*.

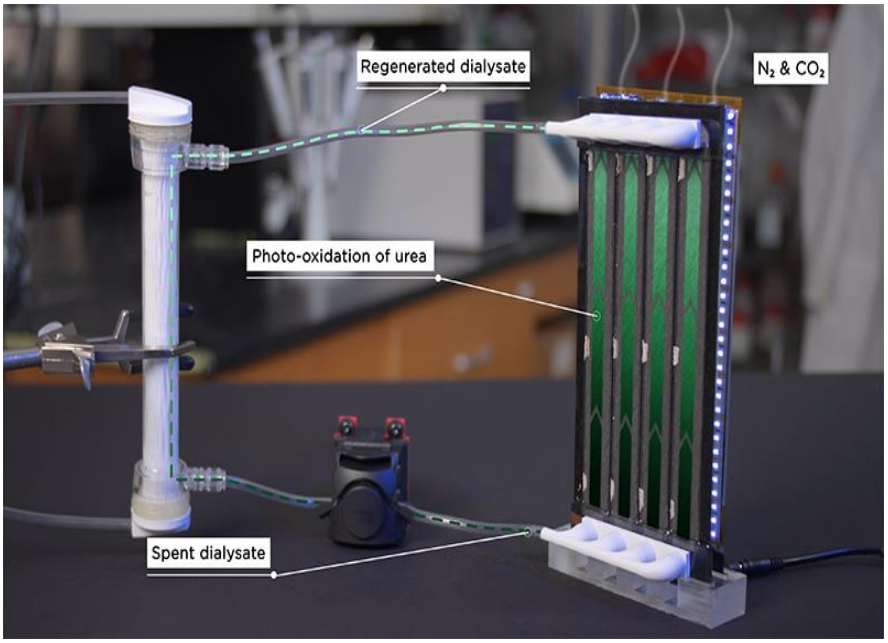


Figure 4. A prototype of a University of Washington CDI patent application photo-oxidation urea removal technology *(15)*. This technology decomposes urea, enabling a small closed-loop volume of dialysate to be used during treatment.

While the idea of making the dialysis process a wearable machine gives promising advancements towards solving these technical challenges, patient safety still remains a concern for wearable dialysis devices. Patients who are dialyzing on the go are subject to a vulnerable state with having a large volume of blood exposed to the external environment. This thesis project aims to propose a solution to emergency situations where the dialyzing tubing experiences great tensile forces that disrupt the blood flow in the system and leads the patient to hemorrhaging.

3. Methods

3.1. Planning Phase- Design Inputs

Prior to designing the valve, the design inputs needed to be identified. A project kickoff meeting was conducted with team members at CDI to identify the primary goals of the valve, including must-haves and nice-to-haves and sharing previous design ideas. Their ideal valve is compatible with CVCs that are already on the market, so that the AKTIV connection device can accommodate as many hospitals as possible. The ideal function of the valve is to stop blood flow as close to the source as possible, which would mean it is located inside the inner diameter of the CVC. If possible, it should block blood flow to and from the body, and activate automatically if there is a rupture or leak in the tubing connecting the catheter to the AKTIV device. This feedback was the basis for beginning the literature review to begin considering the logistics of a design that could accomplish those goals. The literature review consisted of the current dialysis process, blood access types, central venous catheter design and design variables, and types of failure modes. The information led to the design inputs that will be used to begin concept development. These design inputs were a combination of must-haves and nice to haves, as discussed during the project kickoff. Some of the nice-to-haves were discounted because they were deemed not feasible for the final design. The final design inputs were established as a completion of this phase, listed in **Table 2**.

3.2. Concept Development Phase – Design Outputs

The design inputs were the starting point for the concept development phase. This phase functions to "describe the form, function, and features of a product" *(2)*. The computer aided design software *SOLIDWORKS 2020* was used to create the design concepts. The intended function and manufacturing feasibility were reviewed with the thesis committee team. The feedback from the fabrication was used for the next concept,

and this occurred as an iterative process until a final achievable solution was obtained that met the design inputs and showed strong likelihood of being successful.

For the prototype creation, speed of iteration and cost were the biggest factors when choosing fabrication methods. Due to on hand availability, fused deposition modeling (FDM) using a Dremel 3D45 printer was chosen to create physical parts of the models in addition to the purchase of off the shelf components and tools as needed. The *SOLIDWORKS* models were converted to .STL files and imported into Dremel DigiLab 3D Slicer Software. The Dremel DigiLab 3D Slicer Software allowed the researcher to configure the orientation of the components on the platform and adequately input the printer settings. The settings that were adjusted between print iterations were nozzle temperature, platform temperature, build plate adhesion type and support placement. Print speed, infill density, layer height, and shell thickness were left to the default settings. Once the inputs for printing were entered into the software, the file was saved onto a flash-drive, and transferred to the Dremel 3D45 printer.

The materials used for printing were 1KG PLA Filament, 4043D blue and 3D870 yellow, both 1.75mm in diameter, purchased from Fusion Filaments. The decision throughout the prototyping process to use 4042D Blue or 3D870 yellow was random, as multiple printers were used simultaneously. The printer nozzle and platform temperature were first set based on the 3D filament print specifications from the manufacturer. Adjustments were then made in the following iterations accordingly.

Once the print was completed, the components were assembled into the intended final design assembly in addition with any off the shelf components that were purchased. The prototype function was then analyzed for the fabrication feasibility and the valve's potential to stop blood flow. Certain components and assembly steps were excluded if determined that they did not contribute to the overall function. The material properties of

the PLA filament as it relates to mechanical properties were excluded from the overall design function because the prototype was analyzed only for proof of concept.

3.3. Characterization Testing

The final prototype was subjected to characterization which was developed based on the final design selection. The first characterization test functioned to quantify the force required to disconnect the housings. The second test was a simulated use test to observe how the valve would function when fluid is pumping through the system. A full description of the testing is described in the results and discussion section.

4. Results and Discussion

4.1. Rationale for Design Inputs

The team at CDI stated that their ideal valve is compatible with already marketed CVCs, resides inside the inner lumens, blocks blood flow to and from the body, and activates automatically. To begin designing a valve that accommodates these objectives, the logistics had to be considered. First, the design and design variables of available CVCs were investigated. A CVC is characterized as a flexible tube that has multiple inner lumens separate for blood flow into and out of the body. In the case of the CVC depicted in **Fig. 5**, a single dual lumen tube separates into two single lumen tubes at the Dacron cuff, where the catheter exits the body.

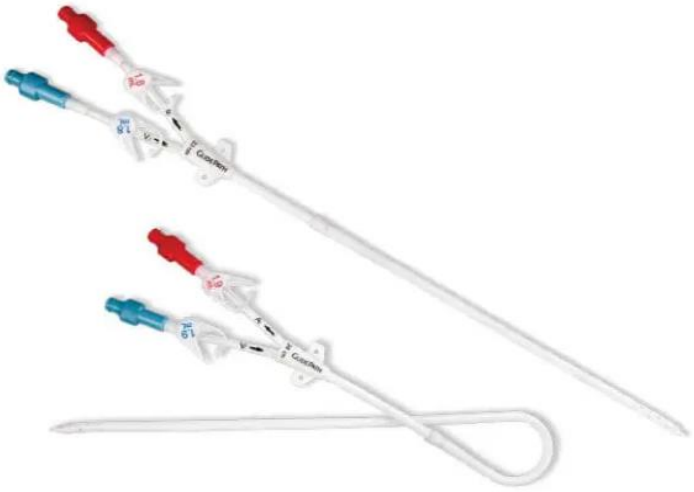


Figure 5. The BD Glidepath Long-Term Hemodialysis Catheter *(17).*

There are several manufacturers of CVCs and even from the same manufacturer, variables like outer diameter dimension, number of lumens, shape of lumens, size of lumens, material, length and other design features like distal tip geometry and side holes are seen (**Table 1).** These variables are important because they ultimately influence the size, shape, and way the valve will integrate into the system. The size of the inner lumen can range from 3-6Fr depending on the shape. This considerably small size poses a challenge of how to get a valve into this space without disrupting the blood flow path. There is no extra space here, and if there was, the logistics of how to get a valve into this lumen of an already manufactured CVC without causing harm to the patient would present new challenges. Due to these factors, the possibility of a valve that is internal to the catheter was discarded, leading to the first design input that the valve is external to the system.

Table 1. Design Variables in Central Venous Catheters *(18), (19), (20).*

Outer Dimension (French)	Placement/ Exit Site	Tip to Cuff Insertion Length (cm)	Tip Type	Lumen Shape	Number of Lumens	Duration	Material
9-15 Fr	Subclavian	15-30 cm	Split	Oval	One	Acute	Silicone
	Femoral		Stepped	Double-D	Two	Chronic	Poly-urethane Polyvinyl chloride
	Jugular		Twinned	Cyclic-C Double-O Co-Axial	Three		

As previously mentioned, it would be ideal to stop blood flow as close to the source as possible. While the feasibility of making an internal valve was deemed unachievable, an external valve should be as close to the exit site of the catheter as possible. This poses the question of placement of the CVC within the body to decipher where the exit site is. Depending on the patient condition, the catheter placement in the body may vary. The most common locations for placement in hemodialysis applications are the jugular,

femoral or subclavian arteries *(21)*. An interview was conducted with Elina Quiroga, MD, MPH, Associate Professor of Surgery at the University of Washington Medical Center, regarding the catheter placement variation. She described the decision-making process stating that "when placed in the jugular vein, the rate of infection is greatly increased, but when in the femoral artery, the catheters have a higher likelihood of kinking and damage due to the extra length. Patients with a catheter in the femoral artery are told to not move". Her recommendation is to see placement in the subclavian vein if the patient's condition allows for it, because the catheter can experience the most flexibility and have a moderate length. Guidance from leaders in the field, feedback from patients and literature review lead to the third design input of having the CVC exit near the clavicle.

Next, the suggestion of how the valve would block blood both exiting and entering the body was considered. At the CVC exit site, the multi-lumen catheter splits into two separate single lumen tubes. These separate tubes define the inflow and outflow of blood from the dialysis machine. Having the valve be located close to the body while stopping blood flow in two separate tubes poses a challenge for integration. A few questions emerged: How will the valve be adhered to the tubing? Can a single valve accommodate two tubes?

The literature review on the design of CVCs showed that luer lock connectors are a standard component for these catheters. By utilizing this type of connector in the valve system, an easy connection could be made to both the inlet and outlet tubes of the CVC. While this luer lock connector is located two to five inches from the body, it is a starting point for the closest location to the body to stop blood flow. In the final design of the AKTIV device, the team at CDI plans to automate the luer lock connection and disconnection. The automation comes from two magnetically coupled connectors, one connects to the CVC luer lock connector, and the second connects to the standard AV tubing of any existing hemodialysis machine. For the design of this valve, the connection

to the wearable will be left out to accommodate the automatic connection plans, while the connection to the CVC ports will utilize the mating luer locks. This will allow for successful integration to many different design types of CVC.

Now that the logistics of valve location within the system have been defined, the next items to be considered were the different types of failures that could occur in the system and what types of stimulus would detect the failures. The failure modes identified for blood pumping through tubing external to the body were cuts (small or large), leaking, unintended disconnection and catastrophic failure. For each failure mode, stimuli like electromechanical, pressure gradients, changes in flow, compression or tensile forces, and manual mechanisms were identified as potential indications of these failures. A small leak in the tubing would likely lead to a reduced flow rate within the system which could be undetected by the patient. While a rupture in the system leading to removal of the catheter would be attributed to a tensile force. Ideally, one valve would be sufficient to deploy under multiple failure modes, but it was concluded that a single stimulus would not be able to activate the valve. Therefore, only one failure mode and one stimulus that show potential of working together were chosen. This valve shall activate in situations where sudden tensile forces lead to disconnection.

The literature review influenced by the CDI's desired valve goals, must-haves and nice-to-haves lead to the required design inputs for the valve, listed in **Table 2**. This review functioned to answer questions regarding the logistics of how, where and what the valve must do per the vision of the AKTIV device. The creation of the design inputs completes the planning phase and is the basis for the concept development phase of this project.

Table 2. Determined design inputs after completion of the Planning Phase.

Design Inputs
Compatible with existing central venous catheters
External to catheter lumen
Exit site is near the clavicle
Connects to standard luer lock
Failure mode is disconnection
Valve activation is tensile force

4.2. Concept Development - The Plug Mechanism

4.2.1. Design Concept

The first design created will be referred to as "The Plug Mechanism". It is composed of seven components: Two housing halves, one plug, one floater, one spring and two magnets (**Table 3**). When fully assembled, the housing halves have a magnet in the distal groove and the floater is enclosed in the mating feature between them. The stem of the floater has a spring between the base and the conical guide. A standard luer lock is overmolded into each of the lumens at the proximal end of the housing halves, while the distal end is open for insertion and removal of the plug.

The plug component has two lumens to separate blood flow to and from the body. The required connection to the wearable is still to be determined because one of the goals of the AKTIV device is an automated connection to the CVC. The connection type can be configured into the design later on, and so it was discounted from this initial design.

The exterior extruded cut on the plug has a magnet that mates with the magnet of the housing halves. The plug functions to open and close the flow path by insertion into the distal opening of the housing halves. Once the plug contacts the base of the floater, the floater travels proximally in the assembly until it bottoms out on the mating seat feature. The assembly is fully connected when the magnets of the housing halves and plug are aligned (**Fig. 6B**).

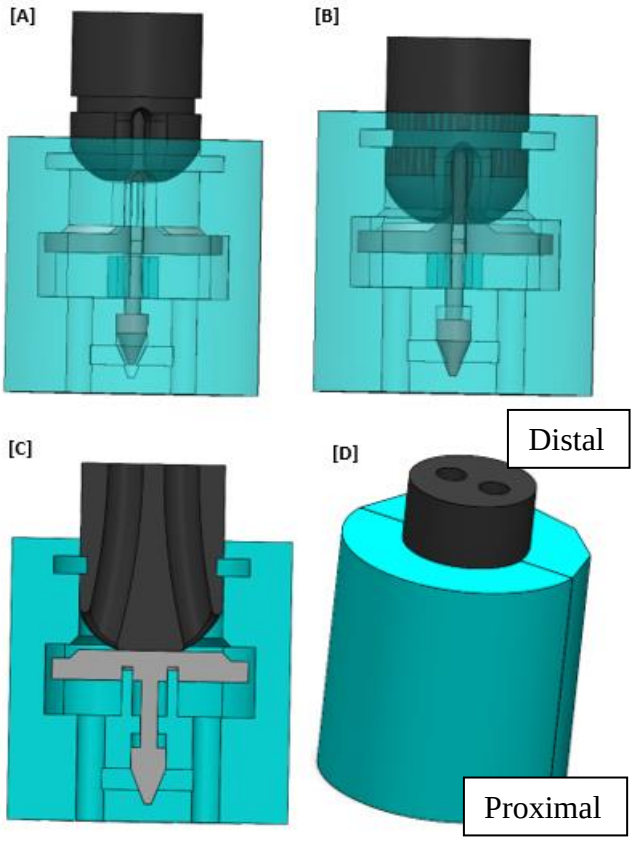


Figure 6. [A] Plug mechanism assembly in disconnected state. [B] Plug mechanism in connected state. [C] Cross-sectional view of flow path through connected state. [D] External view of plug mechanism when fully assembled in connected state.

The blood flow path created by the connected state is shown in **Fig. 7**. ISO standard 10555 states that the minimum connection strength between luer locks and catheters must be 3.37 lbf *(22)*. Therefore, the magnet force between the housing halves and the plug will be designed less than this force, making this connection the weakest point in the system. If the external tubing in the wearable were to experience a large tensile force, the plug would be pulled out of the housing causing a cascade on the rest of the system. The energy stored in the spring while in compression will be converted to

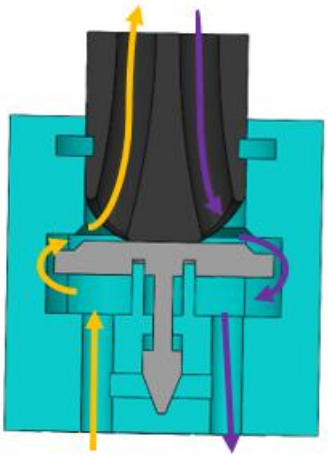
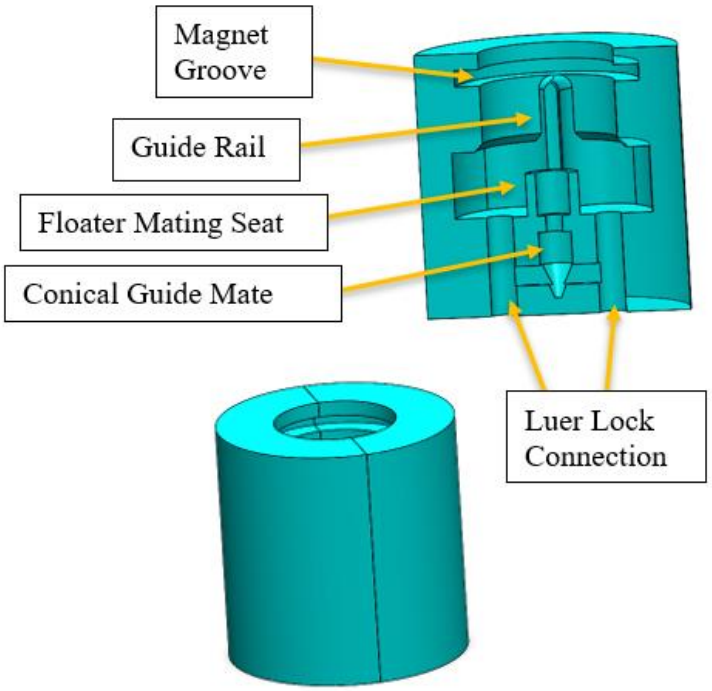
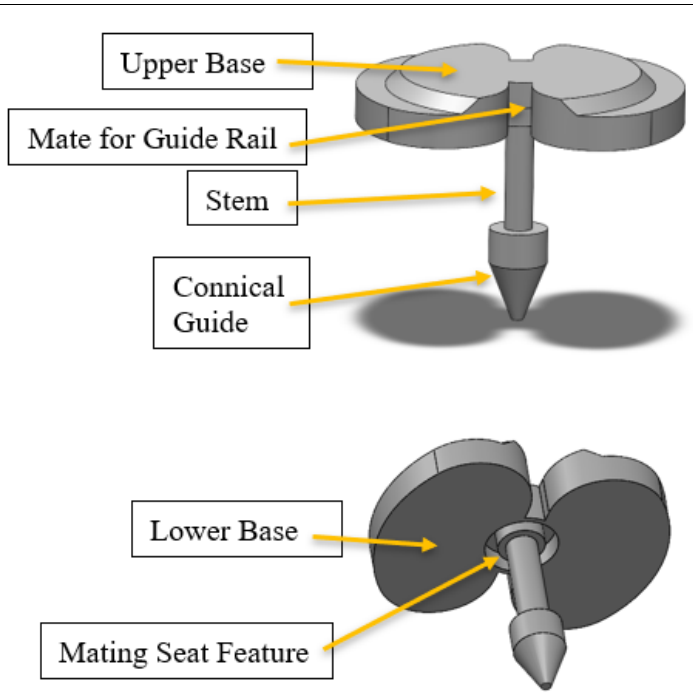
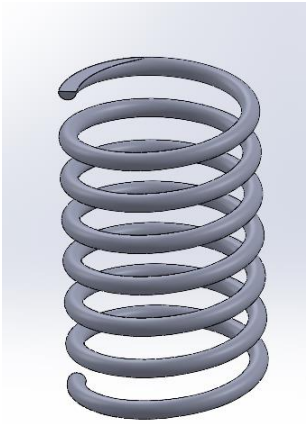


Figure 7. The orange arrows represent the flow path from the CVC to the wearable. The purple arrows represent blood flow path from the wearable back to the body.

energy required to move the floater distally. Once the floater contacts the mating geometries of the housing halves, the flow path is blocked (**Fig. 6A**).

Table 3. Bill of Materials for the Crushing Mechanism Assembly

Item No.	Component Name	Quantity in Assembly	Image
1	Housing Half	2	
2	Plug	1	

3	Floater	1	
4	Spring	Stainless Steel	
5	Magnet	Neodymium	N/A

4.2.2. Fabrication Results - Iteration 1

The settings used for the first iteration of fabrication are shown in **Table 6**. During removal of the floater from the platform of the printer, the stem split into two pieces. The fracture occurred at the point where the support structure fully encompassed the stem, which was not symmetric around the circumference. The side of the stem that had more contact with the support structure likely experienced stress from the heat of the new layers being added. Upon removal from the platform, the force exerted on the component likely translated to this area, causing fracture.

The material properties of the printed components were hard, brittle and lacked flexibility. These properties are characteristic of the PLA filament used, which is not ideal for parts that contact and move between one another, as this friction will lead to wear and breakdown of the material. Print settings like infill percent and pattern can be adjusted to decrease density of the components, which could alter the material properties slightly, but for the scope of this project the material properties will not be considered as it pertains to the intended design function.

The plug experienced distortion and flash on the sections of the part that were touching the platform. Filament buildup was present inside both of the lumens, but was removed mechanically from a deburring post-processing step. The housing halves had flash on edges that were touching the platform, and the interior features printed with low resolution. Despite the resolution being low, sharp angles were observed in the blood flow path. These angles can cause thrombosis and coagulation and should be modified. Additionally, it was determined that assembling a magnet into the housing halves and around the plug is not feasible. Thus, alternate methods for locking the system shall be considered.

Upon fitment of the components together, the upper base of the floater did not create a full seal with the housing half interior. This is attributed to the extruded cut radius in mate for guide rail being smaller than the radius of the guide rail in the housing half (**Fig. 8A**), meaning that blood can leak into the system even when disconnected. Attempting to overcome dimensional errors by pressing the floater into the guide rail caused stress cracking around the radial cut (**Fig. 8B**). Additionally, the mating seat feature in the housing half was smaller than the adjacent mating feature in the floater (**Fig. 8C**). This dimensional mismatch prevents the floater from experiencing full travel during connection and disconnection. Due to the components not assembling as intended, the mechanism of activation was not able to be analyzed.

It was not yet clear whether this is due to design flaws, prototype material selection, processing parameters or a combination.

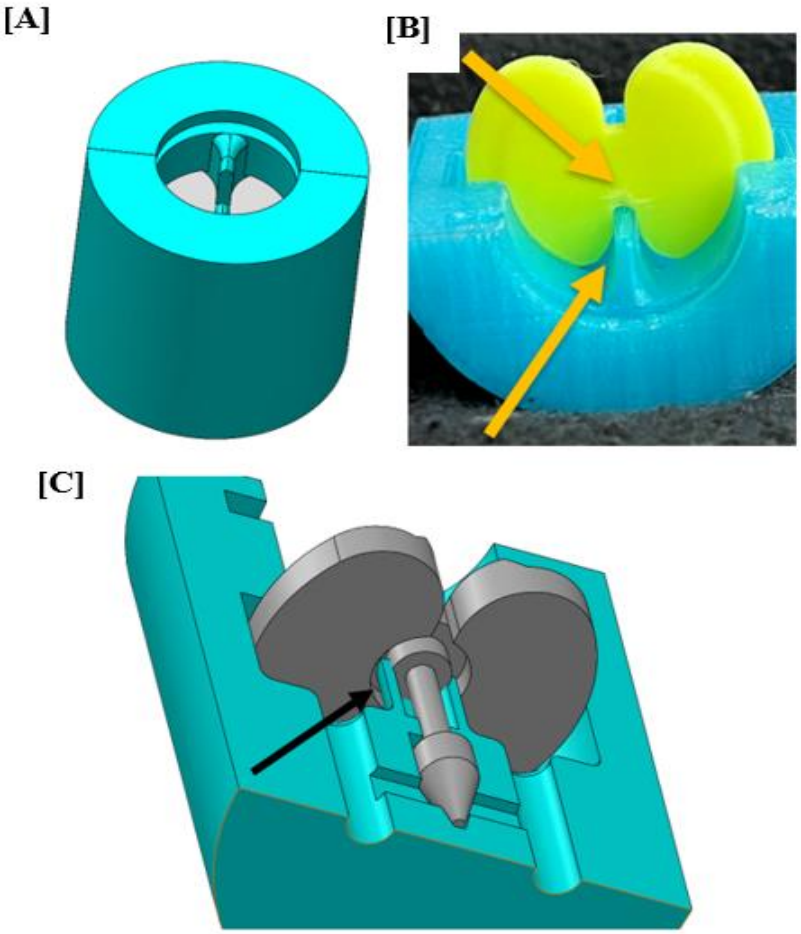
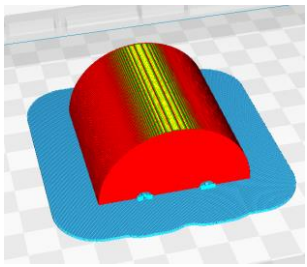
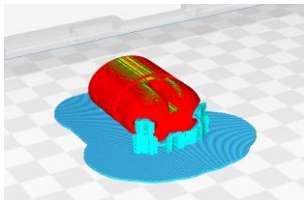
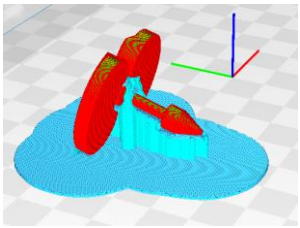


Figure 8. [A] SOLIDWORKS model showing both housing halves with floated enclosed. Th intended design is that geometry of floater seals off internal geometry of the housing halves, preventing blood flow when in disconnected state. [B] Iteration one print of floater and housing half shows that geometry of printed floater does not seal off the internal geometry of the housing half. Stress cracks forming on the floater at the interface between floater mating guide and housing half guide rail after component assembly. [C] SOLIDWORKS model intended design is that mating seat feature of housing half sits inside corresponding mating feature of the floater to assist in floater travel during connection and disconnection.

The proposed changes for iteration two for the housing are to add a fillet to all interior 90-degree angles, decrease the radius of the mating seat feature in the housing half from 0.200in to 0.175in, change build support from everywhere to touching build plate and adhesion type from raft to skirt. For the floater, increase the radius of the extruded cut mating feature from 0.200in to 0.225in, change print orientation from 45 degrees to -90 degrees and change adhesion type from raft to skirt for easier removal of the platform. It was decided that the plug does not need any immediate changes, so this component will be used with iteration two prints of the housing halves and the floater.

Table 4. Iteration 1 settings for the Plug Mechanism.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
Housing	4043D blue		235°C	60°C	Raft	Everywhere
Plug	3D870 yellow		235°C	60°C	Raft	Everywhere
Floater	3D870 yellow		235°C	60°C	Raft	Everywhere

4.2.3. Fabrication Results - Iteration 2

The settings used for the second iteration are shown in **Table 7**. For the floater, switching the platform orientation from 45 degrees to -90 degrees produced a successful print of the stem. Having the stem printed in the Z-direction means that the bond between the successive layers is weaker than the layers between the X and Y axes. While print orientation was successful due to the support structures contacting the component symmetrically around the stem, it is likely that the layers of extruded polymer are weaker than the previous iteration due to the anisotropic nature of this print.

In regards to the appearance of the floater, the resolution of the print was low, especially in the conical guide. This warpage can be attributed to the material fighting gravity as layers were added in the Z-direction. The support structures did not fill all the way to the conical guide, and this section of the component was the lowest resolution, likely because it did not have full supports to assist this section of the print (**Fig. 9A**). Additionally, switching the adhesion type from raft to skirt created flash and an unsmooth surface on the upper base, likely from the removal process (**Fig. 9B**).

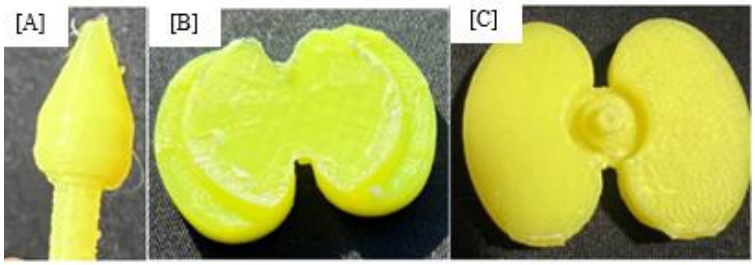


Figure 9. [A] Iteration two print of the floater conical guide. [B] Iteration two floater upper base after removal from the platform. [C] Iteration two floater view from lower base after stem break.

For the housing halves, changing the build support from everywhere to touching build plate created finer detail of the interior geometry with less flash and distortion upon removal from platform. It does not appear that changing the adhesion type from raft to skirt affected the overall appearance of the housing halves, likely because the print orientation has minimal surface area in contact with the platform. Despite

decreasing the radius dimension of the mating seat feature in the housing halves, it was still larger than the floater, which prevented full travel.

The floater was placed inside only one of the housing halves to give a section view of the mechanism (**Fig. 10B**). The assembly was put into the connected state to view the blood flow path. It required a large force to press the components into one another. Despite this large effort, the magnet grooves of the housing half and plug did not align. This misalignment is due to the floater travel distance being prevented by the dimensional errors in the mating seat feature of the housing half. With great enough force, the plug did displace the floater proximally, but the opening for the flow path was not sufficient. This force induced a large strain on the stem causing full fracture (**Fig. 10C**).

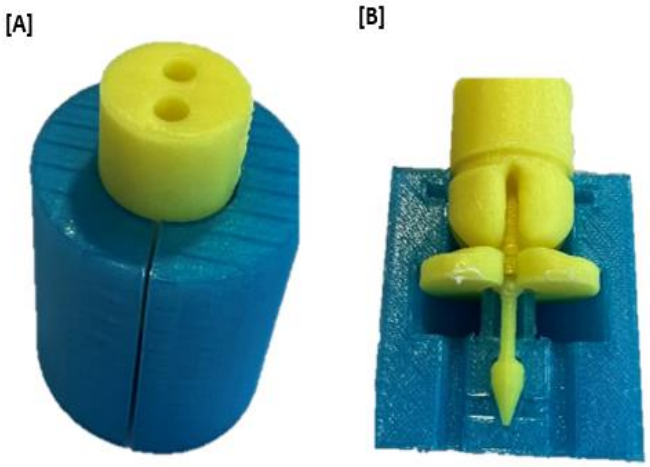
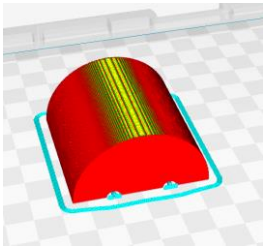
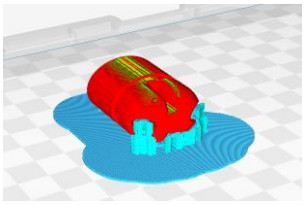
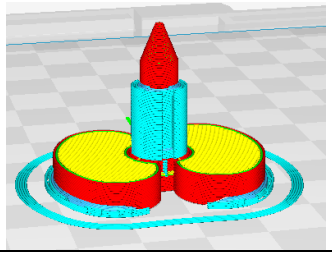


Figure 10. FDM printed prototype iteration two prior to conical stem breakage. [A] Full assembly in the connected state. [B] Sectional view of the assembly in inbetween connected and disconnected state.

The proposed changes for iteration three are to add a snap fit feature to the plug mechanism that would replace the locking function of the magnets. For the floater, increase the diameter of the stem from 0.12in to 0.14in, change build platform orientation from -90 degrees to 0 degrees and switch back to raft adhesion type. Lastly, for the housing, decrease the mating seat feature radius from 0.175in to 0.150in.

Table 5. Iteration 2 settings for the Plug Mechanism.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
Housing	4043D blue		235°C	60°C	Skirt	Touching Build Plate
*Plug from Iteration 1	3D870 yellow		235°C	60°C	Raft	Touching Build Plate
Floater	3D870 yellow		235°C	60°C	Skirt	Touching Build Plate

4.2.4. Fabrication Results - Iteration 3

The settings used for iteration three are described in **Table 8**. The setting changes for the floater showed enhanced appearance in comparison to iterations one and two. The

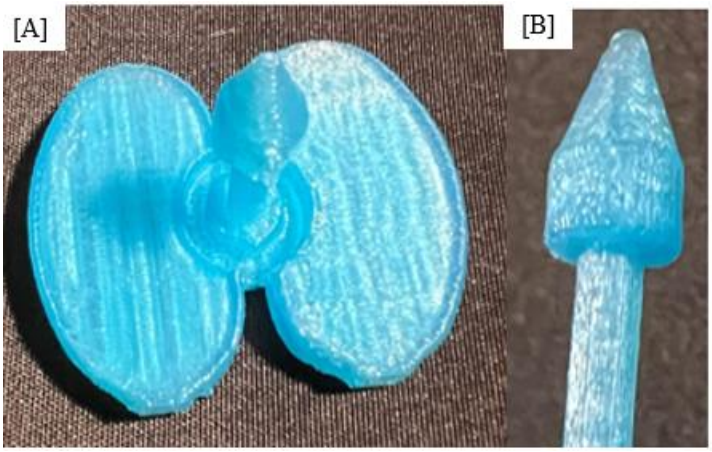


Figure 11. [A] Iteration three print of the floater. [B] Iteration three print of the floater conical stem.

geometry features had finer detail and less flash was observed as shown in **Fig. 11.**

The snap fit feature on the plug enabled for connection to the groove of the housing half, but insertion into the full assembly was prevented by the stiffness of the feature. Therefore, this locking feature is no longer the weakest point in the system and the intended design function will no longer be achievable (**Fig. 12A**). Further process development activities like using a more flexible material or adjusting the width of the base of the snap feature could continue to successfully attain this locking mechanism.

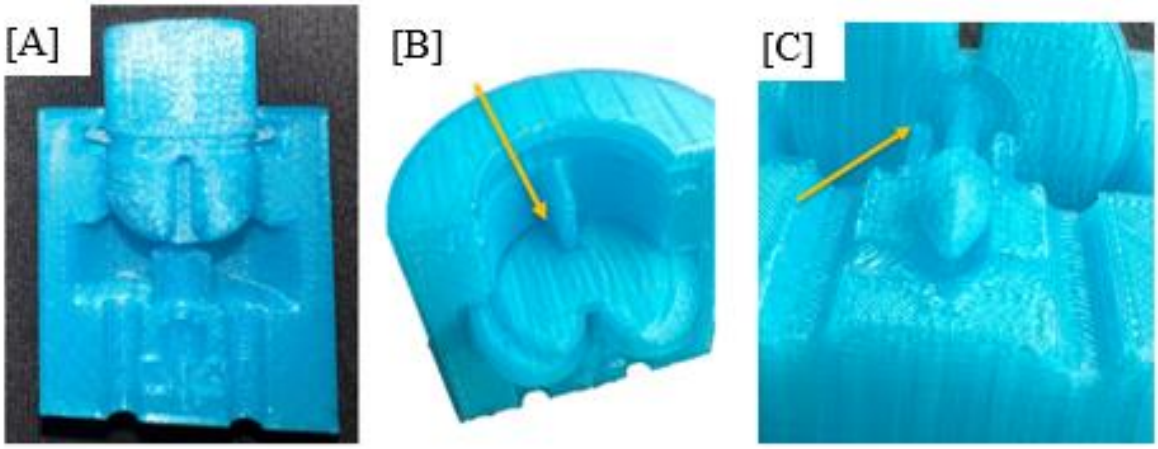


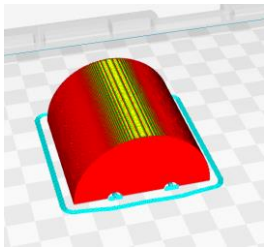
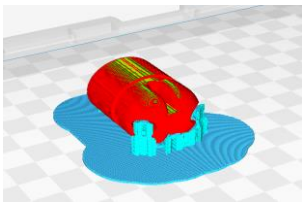
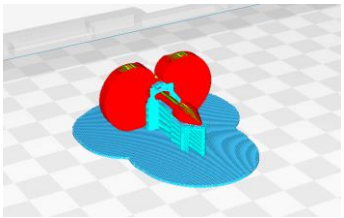
Figure 12.. [A] Plug with snap fit feature and Housing Half. Snap fit feature resting in the mating groove of the housing half, excluding the floater. [B]. Arrow is pointing to the open space between the floater and the housing half. This open space eludes to blood flow through the system during discconection. [C] The mating seat feature of the housing half does not fully sit inside of corresponding feature of the floater. This mismatch in dimensions limits travel of the floater.

When the floater and housing halves were mated together, the flow path still was not sealed. The amount the radius of the mating seat feature in the housing was decreased was not enough to allow the two to interface together, so the floater was unable to travel like the intended design. **Fig. 12B** and **Fig. 12C** point to these flaws.

Assembly of the components showed that they did not meet the intended form, fit and function of the design concept. The ability to press the plug into the housing halves required a large force as the guide rail and mating feature did not interface smoothly. Additionally, when the two housing halves were closed, the distance the

floater moved could not be witnessed as the system is not transparent. It is not certain if these failures are due to design or the limitations of the chosen processing and materials selection.

Table 6. Iteration 3 print settings for the Plug Mechanism.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
Housing	4043D blue		235°C	60°C	Skirt	Touching Build Plate
Plug	4043D blue		235°C	60°C	Raft	Touching Build Plate
Floater	4043D blue		235°C	60°C	Raft	Touching Build Plate

The PLA filament was chosen due to its ease of printing. The data sheet for the PLA filament gives an ultimate tensile strength of 60 MPa, elastic modulus of 3.6 MPa, and flexural modulus of 3.8 MPa *(23)*. These properties are attributed to the components being very rigid and strong, but very brittle, which was shown throughout the fabrication iteration. These properties may be suitable for the outer surface of the housing, but the interior of the housing halves, floater and plug need low-friction to easily slide past one another, without generating particulate.

This design must consider blood compatibility as these materials are in-contact with blood flow. The material selection is ultimately limited by FDA approved blood contacting material. Therefore, some suitable materials for this application may be polyetheretherketone (PEEK), Polysulfone (PSF) or Polyether Block Amide (PEBA). PEEK and PSF are more rigid than PLA with an ultimate tensile strength of 91 MPa and 70MPa and an elastic modulus of 3.9 and 3.2MPa *(24)*. PEBA exhibits a similar ultimate tensile strength of 45MPa but is more flexible with an elastic modulus of 160MPa *(25)*. These materials are not easily 3D printed, but can be processed by injection molding.

The design meets all of the inputs, but analysis of safety of this design is a concern as the nonlinear flow path poses risk of thrombosis and coagulation. Unintendedly, this design is a reversible process. By changing the mode of valve activation to being non-reversible, higher forces could be used to block the flow path, as destruction of the system is no longer a concern. Additionally, this design shuts off flow in both inlet and outlet ports, which is not a requirement for this device. In the event of an emergency, only stopping blood flow from the outlet port is necessary. By taking these factors into consideration, the device has the possibility to be external to the flow path, which would remove introduction of new materials into the system. The challenge of creating a linear flow path was addressed during a brainstorming session with Jeremy Barribeau, a CDI team member. He proposed a conceptual idea of having a segment of tubing, similar to the CVC, and a mechanism that would "crush" the tubing to stop the flow. These ideas inspired the second design concept.

4.3. Concept Development - Crushing Mechanism via Pin

4.3.1. Design Concept

The second proposed design will be referred to as the "Crushing Mechanism via Pin". It is composed of the following components: CVC Connector, Backpack

connector, Pin Assembly, Luer lock to Barb Connectors, and magnets (**Table 4**). This design is external to the system and interfaces between the outlet CVC lumen and the AV tubing of the wearable.

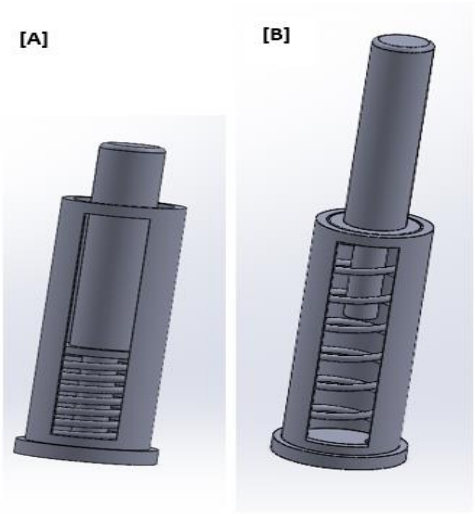


Figure 13. [A] Pin assembly experiences spring compression in the connected state. [B] Pin assembly experiences spring relaxation in the disconnected state.

The CVC connector will attach to the outlet lumen of the CVC via luer lock. It contains the pin assembly, a piece of tubing that is softer than the CVC and AV tubing, and three magnets. The pin assembly is made of three components; pin, pin body and spring. The stem of the pin inserts into the inner diameter of the spring, and the pin body encompasses these components (**Fig. 13**).

The backpack connector contains three magnets, and a luer lock. This is the attachment point to the wearable. When the CVC connector and backpack connector are mated together, the magnets lock the system in place. A retention feature on the backpack connector functions to put the pin assembly in compression (**Fig. 14A**). Similar to the plug mechanism, the magnet force will be designed to be less than the ISO 10555 standard of 3.37lbf, making this connection the weak point in the system *(22)*. Thus, when the system experiences a large tensile force, the CVC connector and wearable connector will disconnect. Upon disconnection, the feature that compresses the crushing pin is removed and all the energy stored during compression of the spring

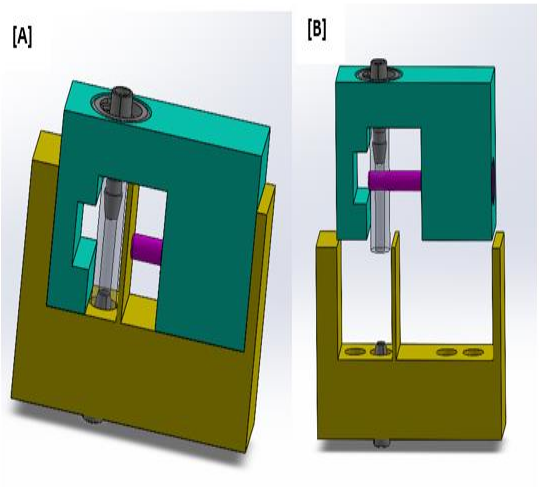
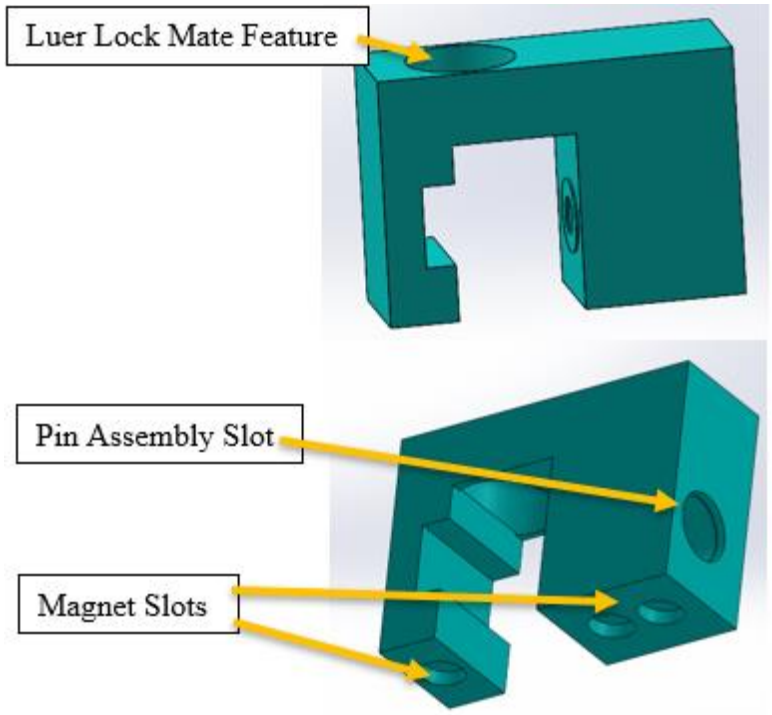
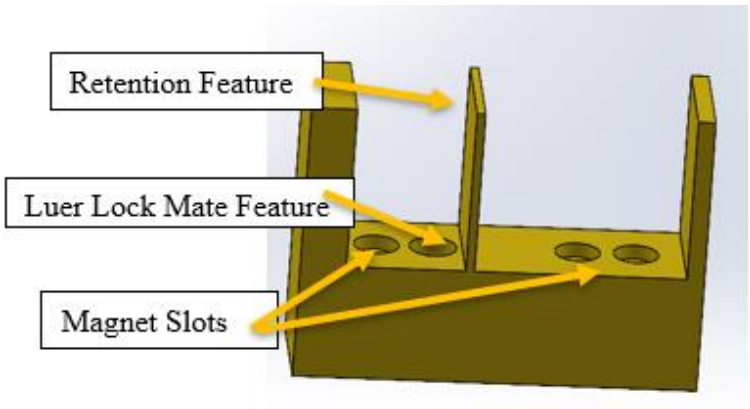
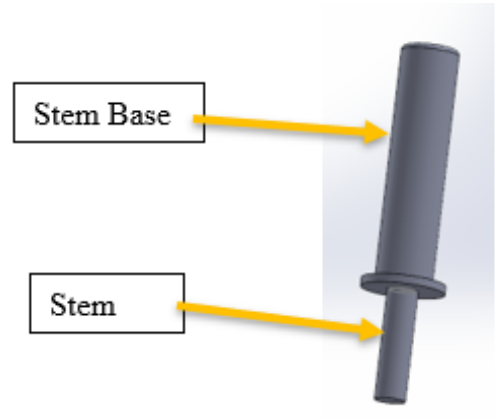
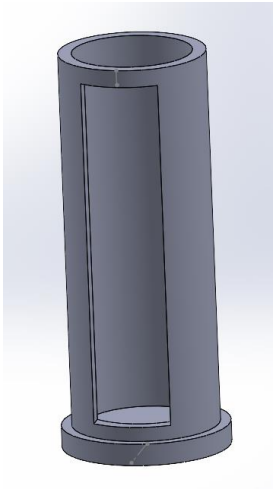
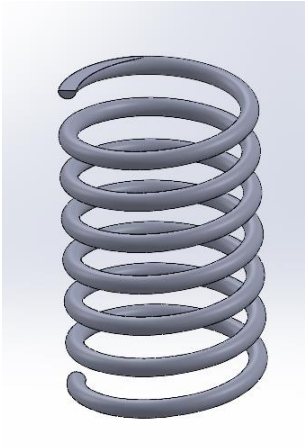


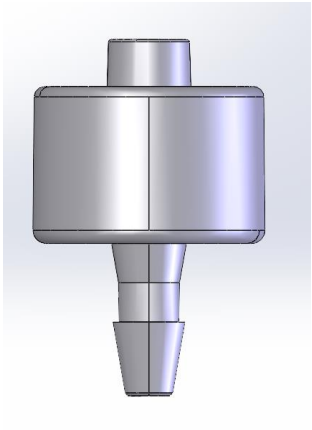
Figure 14. [A] Crushing Mechanism with Pin in connected state. [B]. Crusing mechanism in disconnected state.

will transfer to release the pin, crushing the soft durometer tubing, thus stopping blood flow (**Fig. 14B**).

Table 7. Bill of Materials for the Crushing Mechanism via Pin.

Item No.	Component Description	Quanity	Image
1	CVC Connector	1	
2	Backpack Connector	1	

3	Pin	1	
4	Pin Body	1	
5	Spring	1	

6	Male Luer Lock to Barb Connector	2	
7	Magnets	6	

4.3.2. Fabrication Results – Iteration 1

For this design, multiple options of the non-printed components were obtained to test the best fitment into the assembly. Two springs (McMaster Carr PN: 9657K608 and 9657K605), six magnets (McMaster Carr PN: 5862K137), two Male Luer Lock to Barb Connection (Qosina PN: 11399) and silicone tubing (Masterflex PN: 966410-13).

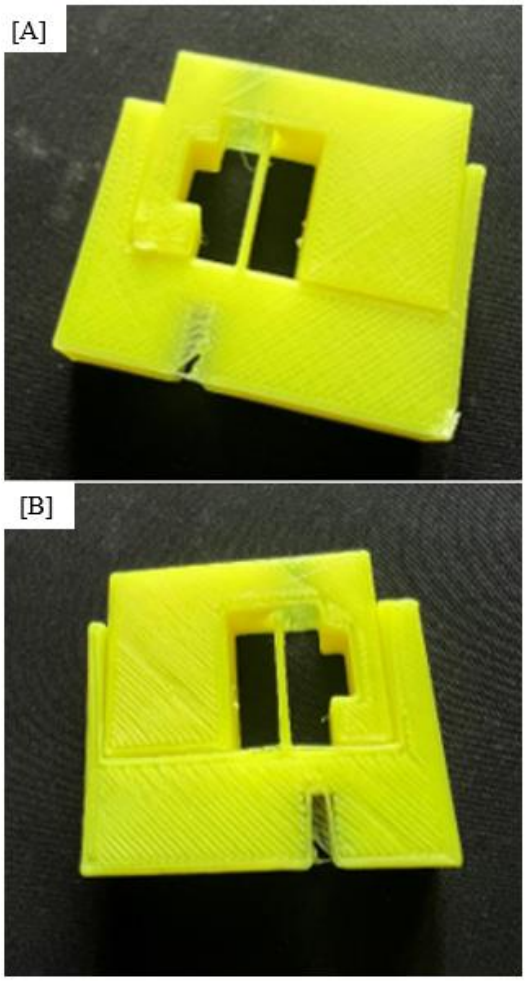


Figure 15. [A] Top side of CVC Connector and Backpack Connector after iteration one print. [B] Platform touching side of CVC connector and Backpack Connector. Wall thickness near the Male Luer Lock to Barb Connector feature was too thin for printer to add successive layers on both sides of components.

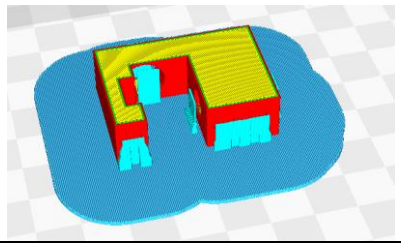
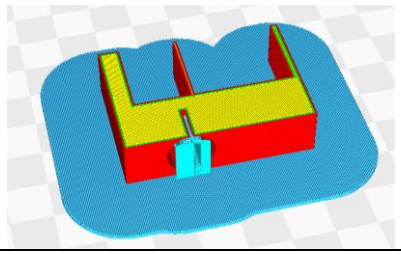
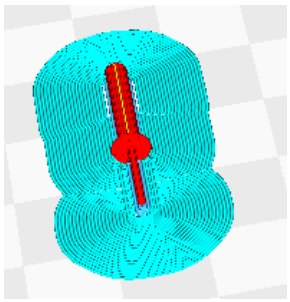
The settings used for iteration one is listed in **Table 9**. The printed CVC connector and Backpack connector had overall poor aesthetic appearance, as signified by flash and warpage. The raft adhesion type used excess material as a barrier between the platform and the part, which did not seem necessary for a successful print. The wall thickness around the mating feature for the luer lock to barb connector was thinner than the layer thickness print capability creating a zero geometry, which translated to a lack of material in those areas (**Fig. 15**). Additionally, the diameter was not large enough to accommodate for fitment of the male luer lock to barb connector.

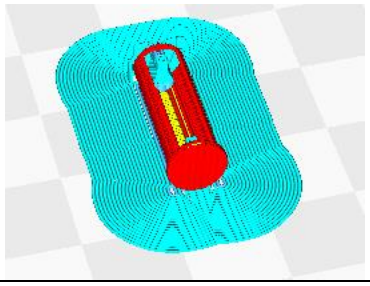
The print of the pin and pin body was not successful. Furthermore, it was realized that the magnets (5862K137) were too small for the slots and the springs (9657K605

and 9657K608) were not long enough to create the desired amount of travel within the pin assembly. Because the magnets and springs were not the proper size and the pin assembly failed, the disconnection of the connectors was not analyzed for this iteration.

The proposed changes for iteration two are to increase the width of the CVC connector and backpack connector from 0.45in to 0.47in, increase the male luer lock to barb connection mating feature diameter from 0.43in to 0.45in, change adhesion type from raft to brim and to obtain new sizes of magnets and spring that will integrate with the dimensions of the assembly.

Table 8. Iteration 1 settings for the Crushing Mechanism via Pin.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
CVC Connector	3D870 yellow		235°C	60°C	Raft	Touching Build Plate
Backpack Connector	3D870 yellow		235°C	60°C	Raft	Touching Build Plate
Pin	4043D blue		235°C	60°C	Brim	Touching Build Plate

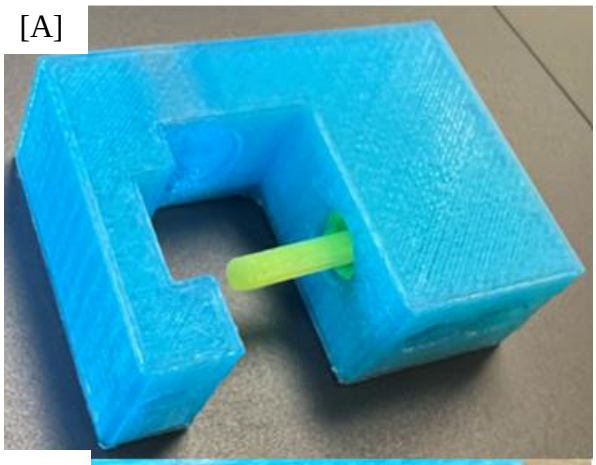
Pin Body	4043D blue		235°C	60°C	Brim	Touching Build Plate

4.3.3. Fabrication Results - Iteration 2

The settings used to print the iteration two components are described in **Table 10**. New magnets and spring were purchased from McMaster Carr (PN: 5862K139 and 9001T15). The print of the CVC connector and backpack connector showed similar surface quality, but there was a higher degree of warpage when connected (**Fig. 16B**). The chosen width increase was not sufficient, as the wall thickness was still too thin for the printer (**Fig. 16B**).

The new magnets were a more adequate dimension but the magnet slot needs to be enlarged and lengthened to allow for better integration. Additionally, the increased diameter for the male luer lock to barb

[A]



[B]

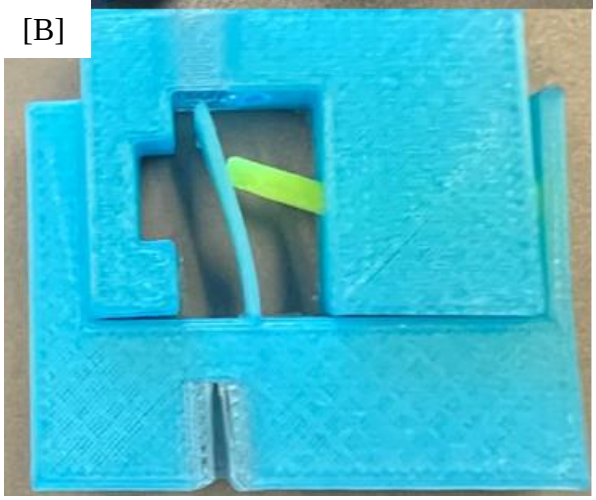


Figure 16. [A] Print of Iteration two CVC Connector, with Pin Assembly loaded into mating feature. Compression of the pin was inhibited due to dimensional mismatch between mating feature of CVC connector and pin body. [B] Backpack Connector loaded into CVC connector to show connected state. Pin body pressed back onto retention feature of the Backpack connector as compression of pin was inhibited due to dimensional issues with the system.

connector mating feature was not sufficient in allowing for interfacing the barb connector into the CVC and Backpack connectors.

The pin, pin body and spring had adequate fitment despite poor appearance and quality of the printed components (**Fig. 17**). The new spring possessed a more desirable length, as it was able to be compressed and relaxed when force was applied to the pin. But the mating slot diameter of the CVC connector was too small for proper fitment of the pin assembly. A high force was needed to install the pin assembly, but eventually was completed. While in the mating feature, the pin did not compress and relax like it did prior to installment. This is attributed to the CVC connector slot compressing on the pin body leading to a reduced overall diameter, which decreased the space needed by the spring to expand when it is compressed.

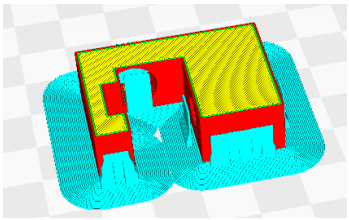
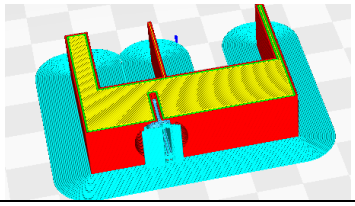
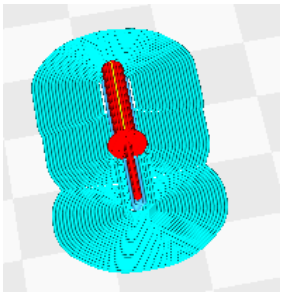
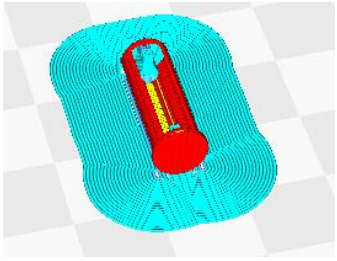
Figure 17. Iteration two print of Pin and Pin Body assembled with spring.

Despite the pin assembly integration failure, the CVC to Backpack connection was still tested. Because the pin would not compress, it exerted a force on the retention feature of the backpack connection, pressing it into the intended flow path (**Fig. 16B**). In order to remove the stress on the pin assembly and increase crushing force, the overall pin assembly needs an increased outer diameter dimension and length. This will cascade to changes in mating dimensions of the CVC and backpack connectors as well.

The proposed changes for iteration three are to change the outer dimension of the pin body from 0.180in to 0.250in. For the pin, increase the outer dimension of the stem from 0.05in to 0.075in and remove 0.020in from the length to allow for more

travel and compression of the spring. For the CVC and backpack connectors: Increase the width from 0.47in to 0.52in, increase the magnet slot diameter from 0.1875in to 0.200in and the depth from 0.0625in to 0.0655in. Lastly, increase the outer diameter of the male luer lock to barb connector mating feature from 0.45in to 0.47in. The printer settings seemed to be sufficient for removal from platform and of support features, so the settings will remain the same for iteration three.

Table 9. Iteration 2 settings for the Crushing Mechanism via Pin.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
CVC Connector	4043D blue		235°C	60°C	Brim	Touching Build Plate
Backpack Connector	4043D blue		235°C	60°C	Brim	Touching Build Plate
Pin	3D870 yellow		235°C	60°C	Brim	Touching Build Plate
Pin Body	3D870 yellow		235°C	60°C	Brim	Touching Build Plate

4.3.4. Fabrication Results - Iteration 3

The settings used for printing iteration 3 are described in **Table 11**. The overall appearance of the printed components was better than iterations one and two with less flash and cleaner lines. The CVC and backpack connector width increase from 0.47in to 0.52in was sufficient in closing the gap that was seen in iterations one and two and the increase in male luer lock to barb connection feature enabled component fitment. The changes to the pin assembly showed improvement on compressibility and distance of travel. The increase in outer diameter of the pin slot in the CVC connector was sufficient in allowing the pin assembly to fit inside without inhibiting pin and spring motion.

The magnet slot dimensional updates were sufficient for fitment of the magnets. When attempting to test the locking connection between the CVC and backpack housing, the magnets pulled out of the slots due to their attraction to one another. To fully test this mechanism the magnets would need to be adhered into the slots. For the purposes of this build, the connection between the CVC and backpack connectors was analyzed without the magnets. In the assembly connected state, the retention feature of the backpack connector was sufficient in compressing the pin assembly (**Fig. 18**). But when the assembly was disconnected, the pin did not have enough force to sufficiently crush the tubing.

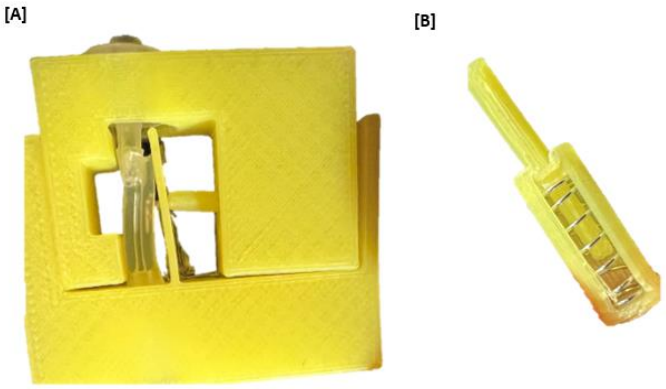
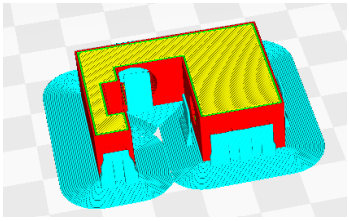
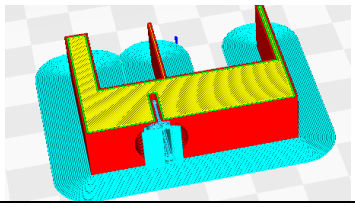
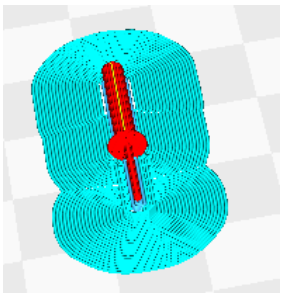
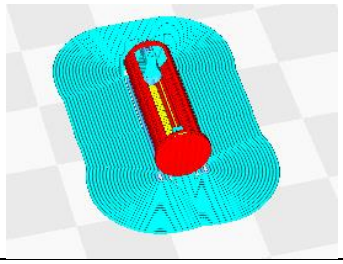


Figure 18. [A] FDM printed prototype of the Crushing Mechanism Assembly and sourced Male Luer Lock to Barb Connector, magnets and scrap tubing. [B] FDM printed prototype of the Pin Assembly and the sourced spring.

Table 10. Iteration 3 settings for the Crushing Mechanism via Pin.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
CVC Connector	3D870 yellow		235°C	60°C	Brim	Touching Build Plate
Backpack Connector	3D870 yellow		235°C	60°C	Brim	Touching Build Plate
Pin	3D870 yellow		235°C	60°C	Brim	Touching Build Plate
Pin Body	3D870 yellow		235°C	60°C	Brim	Touching Build Plate

The Crushing Mechanism via Pin was designed with the intent of being external to the system, maintaining a linear blood flow path, and only inhibiting the outflow of blood from the outlet port of the CVC. While this valve is activated from a tensile force, the force of connection and disconnection was not tested because the pin assembly did not show an achievable solution. The pin did not successfully apply enough force on the tubing to prevent flow. One way to increase this force would be to enlarge the circumference of the pin assembly to allow for a larger spring. But this enhancement

would increase the overall width of the system, and consequentially a heavier device. Additionally, switching the material of the pin assembly from PLA to a metal alloy like stainless steel would give enhanced mechanical properties like strength and rigidity that would translate to a higher force of crush.

While this design has limitations, it did successfully create a linear blood flow path and changed to a disruptive system. By limiting blood contact to only the piece of tubing, the choice of material for the other components is widened. The internal tubing portion should be made of medical-grade silicone or poly (vinyl chloride) (PVC), as these are FDA approved blood compatible materials. The connectors need to exhibit durability while being comfortable residing against the patient body. A suitable material for these materials may be polycarbonate (PC) due to wear and impact resistance *(24)*. The results and observations of this build inspired the third design. This mechanism which utilizes a similar approach to disconnection but changes the mechanism of crushing was conceptualized by Barribeau. The design and creation of the model was completed by the researcher.

4.4. Concept Development - Crushing Mechanism Via Flat Spring

4.4.1. Design Concept

The third proposed design will be referred to as the “Crushing Mechanism via Flat Spring”. The assembly consists of a Backpack Housing, CVC Housing, Overmold

Tube Support, a Flat Spring formed from sheet stock, soft durometer tubing and Male Luer Lock to Barb Connector (**Table 5**).

Barribeau proposed an idea for maintaining the same blood flow environment as CVC catheters by using a piece of tubing within this device. This segment of tubing should be a soft durometer of PVC or a medical grade silicone to allow for easier crushing. This tube will be overmolded into the overmold tube support and slid into the corresponding feature in the CVC housing (**Fig. 19**), which will ensure that during an event that causes disconnection, the tubing remains within the CVC housing. The formed flat spring resides in the mating groove of the CVC housing. When the backpack housing is pressed into the CVC housing, the flat spring is set into compression by the retention features of the backpack housing. The barb connector from the CVC housing inserts and locks into the interior diameter of the soft durometer tubing. The design includes a V-lock feature between the CVC and backpack housing that is replacing the magnet connection from the crushing mechanism via pin. The final dimensions can be adjusted to increase or decrease the amount of force required to remove the components from one another.

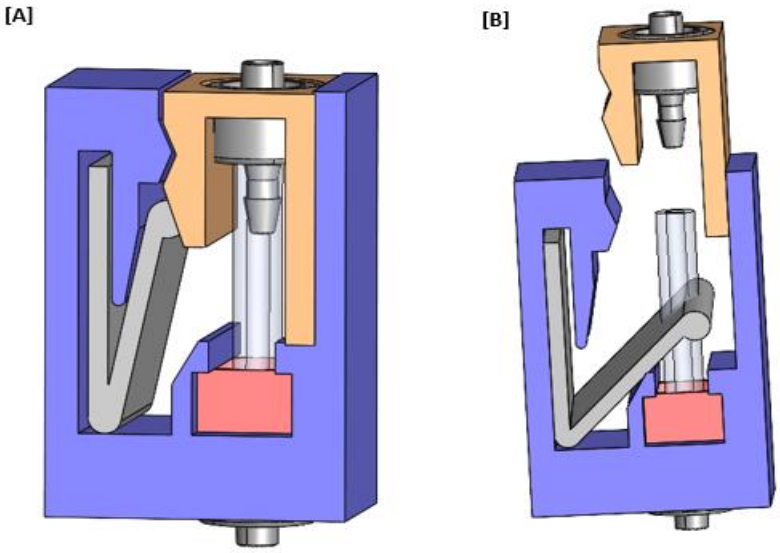
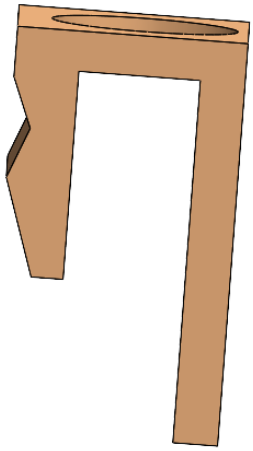
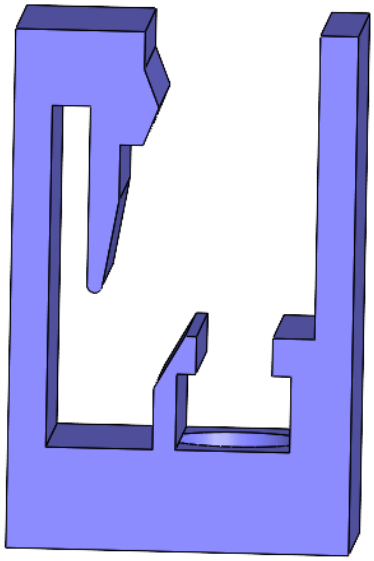


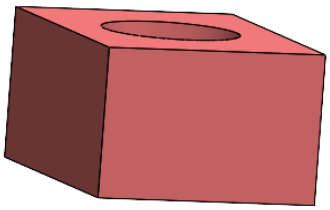
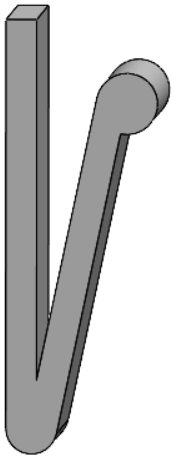
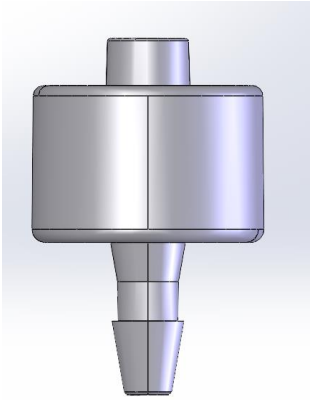
Figure 19. [A] Connected State. [B] Disconnected State.

The CVC housing will connect to the outlet port of the CVC via luer locks, and the Backpack housing will connect to the wearable. When connected, this system will

be the interface between the blood coming from the body and into the dialyzer. If the system were to experience a large tensile force, the backpack housing will disconnect from the CVC housing, and the barb connector will pull out of the inner diameter of the tubing. This will cause the flat spring to go into its relaxed form and crush the soft durometer tubing (**Fig. 19B**). The force of the flat spring will be designed to be sufficient to stop blood flow through the tubing.

Table 11. Bill of Materials for the Crushing Mechanism via Flat Spring

Item No.	Component Description	Quantity	Image
1	Backpack Housing	1	
2	CVC Housing	1	

3	Overmold Tube Support	1	
4	Flat Spring	1	
5	Soft Durometer Tubing	1	N/A
6	Male Luer Lock to Barb Connector	2	

4.4.2. Fabrication Results - Iteration 1

The settings used for the printed components are described in **Table 12**. In addition to the printed components, a few options of flat spring raw stock were purchased from McMaster Carr (PN: 9293K263 and 1845N8). This material was used

to form the flat spring. Additionally, luer lock to barb connector (Qosina PN: 11399) and Polydimethylsiloxane (PDMS) tubing from Thoratec laboratories corporation were used for assembly.

It was discovered that the nominal temperature of 235°C is for only the 3D870 yellow filament and the 4043D blue filament is 220°C per the filament packaging labeling. Dropping the print temperature 15°C greatly increased the overall appearance of the components when printing with 4043D blue and allowed for effortless removal from the build platform and of the supports.

The first CVC and Backpack housing model did not contain holes for the luer locks and tubing because these components are not necessary to observe the crushing mechanism. After fitment of the CVC and Backpack housing was shown to be sufficient they were added in. The print of the overmold tube support structure failed, as the additive layers did not properly adhere during the process. This component will be excluded from the form, fit and function analysis of this iteration.

The constant force spring raw stock (PN: 9293K111) was cut to two-inches and formed to have a 90-degree bend opposite the natural spring direction in the center. The resulting product will be described as the flat spring (**Fig. 20C**). This flat spring was then inserted into the mating feature of the CVC housing so that when the backpack housing was inserted into the assembly, it put the flat spring in a compressive state (**Fig. 20A**).

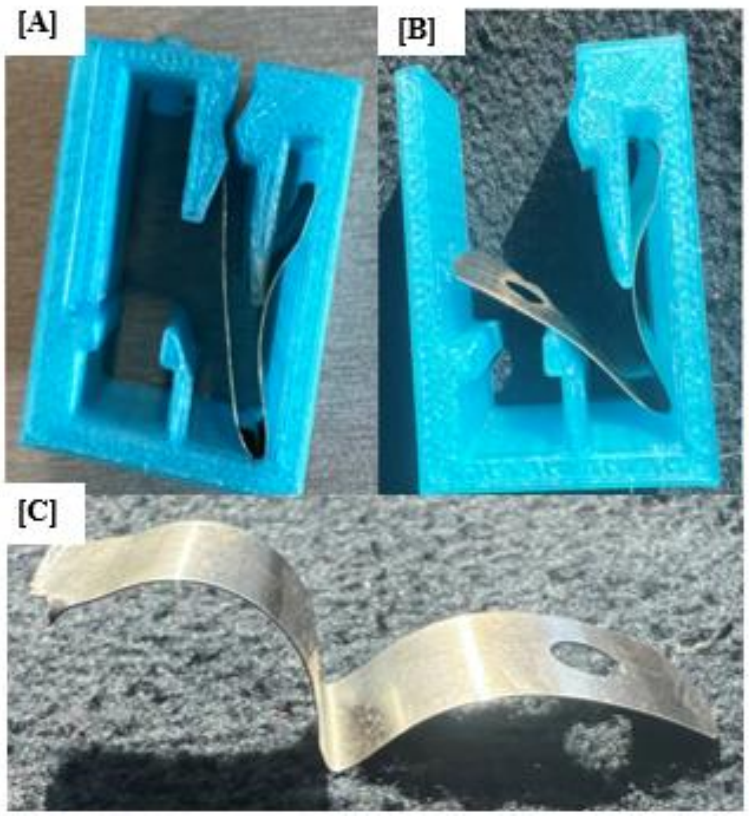


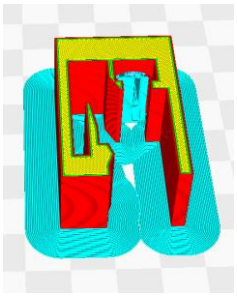
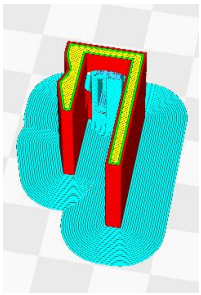
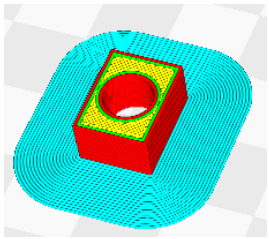
Figure 20. Orientation of how the flat spring shall be installed into the CVC housing component [A] Crushing Mechanism via Flat Spring Assembly set in connected state. [B] Disconnected state from removal of Backpack Housing. [C] Flat spring cut to length from spool and bent into shape.

The flat spring caused displacement of the backpack housing, limiting locking function of the V-lock feature. Upon disconnection of the backpack housing from the CVC housing, the flat spring converted to the relaxed state with great force until it contacted the adjacent wall of the CVC housing. This showed great promise for crushing soft durometer tubing.

The proposed changes for iteration two are to incorporate cuts for the tubing in the CVC housing and the Backpack housing. In the final design, the length of the flat spring from the bend to the retention feature should be decreased so that when residing against the backpack retention feature, it does not transfer as much force onto it, but

for these iterations, the same spring will be used as the fabrication process was difficult. Thus, the height of the CVC housing mating feature will be increased to allow for the flat spring to contact the backpack housing at a lower point.

Table 12. Iteration 1 settings for the Crushing Mechanism via Flat Spring.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
CVC Housing	4043D blue		220°C	60°C	Brim	Touching Build Plate
Backpack Housing	4043D blue		220°C	60°C	Brim	Touching Build Plate
Overmold Tube Support	4043D blue		220°C	60°C	Brim	Touching Build Plate

4.4.3. Fabrication Results - Iteration 2

The settings used for iteration two are described in **Table 13**. The overmold tube support printed successfully, but showed thin spots on the width edges (**Fig. 21**). The overall appearance of the printed components was satisfactory, and removal from the platform and support structures was completed with ease due to using the recommended nozzle temperature.

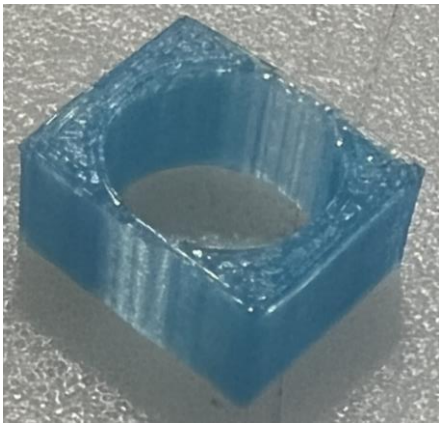


Figure 21. Iteration two print of the overmold tube support. Wall thickness on width edgares are thinner in comparison to the length edges.

All components mated together as intended, except the extruded cuts for the luer lock to barb connector feature were larger than the outer diameter of the luer lock. Cyanoacrylate adhesive could be applied to adhere the components together, but it was decided that the model will be updated instead.

The components were assembled into the mock full assembly, despite not fitting completely snug to test the mechanism of the flat spring (**Fig. 22A**). **Fig. 22B** shows that after removal of the backpack connector, the flat spring successfully contacted the tubing. The contact appears to be sufficient in closing the inner lumen, which would prevent fluid from flowing through.

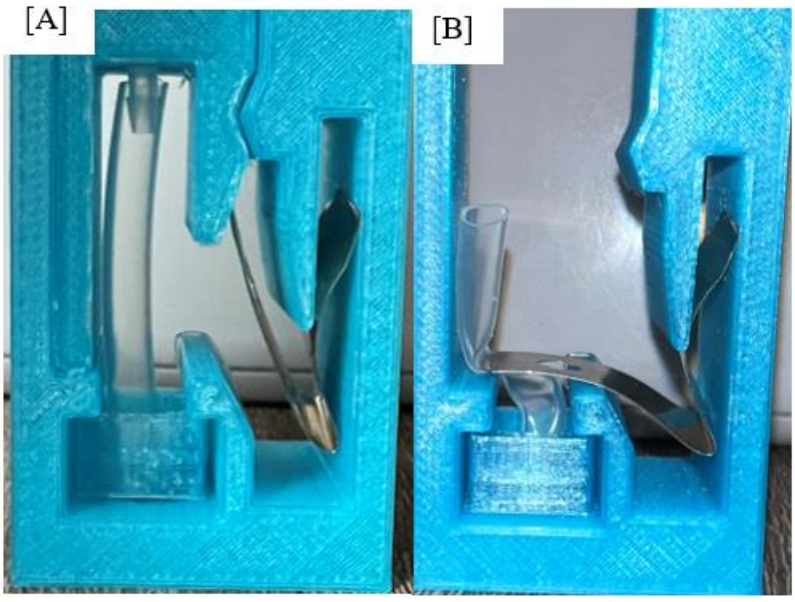
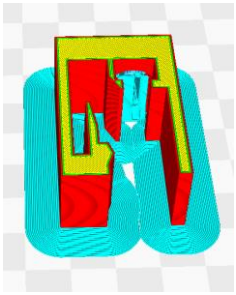
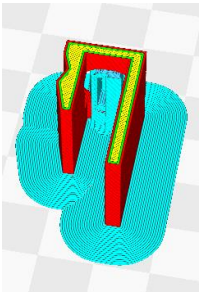
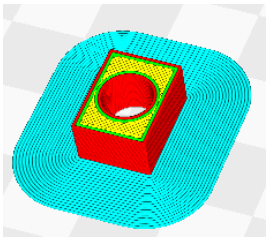


Figure 22. [A] Crushing mechanism via flat spring in the connected state. [B] Crushing mechanism via flat spring in the disconnected state. Flat spring successfully crushed the soft durometer tubing.

The proposed changes for iteration three are to increase the diameter of the luer lock to barb connection from 0.460in to 0.475in of the CVC housing. For the backpack housing and overmold tube support, decrease the diameter from 0.460in to 0.200in. Testing this prototype for proof of concept does not require a connection method at this location, and therefore changing the dimension to fit the outer diameter of the silicone tubing is sufficient.

Table 13. Iteration 2 settings for the Crushing Mechanism via Flat Spring.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Quality	Adhesion Type	Build Support Placement
CVC Housing	4043D blue		220°C	55°C	Medium	Brim	Touching Build Plate
Backpack Housing	4043D blue		220°C	55°C	Medium	Brim	Touching Build Plate
Overmold Tube Support	4043D blue		220°C	55°C	Medium	Brim	Touching Build Plate

4.4.4. Fabrication Results - Iteration 3

The settings used for iteration three are described in **Table 14**. The surface quality of the components was satisfactory with minor flash around the edges of the components. The print results are shown in **Fig. 23.**

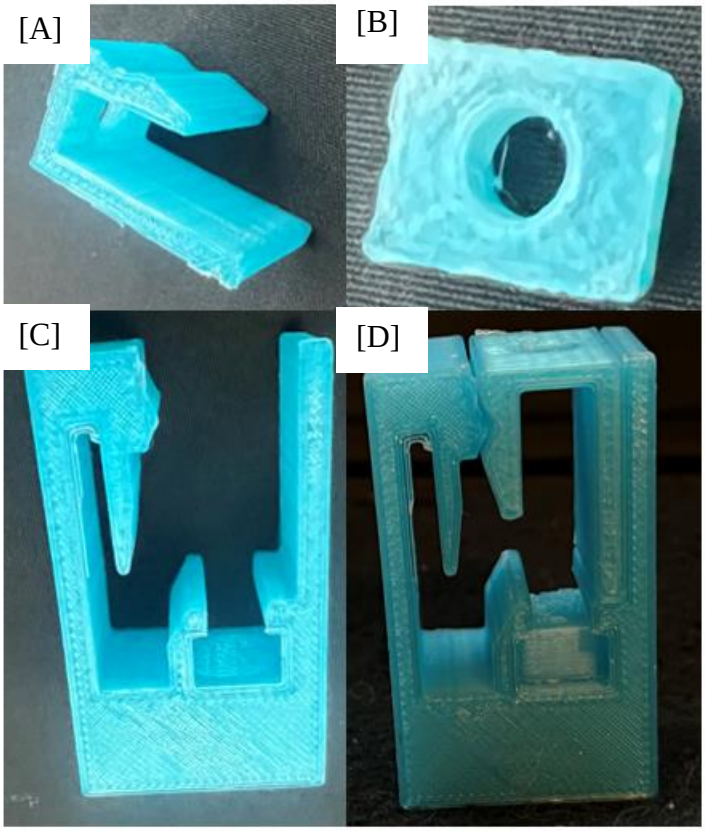


Figure 23. Iteration three prints. [A] Backpack Housing. [B] Overmold tube support. [C] CVC housing. [D] The components in the final assembly.

Increasing the outer diameter of the CVC housing to 0.476in allowed enough room for the luer lock to barb connector to fully seat within the groove. The initial fitment of the components was determined to be satisfactory.

The same flat spring from iteration one was installed into the mating groove of the CVC housing. Polydimethylsiloxane (PDMS) tubing from Thoratec laboratories corporation was loaded through the overmold tube support and slid into the mating feature of the CVC housing. The luer lock to barbed connector was placed into the mating groove of the CVC housing so that the barbed portion inserts into the inner diameter of the PDMS tubing. The outer circumference of the luer lock to barb connection was adhered to the CVC housing using Loctite 4011 cyanoacrylate adhesive. The free end of the PDMS was fed through the 0.200in diameter cut in the backpack housing until the backpack housing was mated into the CVC housing (**Fig 24A**).

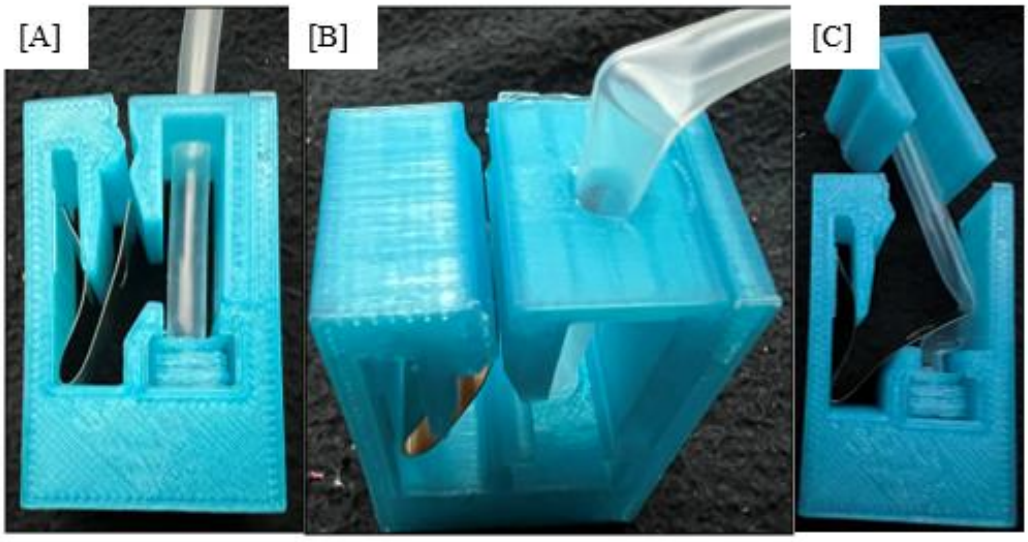
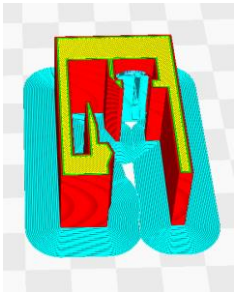
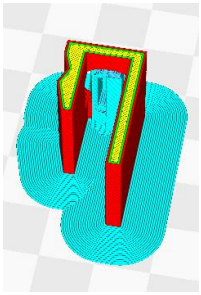
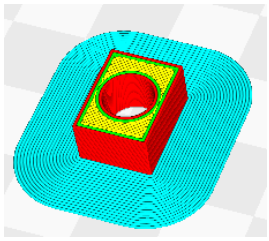


Figure 24. [A] The crushing mechanism via flat spring assembled into connected state, including luer lock adhered into CVC housing. [B] Top view of the crushing mechanism via flat spring. The Backpack housing was modified to remove the luer lock mating feature and create a hole that fits the outer diameter of the PDMS tubing. [C] The crushing mechanism via flat spring in the disconnected state.

Table 14. Iteration 3 settings for the Crushing Mechanism via Flat Spring.

Component	Filament	Orientation on Platform	Nozzle Temperature	Platform Temperature	Adhesion Type	Build Support Placement
CVC Housing	4043D blue		220°C	55°C	Brim	Touching Build Plate
Backpack Housing	4043D blue		220°C	55°C	Brim	Touching Build Plate

Overmold Tube Support	4043D blue		220°C	55°C	Brim	Touching Build Plate

The crushing mechanism via flat spring has met all design inputs while showing promise for stopping fluid flow through the interior of the lumen and was therefore chosen as the final design. **Fig. 25** shows two representative depictions of how the designer envisions the valve to integrate between the CVC outflow port and the AKTIV device. This prototype will be subjected to characterization testing to quantify the performance in stopping flow through the tubing after experiencing a tensile force causing disconnection.

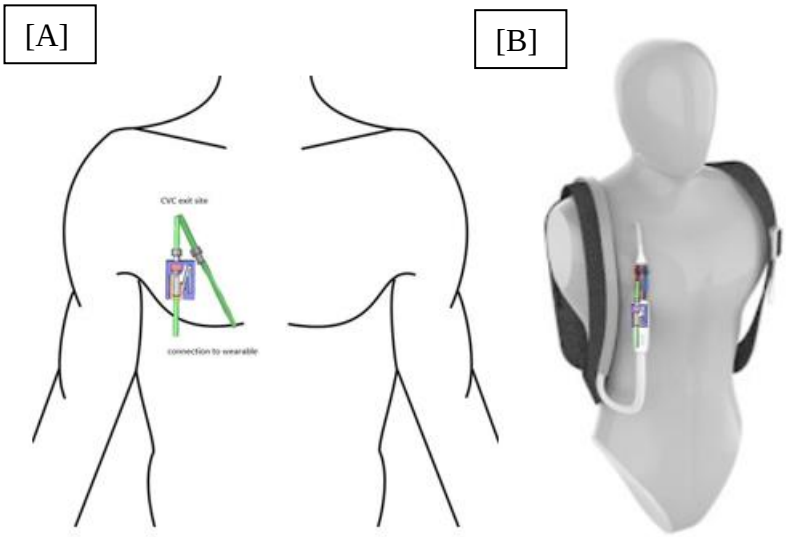


Figure 25. Schematic of how the crushing mechanism via flat spring valve would be placed within the wearable/portable hemodialysis system.[A] This image excludes the wearable from the depiction to emphasize that the valve is an intermediate connection between the CVC outflow port and the associated AV for the wearable. [B] This schematic was created by Barribeau and adapted by transposing the Crushing Mechanism via Flat Spring to reflect the researcher‘s vision for how the AKTIV device will be made wearable with the valve incorporated into the connection *(1), (16).*

4.5. Characterization Testing

The purpose of the characterization testing was only to get a baseline of how the prototype is performing. The described test methods were limited based on available tools and methodology. The materials for this prototype are not the final ones, therefore the test methodology did not need to be fully developed. The chosen methodology will need to be developed further for the final product as materials are critical to the overall function of the device.

4.5.1. Disconnection

The final prototype disconnection force was characterized by using hanging weights. **Fig. 26** details the test setup. A cup was connected to the CVC housing via a C-clamp and string, and the backpack housing was suspended from an immobile point via a string. Weights were added to the cup until the CVC and backpack housing separated. Once the components disconnected, the cup and weights were measured on a scale and recorded. The results from the disconnection characterization test are listed in **Table 15**.

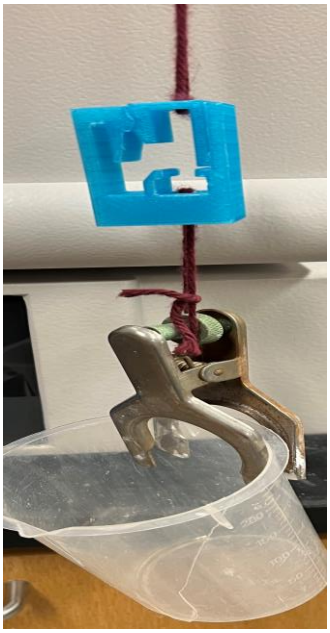


Figure 26. Disconnection characterization set up for the final design. The backpack housing was oriented to be on top of the CVC housing.

The backpack and CVC housings disconnected in the range of 0.338-0.690 lbf. Each successive test had a smaller force value, suggesting that the retention feature was experiencing wear. The intended function of this device is that it is not reusable, so the concern about wear after several disconnections is inconsequential. An acceptable force for the final design would require characterization of the joint between the CVC and the luer lock connection to find out the standard deviation. The nominal value would be set three standard deviations below the tail in order to ensure

the housings would disconnect before the CVC to luer lock. The nominal value may be adjusted to a different value depending on how tight the distribution ends up being.

Table 15. Results from force required to disconnect the CVC and Backpack housing.

Test No.	Cup/Weights Measurement (g)	C-Clamp Measurement (g)	Total Weight (g)	Total Weight (lbf)
1	245.66	67.31	312.97	0.690
2	220.87	67.20	288.07	0.635
3	170.09	67.28	237.37	0.523
4	167.65	67.30	234.95	0.518
5	138.95	67.24	206.19	0.455
6	138.36	67.25	205.61	0.453
7	137.09	67.31	204.40	0.451
8	90.96	67.28	158.24	0.349
9	87.04	67.27	154.87	0.341
10	86.38	67.30	153.68	0.339
11	86.25	67.28	153.31	0.338
		Average	209.94	0.463
		Std. Dev	55.03	0.121

4.5.2. Simulated Use

The prototype showed promise for being able to stop fluid from flowing through the interior of the tubing. Therefore, this prototype was subjected to a simulated use test to evaluate the valve potential. **Fig. 27** depicts the test set up. While setting up the test, it was discovered that the intended flow direction for the valve will need to be reversed to make proper connection with the pump. This does not affect the results of the test, as it can be argued that this valve could be used on either inflow or outflow port of the CVC. Additionally, this set up does not obey the Hagen-Poiseuille law,

Figure 27. The Simulated Use characterization test set up for the final design. The PDMS tubing extending from the Backpack housing connects to the periastaltic pump via connections to additonal tubing.

$$\boldsymbol{Flow = Pressure\ Gradient} \times \frac{\boldsymbol{\pi \times (Tube\ Radius)^4}}{\boldsymbol{8 \times Tube\ Length \times Viscosity}} \qquad (1)$$

in the same way that the dialysis process does because of the difference in tube length and fluid viscosity. The flow or pressure gradient could be calculated and adjusted to meet similar relations, but this pump was unable to make pressure adjustments. For the proof of concept function, these differences are not critical, as the function of the valve can still be assessed.

The tubing of the peristaltic pump was placed in a beaker of DI water, and the prototype was placed in an empty beaker for waste. To attempt replicating the flow rates used in traditional dialysis, the pump was first set to 300 mL/min. This rate was

too fast for the 0.180in inner diameter and 50in long tubing as the internal pressure created caused the tubing to convulse. The rate was decreased until the tubing was stable, which was determined to be 50 mL/min.

To begin the simulation, the inner diameter of the tubing was primed with DI water, and once the water was flowing through the entirety of the tubing, the prototype was subjected to disconnection. The disconnection occurred by manual removal of the backpack housing from the CVC housing. The mode of action of the flat spring was observed in addition to the fluid flow through the tubing. This was repeated three times.

The flat spring successively stopped the DI water from continuing through the tubing at the contact point without catastrophic rupture to the tubing during all three attempts. There was minor leaking at the overmold support tube, but this is attributed to the silicone tubing not being properly adhered to the system. In the final device, this is not problematic because over molding the tube into the overmold support tube will provide a leak-proof seal.

5. Conclusions

5.1. Summary

The goal of this project was to design a proof of concept prototype that demonstrates the ability to prevent flow through a system. Literature review was conducted regarding the limitations of the dialysis process to gain a better understanding of the overall process for design decision making. Using the knowledge from the literature review in addition to direction given from the team at CDI, the required design inputs were created as the basis for design of this product. After several concept and fabrication iterations, a final design was reached. This prototype met all the design inputs and proved to have an achievable outcome. The final design was subjected to a characterization testing to quantify disconnection force and observe the valve function in a simulated use test. The results

were that the valve successfully limited water flow through the interior lumen of silicone tubing.

The final prototype is the basis for further prototypes that will be conducted by the CDI team for continued development into a manufacturing ready product. While the purpose of this project was a valve that will be incorporated into a portable hemodialysis machine, it has the potential to be used in applications other than hemodialysis due to the simplicity and standard connection to catheters.

6. Future Work

Future work on the emergency safety valve will include enhancing the disconnection force, miniaturizing the device, increasing the blood compatibility of the tubing segment and selection of final materials for the other components. The disconnection characterization results showed very little force to disconnect the components, which is unsatisfactory for practical performance. The force required to disconnect should be influenced by the ISO standard 594-1, which specifies that the luer lock to catheter tensile strength be minimum 3.37 lbf *(26)*. But characterization of the entire disconnection force should be a determined safety factor less than this value. Further development will need to be completed on the locking feature to obtain a satisfactory force of disconnection.

The size of the prototype should be further miniaturized. This will be beneficial for overall patient quality of life, as a big bulky device would be uncomfortable and harder to integrate underneath clothing. For the final prototype, the width of the flat spring was the limiting factor for the size. Custom styles of flat spring with thinner width would allow for the size of the housings to be reduced while maintaining spring force.

The materials selected for the final design should be based on performance, biocompatibility, patient comfort, manufacturability and serializability. According to the ISO standard 10993 for medical device biocompatibility, this device would be considered a surface-contacting medical device and a direct blood-contacting medical device with

long-term exposure *(27)*. Devices that have direct contact with blood can cause adverse biological reactions because the material induces platelet activation, complement activation, thrombin generation and leaching of plasticizers *(28)*. A recent study completed by Xiaojie Lin *et al*. has implemented a surface modification to the standard CVC catheter material, poly (vinyl chloride) (PVC). This modification has shown to prevent blood protein adsorption, human platelet activation and complement activation *(28)*. Being able to apply this technique to the section of tubing in the crushing mechanism via flat spring would reduce risk to the patient and create a more biocompatible part.

This device is characterized as a surface contacting device per ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process *(27)*. This standard includes several polymers that are deemed low risk as surface contacting devices. Using this standard as guidance for choice of materials selection would allow for an easier path to FDA approval. The CVC and Backpack housing would ideally be lightweight but rigid. Acrylonitrile butadiene styrene (ABS) and Polycarbonate (PC) would be ideal choices for their mechanical strength, impact resistance and ease of processing in 3D printing and injection molding. PC is susceptible to degradation from water contact, which would be an issue as this system ideally encounters situations like showering and bathing. The surface composition of PC is not resistant to scratching, which would reduce overall appearance and likely cause particulate generation. ABS material has poor solvent and fatigue resistance due to UV exposure, which may not be an issue as this device will be located underneath clothing. All of these design considerations will be addressed by the Center for Dialysis Innovation team to produce a production ready product.

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