A Novel Pneumatic Silicone Sleeve for Transhumeral Prostheses That Autonomously Regulates and Adjusts to Socket–Limb Pressure to Improve Amputee Comfort

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Abstract:

Despite rapid technological advancements in the prosthetic industry, approximately 50% of upper arm transhumeral prosthetic devices are abandoned. This high disuse rate is primarily due to discomfort from static and inflexible sockets that cannot adapt to the natural volume and pressure changes of the residual limb with time. Prosthetic abandonment wastes immense healthcare dollars, resources, and healthcare provider time. More importantly, abandoning prostheses resurfaces dependency in amputees and hinders opportunities for patients to fully reintegrate into society with self-worth and confidence.

The objective of this study was to create a low-cost, adaptive prosthetic sleeve that improves patient comfort and wearability by automatically adjusting to changes in external arm pressure or increased growth circumference, and therefore reduces the likelihood of prosthetic abandonment. This was accomplished through creating a smart, transhumeral, pneumatic silicone sleeve that autonomously inflates and deflates in response to simulated residual limb pressure and volume fluctuations. The sleeve was developed by 3-D printing silicone molds based on the dimensions of a silicone residual limb model that replicated the feel of natural tissue.

After multiple iterations, and input from an amputee patient, a fully functional pneumatic sleeve was fabricated that automatically inflates or deflates in response to patient activity or limb swelling to maintain a consistent predetermined sleeve pressure and comfortable socket-limb interface.

The silicone sleeve demonstrated strong real-time adaptability, maintaining a consistent target pressure range of 5.0–5.25 kPa with high precision (±0.03–0.05 kPa of variation within target range) after external pressure spikes across four consecutive trials. The pneumatic system's high responsiveness and efficiency was shown through its fast pressure recovery within 7–16 seconds. Additionally, the system's consistent performance across varying magnitudes of pressure disturbances, simulating different amputee activities or circumference changes, validated the sleeve's autonomous regulation and real-time accuracy.

The sleeve is biocompatible and can be incorporated into existing prosthetic sockets without requiring a completely new prosthetic device or can be the first step towards a favorable alternative to conventional static sockets. This low-cost sleeve model costing approximately $300 has the potential to not only improve amputee comfort, but also save precious resources and health care dollars. Advanced research and refinements using patients' clinical data needs to be performed so that this novel prototype can be integrated into modern commercial prostheses and serve patients.

Section 1 - Background and Purpose

1.1 Introduction:

Modern prostheses have advanced over the past few years in numerous ways, including neurally-controlled and advanced myoelectric devices enabling amputees to reintegrate into society. However, despite these recent advancements, upper-limb prosthetic devices are abandoned at alarming rates, with studies reporting rejection rates approaching 50% in some amputee populations in the U.S. (Salminger et al., 2020). A single myoelectric prosthesis for a transhumeral amputation can cost $50,000–$60,000, and lifetime prosthetic care for a single-limb amputee has been estimated in some cases to exceed $800,000 (CostHelper Health, n.d.). As such, each abandoned prosthesis causes considerable waste of finances and already constrained health care resources. Besides financial implications, prosthetic abandonment affects amputees by reducing their activity levels and self-reliance, causing social detachment, and psychological and physical suffering. Most importantly, prosthetic abandonment leads to lost opportunities for amputees to reintegrate into society with confidence and self-worth (Baldock et al., 2023).

Transhumeral rejection is most common, composing up to 50% of rejected prostheses in some studies (Salminger et al., 2020). Transhumeral amputees suffer from phantom limb pain and discomfort more frequently than distal amputees. Abandonment is primarily due to a poorly fit, rigid socket that can cause discomfort, pressure, weight, and phantom pain (Baldock et al., 2023) (Biddiss & Chau, 2007).

Traditionally, fixed geometric sockets are produced by 3D scanning a residual limb or casting it using plaster. However, the fitting and comfort of sockets alter over time and activity due to residual limb volume fluctuations and natural changes in the size of a residual limb due to muscle loss or increased fibrous tissue, blood, and interstitial fluid. Swelling can occur from inflammation gradually or can occur variably throughout the day based on the diet and physical activity of an amputee (Baldock et al., 2023).

Volume fluctuations are generally more extreme in lower extremities due to the larger amount of weight placed on the limb, but still occur noticeably in upper extremities. Although upper limb amputees are equally prone to discomfort and pain due to swelling, only 17.1% of research designs focus on adjustable upper limb sockets (Baldock et al., 2023).

Volume fluctuations are currently addressed in two ways. 1) In fixed sockets, patients manually add or remove padding, usually in the form of sock-like sleeves, to maintain correct compression and interface pressure. However, this method places a manual burden on users to constantly adjust their padding at various times of day (Ahmadizadeh et al., 2020). This method is not precise and requires the user to have the padding readily available at all times. 2) The second approach involves dynamic, self-adjusting prosthetic sockets that adapt to a residual limb. Two relevant methods are discussed.

2a) Inflatable Bladders: Some adjustable prosthetic sockets incorporate inflatable bladders that are fluid or air-filled pockets attached on the interior of a rigid socket. Inflatable bladders are common in

lower limb sockets, but no known commercially available and autonomous transhumeral designs exist to date. The volume of the substance inside the bladders changes to alter the overall internal pressure and fitting of the socket to the residual limb. Inflatable bladders are often able to maintain a constant internal socket pressure, but are limited in that the socket shape can only be reduced from an initial volume (Baldock et al., 2023).

2b) Circumferential Adjustments: Another adjustment method involves circumferential adjustments, which modify a socket using straps or wires placed circumferentially around the exterior socket wall. They can be used for both upper and lower limb sockets, but place a tedious manual burden on users to adjust the dial throughout activity (Baldock et al., 2023).

Beyond socket adjustments, silicone "glove-like" sleeves are worn on a residual limb before donning the upper-limb prostheses to cushion the interface between the residual limb skin and the socket. Once donned, the silicone layer maintains a fixed thickness and cannot adjust to fluctuations in residual limb size throughout the day, causing a too loose or too tight fitting on residual limb. As swelling or shrinkage of limb occurs during activity or physiologically with time, the sleeve either compresses the limb excessively or loses contact, resulting in poor suspension, and high discomfort and pain (Amputee interview, personal communication, September 2025). This lack of adaptability leads to small pressure variations within the socket-limb interface and causes significant discomfort or pain and ultimately prosthetic rejection. These silicon suspension sleeves were first developed in the late 1980s, with modifications by Fillauer et al. in 1989 (Silicone Suction Socket, U.S.A) and 'Ossur Kristinsson in 1993 (ICEROSS system, Iceland). Gaber et al reported that although these sleeves improved suspension and freedom of movement in prostheses users, 56% of patients in their survey discontinued use due to skin problems, discomfort, pain, or difficulty donning it independently without assistance (Gaber et al., 2001). Similar limitations were reported by Broomfield and Dykes who added that although silicon sleeves had mechanical advantages, they also caused excessive perspiration and were incompatible with myoelectrical contacts restricting their use (Lamers et al., 1999).

As such, my objective was to create a novel silicon sleeve that overcomes some of these limitations.

Section 2 - Parameters of Research and Process

2.1 Design Process of Novel Silicone Sleeve

2.1.1 Design Inspiration

The methodology behind a blood pressure cuff was studied and applied in the design of the silicone sleeve. The inflation and deflation of a blood pressure cuff, where the volume of air within the cuff can both increase and decrease in volume in real-time, avoids the limitations of traditional fixed sockets and static silicone sleeves.

2.1.2 Equipment (Software and Printer)

Design Platform:

Fusion 360 (Autodesk Fusion 360. Autodesk, Inc., 2024) was used as the Computer Assisted Design (CAD) software to design the 3-dimensional (3D) printed silicone molds. All design changes were made through the Autodesk software.

3D Printer:

Bambu Lab X1 Series Printers (Bambu Lab, 2024) were used exclusively to print the 3D material and silicone molds. All prints were restricted to a single extruder and biodegradable thermoplastic polymer Polylactic Acid (PLA).

2.1.3 Material Considerations for Inflatable Sleeve:

1. **Sleeve Material:** There were two main criteria in deciding the material of the sleeve: a) The material must be flexible enough to stretch to various residual limb sizes and inflate without rupturing and b) a non-irritating, skin-safe, biocompatible material that would not introduce any hypersensitivity or irritation to the residual limb. It was decided that silicone was the best material to satisfy these two priorities, especially because current liners and several other clinical-use materials are made of silicone. Although Thermoplastic Polyurethane (TPU) was also a viable option, TPU is firmer, more rigid, and less stable with weight loads. Silicone offers greater flexibility, which improves socket suspension and comfort. Additionally, its superior elasticity and tear resistance is optimal for sleeve inflation (Cagle et al., 2018).
2. **Shore Hardness & Flexibility:** When using silicone, the flexibility and hardness of it can range depending on the type of gel and ratios of parts used. There are two shore hardness scales, which measure how flexible and conforming the silicone is. The Shore A scale is used to measure materials such as medium-firm rubbers and silicones, which are still relatively flexible, but stiffer. The Shore OO scale is used to measure much softer and rubbery materials, such as soft foams and

gels. Silicone falling within the Shore A scale was used to ensure the shape was flexible but still rigid enough to properly provide compression to the limb and function as a prosthetic liner.

3. **Type of Silicone Gel:** There are various types of silicone gels with different consistencies and flexibilities. PlatSil Gel-10 was used to create the silicone sleeve. It has two parts, Part A and B, that operate in a 1A:1B (by weight or volume) ratio. It has a 5-6 minute working time that cures fully in about 30 minutes to a Shore ~ A10 hardness. PlatSil Gel-10 is used for prosthetic devices, has a short curing time, and is skin-safe with medical-grade use (Brick in the Yard, n.d.).
4. **Prosthetic Deadener:** Prosthetic deadener is an additive used in the film and special effects industry to soften or soften silicone, especially to create realistic theatrical prostheses. It is commonly added to silicone elastomers, such as Platsil Gel-10, to reduce hardness and a rigid, snappy feel, making the material softer and more elastic. Prosthetic deadener was added to the PlatStil Gel-10 ratio to ensure silicone elasticity. Smooth-On Slacker 1 is a type of silicone deadener and was used in the silicone mixture (Polytek, n.d.).

2.1.4 Design of Silicone Molds

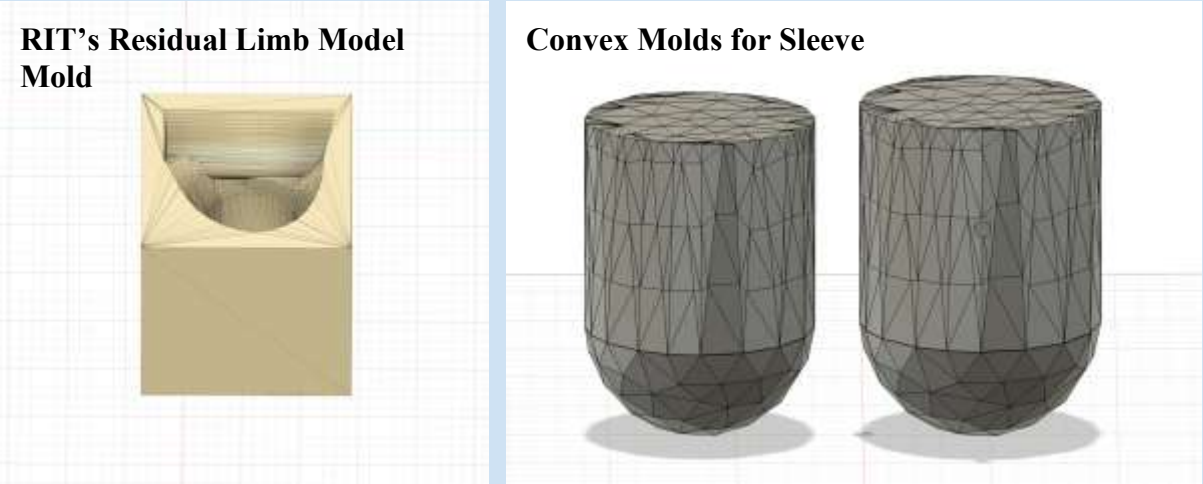

Figure 1: Silicone Mold Designs in Fusion 360
The CAD renderings of the 3D-printed molds created to form the inflatable silicone sleeve. The left image shows the original residual limb mold sourced from the RIT AMPrint Center, and the right shows the modified paired convex molds that were created from modifying the original mold. *Figure created by the student researcher using Google Drawings with screenshots from Autodesk Fusion 360, 2025.*

To create the silicone molds, the mold used to cast a transhumeral residual limb model from previous Rochester Institute of Technology (RIT) AMPrint Center research was imported into Fusion360 and modified. The mold was based on the average female mid-level amputation length (mid-humerus): 17.92 - 32.26 cm (50 - 90 %) and the average circumferences of transhumeral amputees: Proximal (near

the shoulder): 25-35 cm (10-14 inches), Mid-level: 20-30 cm (8-12 inches), Distal (near the elbow): 15-25 cm (6-10 inches) (Figure 1).

Figure 1 demonstrates the two modified limb molds that I fabricated (right image) within the Fusion360 platform. As displayed by the figure, the two minimal different size molds are convex as compared to the original hollow RIT mold used for pouring material in them. My convex molds enabled the successful creation of the inflatable silicone sleeve (which must be hollow inside to fit around a limb stump). Initially, I had attempted to create the silicone sleeve by painting the insides of the RIT's hollow mold using a brush, but the resulting silicone sleeve was uneven with noticeable defects and holes. This was due to uneven coating, the force of gravity pooling silicone at the bottom of the mold, and ripping while attempting to remove the silicone from the mold. As a result, two convex molds were created so that silicone could be poured directly on top of them for a uniform spread. Because the silicone sleeve required an outer and inner layer, the first mold was scaled by 1.05x to create the second outer sleeve mold. This outer sleeve mold also had a tiny cylindrical projection to allow for creating a hole within the outer sleeve for eventual pneumatic tubing insertion. These pour molds are further described in Section 2.1.5: Silicone Sleeve Methodology & Design.

2.1.5 Silicone Sleeve Methodology & Design

Air Bladder Mechanism: To design the air bladder, two separate layers separated by an air chamber needed to be constructed. Thus, as air flows into the air chamber, the outer sleeve and inner sleeve would push away from each other and inflate, providing tighter compression to a limb. By contrast, if air left from the chamber, the sleeves would become slack and provide a looser compression. Figure 2 demonstrates the schematic representation of the air inflation mechanism and the two-layer silicone design of the sleeve.

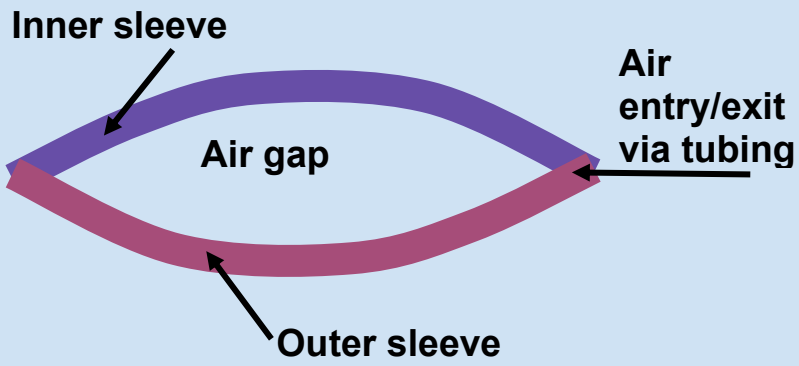

Figure 2: Air Bladder Mechanism
Schematic representation of the mechanism behind inflation and deflation of air bladder. The system consists of two sleeves (inner and outer) separated by an air gap. Pressurized air enters or exits the gap through tubing, inflating or deflating the bladder. *Figure created by the student researcher using Google Drawings, 2025.*

Silicone Ratio: The Silicone Plastisol Gel-10 consistency used was a 1:1:0.5 ratio of Part A: Part B: Slacker. The ratio was measured by weight on a scale. While a 1:1:1 ratio was initially tested, the consistency was very tacky and some areas were left-uncured. Additionally, decreasing the deadener to 0.5 allowed some rigidity while also maintaining softness and elasticity in comparison to total deformation.

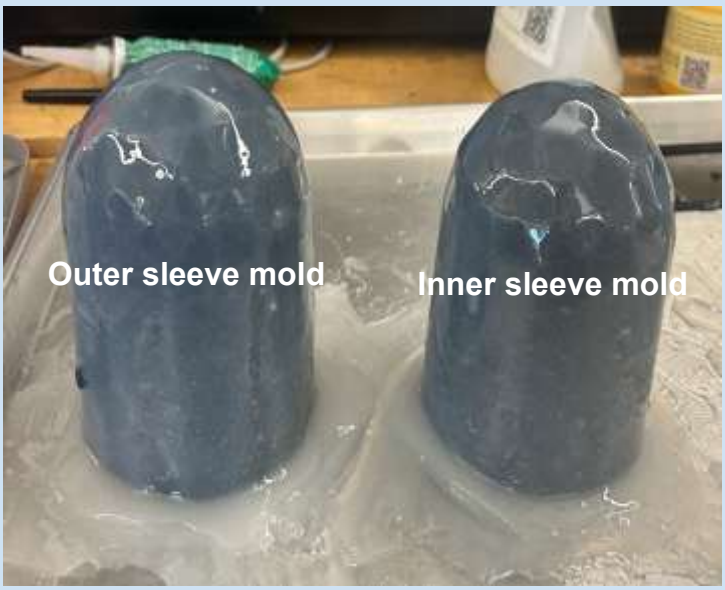

Figure 3: Pour Methodology
Photograph of the two convex molds used in the silicone pour process, one for the outer sleeve and the other for the inner sleeve. The silicone mixture was poured in 3 successive layers on each mold to achieve a total bladder thickness of approximately 4 mm. *Figure created by the student researcher using Google Drawings, 2025.*

Figure 4: Silicone Sleeve Integration with Residual Limb Model. Photograph showing the fabricated silicone sleeve over the residual limb model. The inner and outer silicone layers were sealed at the proximal end to create the middle air pocket. *Figure created by the student researcher using Google Drawings, 2025.*

Pour Methodology: The silicone ratio mixture was poured 3 times on each mold to create the optimal silicone bladder thickness of 4 mm. Before adding each additional layer, the prior layer must have cured fully with a minimum of 30-40 minutes of time in between to avoid tackiness or improper silicone curing. As shown in Figure 3, the mixture was poured directly into the middle of each mold to work in the same direction as gravity and uniformly trickle down the convex mold. Although there was pooling on the tray where the molds lay on, this silicone was excess and cut off once the silicone fully cured.

Fusing Silicone Casts: Once the two individual silicone layers completely cured, they were fused together at the top using silicone sealant DAP All Purpose Adhesive Sealant, applied only at the top junction to ensure no direct skin contact (DAP products inc., 2024). The silicone layers were fused at the

top to maintain the air chamber in between the outer and inner sleeve and prevent air from escaping. Figure 4 demonstrates the silicone sleeve (inner and outer layer fused) fitting over the residual limb silicone model.

2.2 Pneumatic System Design Parameters

1. **Uniform Method of Inflation:** Unlike prior pneumatic sockets that use multiple independently inflated chambers for localized pressure adjustment (Lee et al., 2024), the sleeve contains a single large air chamber between the two layers that provides uniform inflation and evenly distributes pressure across the limb. This approach avoids stress or skin irritation that could be caused by localized pressure adjustments. Additionally, universal inflation spreads pressure over a larger surface area that can reduce stress concentrations on a limb.
2. **Inflation and Deflation:** The sleeve has both an integrated air pump and valve, allowing for both inflation and deflation. As a result, the sleeve-limb interface pressure can both increase and decrease to be maintained in the ideal pressure range for a patient.
3. **Portable & Weight-Efficient:** Lastly, although the designed system was not wireless, all hardware and components used (air pump, valve, etc.) were designed to be compact and weight-efficient to avoid excessive bulk. With the use of a printed circuit board (PCB board), the assembly could easily be compacted and made wireless to enable an amputee to complete their full activities of daily living while receiving autonomous pressure adjustment.

2.3 Circuit Design

The developed circuit inflated and deflated the silicone sleeve to maintain a specific user-specified pressure range within the silicone sleeve (comfortable pressure range). The circuit achieved this through the integration of individual components and the execution of Arduino Code (Arduino IDE, Version 2.3.2.). The circuit integrates an Arduino Uno microcontroller, L298N motor driver (dual H-Bridge integrated circuit to control direction and speed of 9V DC motor), air pump motor, solenoid valve, and air pressure sensor to automate the sleeve's inflation–deflation process (Figure 5).

The Arduino Uno is the brain, or the control unit behind the functionality of the entire system. It links all the other components together by receiving pressure feedback, processing it, and then actuating the motor or valve. An analog air pressure sensor (HiLetgo Digital Barometric Pressure Sensor) reporting from the 0 - 40 KPa range was used to continuously monitor the air pressure within the sleeve's air chamber. This air pressure would spike in the case of external pressure from a socket caused by the swelling of a limb and decrease if the residual limb shrunk and the socket fitting became loose. This sensor outputs a voltage proportional to the measured pressure, which the Arduino interprets and uses to output a signal that will actuate the pump or the valve. The L298N driver amplifies this low-voltage signal from the Arduino so it is strong enough to operate the 9V DC motor and valve. Lastly, the motor is responsible for inflating the

bladder through tubing connected to the sleeve, while the valve sucks air from the chamber when pressure exceeds a specified range. Figure 5 demonstrates the circuit layout and communication and routing between all components. It also shows the physical assembly of the hardware in the prototype.

2.3.1 Circuit Components

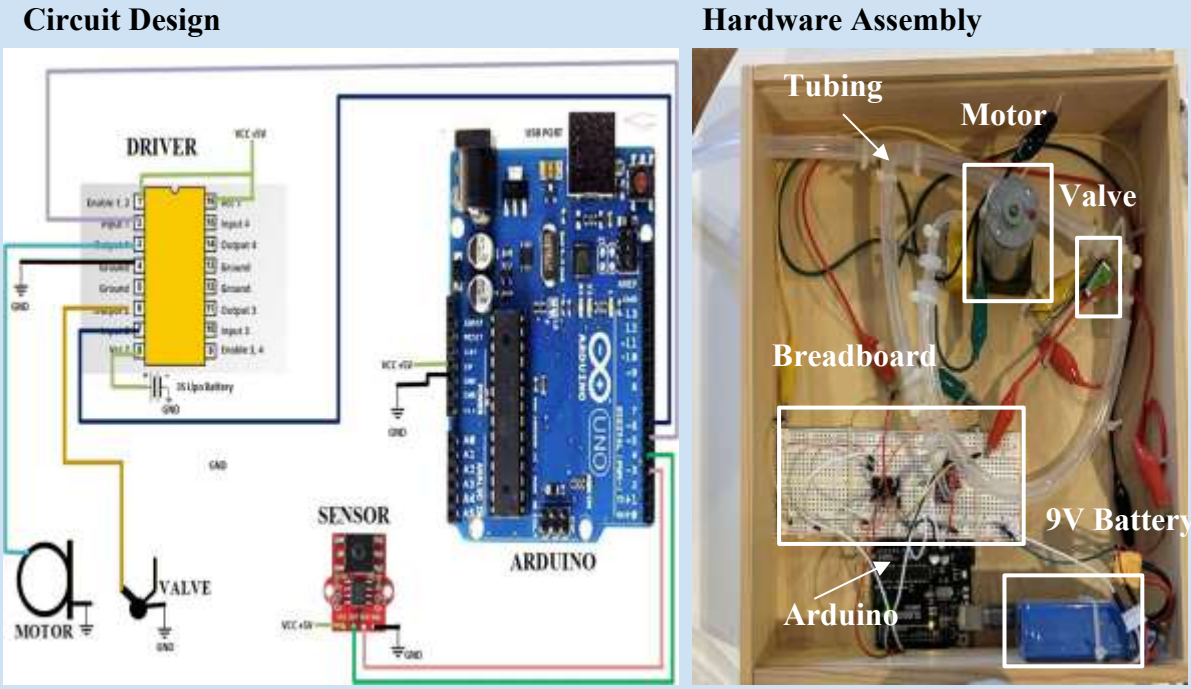

Figure 5: Circuit Design and Hardware Assembly
The left schematic diagram displays the routing and communication between the Arduino Uno, air pressure sensor, motor, and valve via the L298N motor driver. The right image demonstrates the complete physical hardware assembly including the motor, valve, tubing, breadboard, 9V battery, and Arduino. Together, both diagrams demonstrate the wiring and physical integration of the sleeve's inflation-deflation control system. *Figure created by the student researcher using Visio & Google Drawings, 2025.*

2.3.2 Logic Behind Inflation-Deflation

The logic behind inflation and deflation is further described by Figure 6. For inflation, if the recorded air pressure exceeded the range of 5.0-5.2 KPA, the motor would disable and turn off to prevent any further inflation. If the air pressure was less than the range, air would continue to fill in to get into the desired range.

Similarly, the valve operates if pressure exceeds the desired 5.0-5.20 range to reduce air from the chamber and provide a loose fit. If air is below that range, the valve will turn off to allow the filling of air.

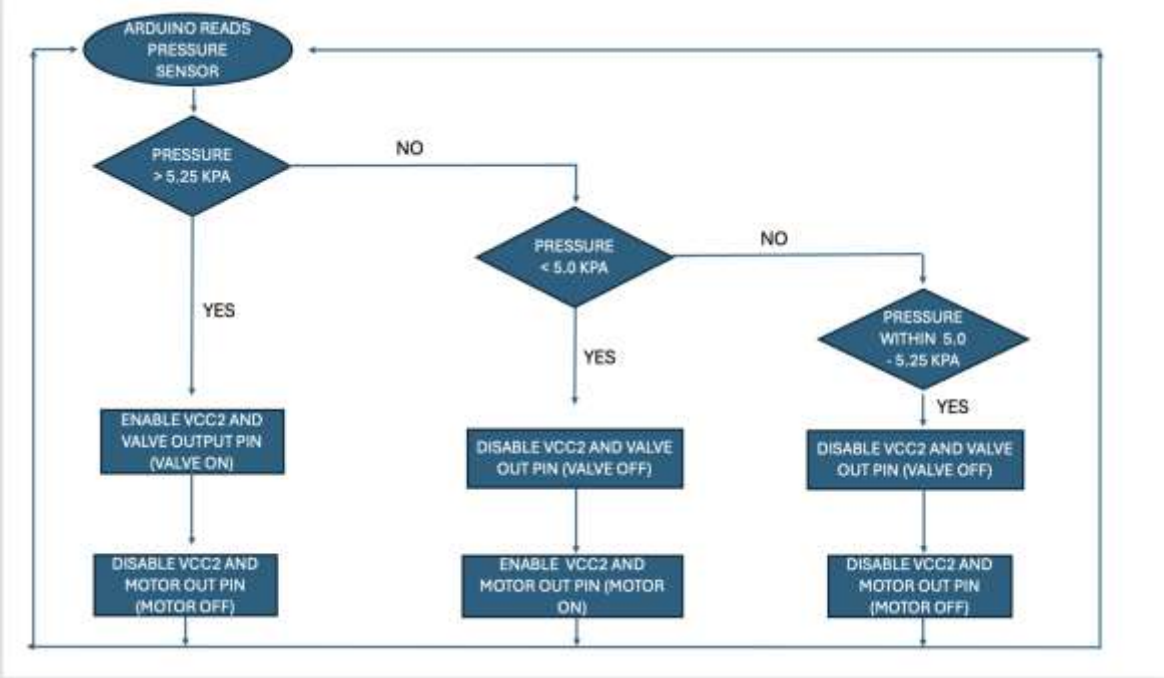

Figure 6: Closed-Loop Inflation–Deflation Control System Flowchart
This flowchart demonstrates the control logic and if-else loop behind the sleeve's inflation and deflation. If pressure exceeds the high press point of the target pressure range, the Arduino will turn the valve on and motor off, releasing air from the chamber. If pressure is below the low press point, it will turn the valve off and motor on to inflate the sleeve. When pressure falls within the range, it will turn both the valve and motor off. *Figure created by the student researcher using Microsoft PowerPoint & Google Drawings, 2025.*

2.4 Arduino Code

The Arduino code implemented the inflation-deflation logic outlined in Figure 6. The program continuously reads real-time pressure data, averages it through a low-pass filter, and actuates the motor or valve depending on whether the pressure exceeds or falls below the threshold (5.0–5.25 kPa). Representative code excerpts are shown below, and the complete source code is provided in the Appendix.

2.4.1 Code Excerpt 1

```
#define PUMP_PIN 5
#define VALVE_PIN 6


//on 9V
// (3/12)*255 = 63
// (3/12)*255 = 63  analogWrite(pin, 0..255)
```

```
#define AW_3V_LEVEL 63
#define AW_PUMP_V_LEVEL 120

#define LOW_PRESS_POINT 5.0
#define HIGH_PRESS_POINT 5.25

#define FL_AV_FILTER_SIZE 30

float x_arr[FL_AV_FILTER_SIZE]; // keeps FL_AV_FILTER_SIZE data points back in time
float floatingAverage(float x_new){// lowpass
 static int i_cur = 0;
 x_arr[i_cur] = x_new;
 i_cur = (i_cur + 1) % FL_AV_FILTER_SIZE; // inc. mod the size of the array
 // compute the average:
 float x = 0;
 for(int i=0; i<FL_AV_FILTER_SIZE; i++)
   x = x + x_arr[i];
 return x/FL_AV_FILTER_SIZE;
}

float pressure(){
 int32_t p = HX.read();
 float P = ((p+540000)*2.98023e-7)*20. - 50. + 43.; // kPa
 //p = LowPass(p);
 return P;
}
```

Target Pressure Range: This first section of the Arduino code establishes the target pressure range as specified by a user or clinician. The program/sleeve will seek to maintain this pressure throughout activity. The constant LOW_PRESS_POINT (5.0 KPa) defines the lowest point in the range of ideal pressure range while HIGH_PRESS_POINT defines the highest point (5.25 KPa). Whenever pressure drifts outside this range, the program will actuate the motor or pump to return the pressure back to range.

Pressure & Noise Filtering: To prevent data noise or small fluctuations from triggering unnecessary motor/valve actuation, two filters were implemented. The first filter, the floatingAverage() function, reduces the possibility of high frequency fluctuations in pressure readings. The floatingAverage() function operates by taking the average of the number of data points in an array as defined by FL_AV_FILTER_SIZE. In this case, it will take an average of 30 pressure readings, which the program will compare to the target pressure change and decide whether to actuate the motor or valve. As

a result, this filter is ideal for averaging out and normalizing pressure readings which can easily fluctuate. Because volume accumulates gradually in a limb which will affect the sleeve-limb interface pressure gradually with time, it is essential to normalize the pressure values and ensure that the control algorithm responds to true physiological changes.

Instantaneous Pressure Calibration: Lastly, the pressure() function reads the raw value from the HiLetgo pressure sensor and calibrates/processes it to convert the electrical signal into kPa pressure units. It returns this filtered pressure value as the instantaneous pressure which is then compared to the target pressure range.

2.4.2 Code Excerpt 2

```
void PumpAndValve(float p){
 if(p>HIGH_PRESS_POINT){
   //digitalWrite(2,LOW); // pump - OFF
   analogWrite(PUMP_PIN, 0);
   //digitalWrite(7,HIGH); //open valve
   analogWrite(VALVE_PIN, AW_3V_LEVEL);
   state = 'v';
 }else if(p<LOW_PRESS_POINT){
   //digitalWrite(7,LOW); // valve - OFF
   analogWrite(VALVE_PIN, 0);
   //digitalWrite(2,HIGH); // start pump
   analogWrite(PUMP_PIN, AW_PUMP_V_LEVEL);
   state = 'p';
 }else{
   //digitalWrite(7,LOW); // valve - OFF
   analogWrite(VALVE_PIN, 0);
   //digitalWrite(2,LOW); // pump - OFF
   analogWrite(PUMP_PIN, 0);
   state = 'n';
 }
}
```

The second code excerpt shown below demonstrates the logic behind choosing to actuate either the pump or motor when pressure falls outside of the target range.

The code uses a simple if-else if -else loop to determine how it should maintain the target pressure range. The method PumpAndValve handles all possible cases of whether the pump should be actuated, the valve should be actuated, or neither.

Valve Actuation: If the calibrated pressure exceeds the target range HIGH_PRESS_POINT, then the pump-pin is set to 0 V, signaling it to turn off. The valve pin is set to its actuation level (63 PMW,

corresponding to ~3 V), signaling it to turn on and deflate the sleeve to reduce the pressure.

Pump Actuation: If the calibrated pressure is less than the target range LOW_PRESS_POINT, then the valve-pin pump-pin is set to 0V, ensuring no air continues to leave the bladder. The pump-pin is set to its actuation level (PWM value 120), actuating the air pump and inflating the bladder to restore pressure within the optimal range.

Maintaining Pressure: Lastly, if pressure falls within the set range of 5.0-5.25 kPa, both the valve-pin and pump-pin will be set to 0 volts so the system can maintain the ideal pressure range without air entering or leaving the chamber and providing inflation or deflation.

2.4.3 Code Excerpt 3

```
void loop() {
 float p = pressure();
 p = floatingAverage(p);
 PumpAndValve(p);
```

Lastly, Code Excerpt 3 below indicates the loop used to compare the pressure to the target pressure range. After pressure is read, the pressure is calibrated and averaged using the floatingAverage method. Then, the calibrated pressure runs through the PumpAndValve method to decide whether the pump or valve needs to be actuated to maintain the target pressure range.

2.4.4 Code Summary

Overall, the code establishes a closed-loop pneumatic control system that:

1. Continuously measures pressure via the HX710B sensor
2. Filters and averages the pressure using a defined filter size to eliminate random pressure fluctuations
3. Feeds the filtered pressure into the PumpAndValve method, which actuates the pump, valve, or neither
4. Runs continuously for autonomous and controlled pressure adjustment

This control architecture ensures precise and constant maintenance of the ideal pressure range for an amputee, ensuring the silicone sleeve always provides a firm yet comfortable fitting.

2.5 Testing Set-Up & Conditions

Sleeve & Residual Limb Simulation: The silicone sleeve was fitted over the 3D-printed stump to replicate the sleeve fitting over a transhumeral limb stump. Using the set-up photographed in Figure 7, the sleeve was suspended on a ring stand to account for gravitational forces that would be placed on the

stump during operational conditions.

Initial Pressure Simulation: Initially, residual limb volume fluctuation was modeled using clinical Foley catheters placed at 90 degrees, 180 degrees, 270 degrees, and 360 degrees circumferentially in the space between the 3D-printed limb model and silicone sleeve. The Foley catheters have small balloon-like pouches that hold a maximum of 5 mL of fluid to inflate and simulate limb swelling. However, when fluid was inserted into these catheters, no clear pressure spike was observed, as the 4 localized volume increases did not represent circumferential swelling strongly. Thus, the setup was revised so that a clear pressure spike could be observed.

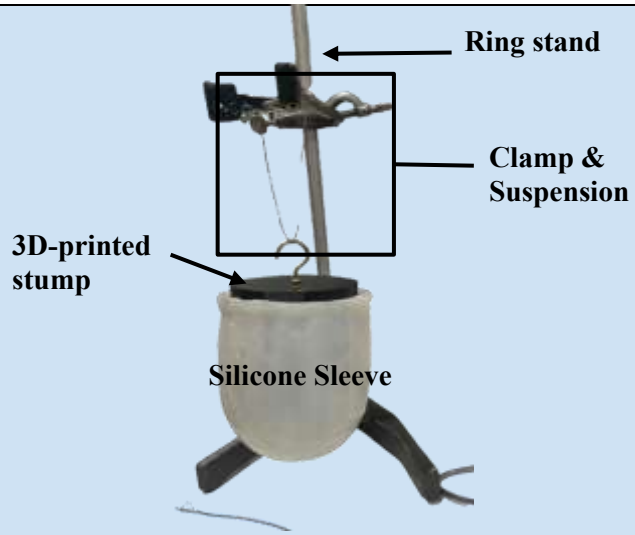

Figure 7: Sleeve on Simulated Transhumeral Stump
Photograph of the inflated silicone sleeve fitted on the 3D-printed transhumeral stump model. The 3D-printed insert was also the pour mold used for creating the sleeve. The sleeve was suspended above the ground to model realistic donning conditions and account for the effect of gravitational forces. *Figure created by the student researcher using Google Drawings, 2025.*

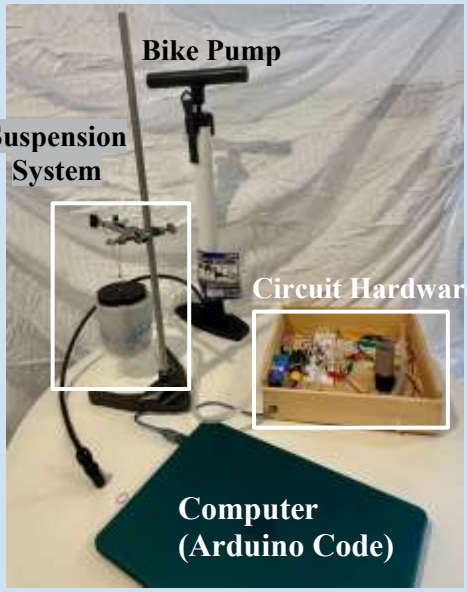

Figure 8: Complete Testing Set-Up
Photograph of the complete testing set-up, including the silicone sleeve, circuit hardware, computer running Arduino code, and bike pump for external pressure simulation. *Figure created by the student researcher using Google Drawings, 2025.*

Revised Socket-Limb Interface Pressure Simulation: In the revised simulation, exaggerated pressure changes at the socket-limb interface were modeled to demonstrate proof of concept using three layers. The innermost layer was the 3D-printed residual limb stump, the second layer was the silicone sleeve fitted over the limb and functioning as the adaptive interface, and the 3rd outer layer was an inflatable packaging wrap placed circumferentially around the sleeve to simulate external socket pressure. In a real-world implementation, a volume fluctuation in the residual limb would cause the socket to compress the silicone sleeve tighter and drive the interface pressure up. Therefore, the wrap was inflated once using a bicycle pump to replicate a pressure increase caused by a tighter socket-limb interface. This increase in external pressure caused the measured sleeve

pressure to exceed the target “comfortable” pressure range, which immediately self-adjusted via the circuit and pressure valve mechanism, restoring the pressure back to the target range.

Complete Testing Set-Up: Figure 8 demonstrates the complete testing set-up. The testing included the bike pump, suspension system, circuit hardware, and computer with Arduino Code.

Target Pressure Range: The set target pressure range used throughout the simulation was 5.00 - 5.25 kPa. This range can be modified by a clinician or amputee preference.

Section 3 - Results

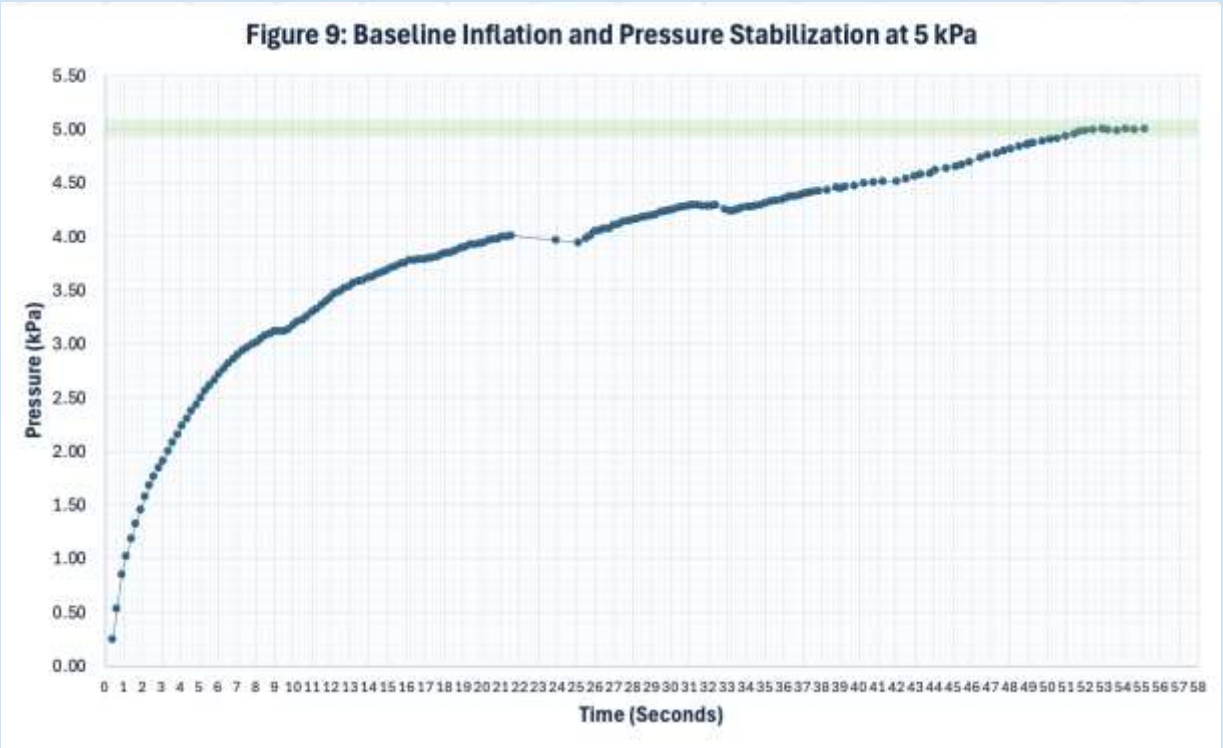

Figure 9: Baseline Inflation and Pressure Stabilization at 5.0 kPa
The silicone sleeve system inflated until the air pressure reached the 5.0-5.25 kPa target pressure range. The sleeve stabilized at 5.0 kPa in under a minute (as shown by the green rectangle), with minimal fluctuations above and below that range. *Figure created by the student researcher using Microsoft Excel & Google Drawings, 2025.*

The baseline inflation illustrated in Figure 9 verified the accuracy of the silicone sleeve’s pneumatic system and its ability to autonomously reach the target pressure range. During baseline inflation, no external pressure was placed on the sleeve and it self-inflated to 5.0 kPa in under a minute. Once the pressure reached the target range (5.0–5.25 kPa), continuous inflation stopped and the pump valve began to automatically adjust and cycle on and off to maintain the pressure. This demonstrated the

pneumatic system's precision and stability in maintaining target pressure without overshoot or drift.

Trial 3, depicted in Figure 10, was one of the most accurate trials and demonstrated the pneumatic system's response to external socket pressure. The stable target pressure (5.0-5.25 kPa) was deliberately increased, and the vertical line indicates the time at which the external wrap was inflated using the bike pump. Following this event, the pressure rapidly increased and spiked. Once the Arduino code identified that the pressure was above the target pressure range, the valve automatically opened and air rapidly left the silicone chamber within 1 second (steep downslope), decreasing the pressure below the target pressure range. Immediately following, the program activated the pump to refill air and restore the stable target pressure range of 5.0-5.25 kPa (gradual upslope). Once the pressure was restored within this range (blue rectangle), called the "steady state" range, the pressure stabilized, demonstrating accurate functioning of the prototype.

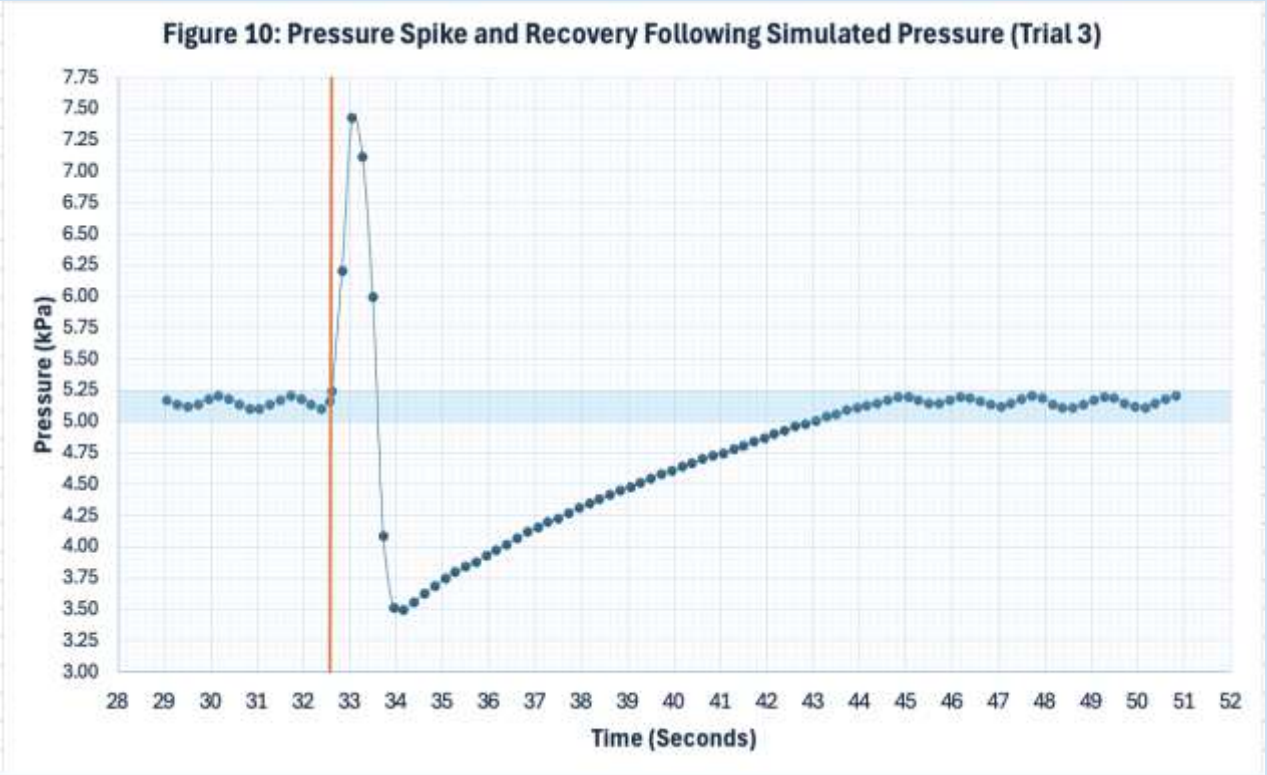

Figure 10: Pressure Spike and Recovery Following Simulated Pressure (Trial 3)
After the simulated external socket pressure indicated by the red line, the internal pressure rapidly peaked due to the elevated socket-interface pressure. In less than a minute, the control system opened the valve to release pressure and then steadily inflated to restore the target pressure range. *Figure created by the student researcher using Microsoft Excel & Google Drawings, 2025.*

As shown in Figure 11, an overlay of four consecutive trials demonstrates the precision and reproducibility of the sleeve's control system. Each trial followed a consistent pattern: a pressure spike after external pressure, rapid pressure decrease as the valve opened, and a steady recovery towards the

target pressure range as the pump refilled air to the desired level. While the timing of applying external pressure and recovery time varied slightly between trials, full recovery occurred in less than a minute in each case. Once the steady state was reached, the system consistently maintained the target pressure range.

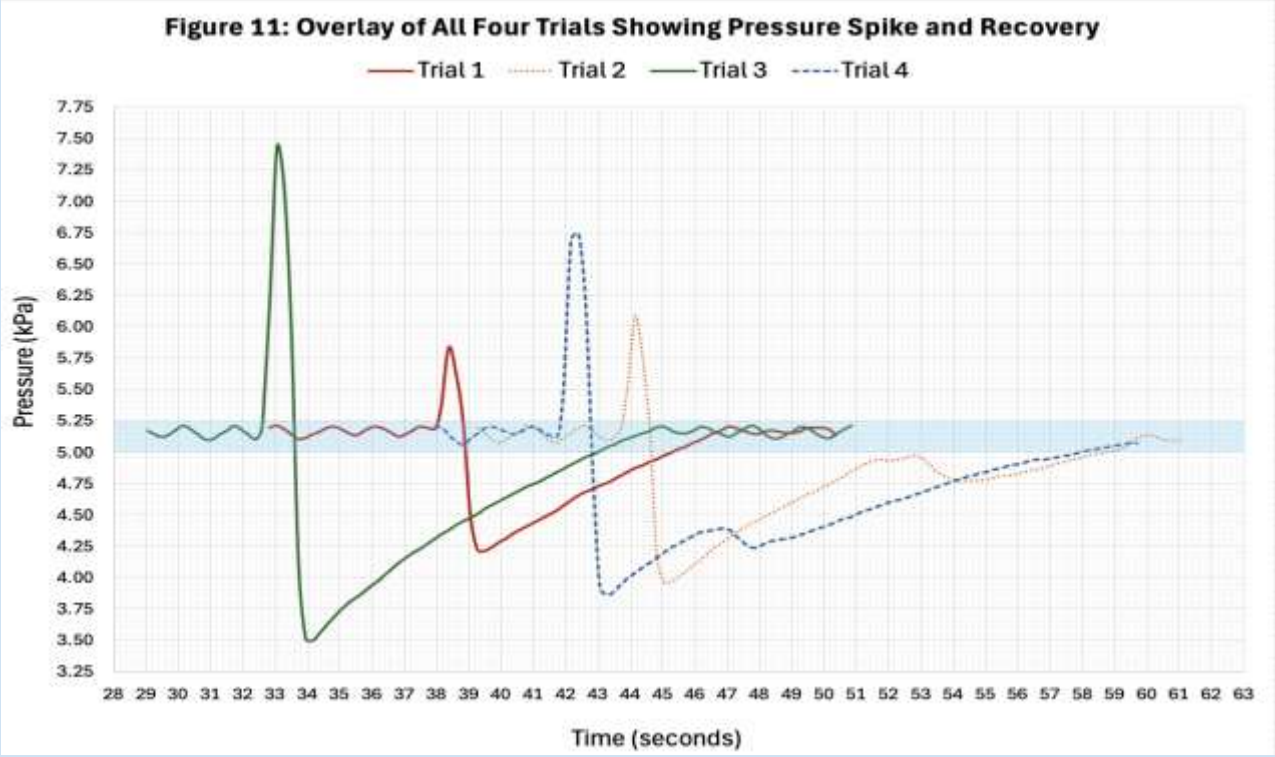

Figure 11: Overlay of Four Trials Showing Pressure Spike and Recovery
All four trials exhibited an initial pressure spike due to the simulated external socket pressure, followed by recovery to the target pressure range in under a minute. The similar spike and recovery patterns demonstrate the consistency and reproducibility of the sleeve's control system. *Figure created by the student researcher using Microsoft Excel & Google Drawings, 2025.*

Table 1 summarizes the control system's performance across four consecutive trials. Each trial maintained the same target pressure range. Peak pressure across trials deliberately varied across trials to simulate different external pressure scenarios, and the recovery duration in each trial was consistently abrupt within seconds and efficient. Higher peak pressures usually corresponded to a longer recovery duration, except for trial 3. The steady-state mean for each trial remained within the target pressure range of 5.0-5.25 kPa, indicating desired pressure maintenance and system reliability. Furthermore, the steady state standard deviation was <0.05, indicating excellent repeatability and confirming the system precision.

Table 1: Summary of Target Pressure Recovery and Control System Performance Across Four Trials

Trial #	Target Pressure (kPa)	Peak Pressure (kPa)	Recovery Duration (s)	Steady State Mean (kPa)	Steady State Standard Deviation (kPa)
1	5.0 - 5.25	5.83	7.44	5.16	0.03
2	5.0 - 5.25	6.08	14.87	5.08	0.04
3	5.0 - 5.25	7.43	10.43	5.16	0.03
4	5.0 - 5.25	6.74	15.99	5.04	0.05

Section 4 - Discussion

4.1: Discussion of Results

The goal of this research was to design a novel silicone sleeve that provides autonomous pressure adjustment in response to external socket pressure caused by residual limb volume fluctuations for optimal patient comfort and wearability. The pneumatic sleeve was designed to provide automatic uniform inflation and deflation and maintain the socket-limb pressure within an ideal target range as specified by a clinician or amputee patient.

4.1.1 Uniform Inflation

The single-chamber design between the outer and inner sleeve ensured even and circumferential pressure distribution across the socket-limb interface. In addition to preventing stress or pain caused by localized pressure adjustments, uniform inflation also resulted in time-efficient and quick pressure recovery. As demonstrated by the baseline inflation and four consecutive trials with varying external pressure increases, the silicone sleeve maintained or recovered the target pressure range within seconds. By contrast, individual air chambers could introduce lag or discoordination, resulting in inefficient pressure recovery.

The inflation in each graph is modeled by logarithmic-like growth, where the pump initially inflates the silicone sleeve rapidly before slowing down upon reaching the target pressure range. The consistent and evenly distributed pressure overall highlights the system's simplicity yet effectiveness in providing reliable pressure regulation through a single universal air chamber.

4.1.2 Steady State/Target Range Maintenance

The pneumatic system control loop had high consistency and minimum fluctuation across all four trials. As shown in Table 1, the steady state mean across all trials fell within the 5.0-5.25 kPa target pressure range demonstrating true recovery and pressure accuracy after external pressure/residual limb

volume fluctuation. Additionally, the minimal standard deviation for the steady state values across all trials (±0.03–0.05 kPa) demonstrated the high level of precision the system had for stable pressure maintenance.

Interestingly, the baseline steady state pressure values were on the lower end and fluctuated around the low press point of 5.0 kPa rather than throughout the 5.0-5.25 kPa range. By contrast, the steady state values of the four trials (Figure 12) fluctuated across the entire 5.0-5.25 kPa range. A possible explanation for this difference is that during baseline inflation, where only the pump was actuated, the control algorithm prioritized preventing overshoot by cutting off the pump as soon as the lower boundary of the target range (5.0 kPa) was reached. This produced stable but lower steady state values that fluctuated around 5.0 kPa. In contrast, in each of the four trials that involved a spike due to external pressure disturbances, the system required both pump and valve actuation to restore the target pressure range. This dual adjustment caused the pressure to fluctuate more dynamically within the full 5.0–5.25 kPa range during the steady state. Despite these differences, both conditions maintained the target pressure range.

Overall, each trial's steady state consistency and negligible standard deviation (<0.05) validated the system's closed-loop precision and ability to restore and maintain a target pressure range defined by a user even after external pressure events.

4.1.3 Response to External Pressure Spikes

Trials 1-4 showed the pneumatic system's response to external pressure spikes which simulated increased socket-limb interface pressure caused from residual limb volume fluctuation. Each trial demonstrated a rapid recovery time (from 7-16 seconds) after the external pressure peak was reached, demonstrating the high responsiveness and efficiency of the control system. While residual limb volume fluctuations in real-word scenarios are typically more gradual than the sharp spikes produced in test, the system's performance under rapid pressure changes also support gradual, less extreme changes. As shown in Trial 1, which has the smallest peak pressure, the same type of recovery was initiated to restore the target pressure range as Trial 3, the largest peak, just at a faster rate. As a result, gradual changes above the range would occur faster due to the small peaks and will be restored sooner to the ideal target pressure range.

For each different magnitude of induced pressure spikes, represented by the varying peak pressures and length of the peaks, the control algorithm quickly restored the target pressure range. This demonstrates the system's ability to maintain the comfortable target pressure range for an amputee during different activities, movements, or fluid changes, where one situation may result in a peak external pressure that has a greater magnitude than another. Under real-world conditions, with different stresses

placed on the socket due to different activities by the patient, the system will maintain the target pressure.

In each of the four trials, after the external pressure spike, each trial had an overshoot by the valve where the pressure dipped below the target pressure range. Although the overshoot was minor and quickly corrected by the pump, future iterations could reduce it by adjusting by improving the valve's response speed and closure when the target range is reached to prevent valve overshoot and pump overuse.

Lastly, although the pressure spike only corresponded to the simulation of residual limb swelling/a high pressure socket-limb interface, if the residual limb decreased in size due to limb atrophy, the system would also provide pressure compensation to restore the target pressure range for optimal fit. The graphs demonstrate that when the pressure decreased below target range due to valve overshooting, the pump was turned on and steadily yet promptly increased the air pressure until it reached target range. Thus, a similar steady pump actuation could be expected in cases of volume shrinkage in a residual limb or activities where decreases in pressure are caused to the socket-limb interface.

4.1.4 Constant Adjustment & Air Leakage

Once inside the target pressure range of 5.0-5.25 kPa, all trials displayed negligible fluctuation and standard deviation. Although these fluctuations were slight and still within the set target pressure, they can be explained by the tubing connection to the silicone sleeve. Although the connection is airtight, since the air chamber remains open to the tubing environment, air can still flow within the closed system from the air chamber back to the tubing even when no pump or valve is actuated. Thus, even once inside the target pressure range, air pressure can minimally decrease and increase, prompting the motor to continue actuating periodically for short periods of time. The valve did not contribute to these changes because even opening valve slightly causes a rapid decrease in pressure.

Although the pump continuously maintained pressure, it also led to increased pump duty cycle and potential wear over time. Thus, adding a pressure-sealing mechanism or an internal seal to prevent backflow of air from the sleeve to open tubing could be explored.

4.1.5 Device Abilities & Advantages

Besides the primary advantage of creating comfortable prosthetic sleeves and increasing wearability, this prototype can offer other benefits. The total cost of materials for making this prototype was approximately $300. Clinical prosthetic devices vary in cost ranging up to $5,000-$70,000 (Orthotics Limited, n.d.). Thus, abandoning ill-fitting devices or repeat fabrication for patients puts a significant financial burden on the prosthetic industry and healthcare system. If a single $300 silicone sleeve can be manufactured for different patients using different size upper arm prosthesis, it will eliminate wastage and the need for repeat device fabrication, potentially saving thousands of health care dollars. Moreover, the

adaptable and flexible quality will allow its use over long time periods as patients' residual limbs heal and change in size over time. Increased wearability of prostheses will additionally allow amputees to become integrated workforce members, not only for their own economic benefit but also for improving their confidence and assimilation in society.

4.2 Future Improvements, Applications, and Plans:

4.2.1 Future Improvements

During testing, a rigid 3D-printed insert was used to simulate the transhumeral stump. To ensure more accurate testing and residual limb consistency, using a material that more closely resembles the human arm could be used. For example, the silicone RIT residual limb model replicates the layers of muscle and fat found in a transhumeral stump. It would be valuable to conduct this experiment using a tissue-like material or even actual patient volunteers. As noted in the design considerations for the pneumatic system, compacting the circuitry into a portable, weight-efficient system (similar to wireless blood pressure cuff compartments) would be essential for the clinical prototype to enable amputees to complete activities of daily living freely wearing their silicone sleeve and prosthesis.

Lastly, although there are many benefits towards uniform inflation, it may be worth evaluating segmental, multi-zone air chambers to allow more localized pressure control. While most amputees and prosthetists agreed that distributing pressure over a greater surface area is important for comfort, in certain cases such as osseointegration, bony prominences, or sensitive/uneven residual limb tissue, localized pressure relief may provide advantages such as improved accommodation of irregular limb contour or targeted pressure adjustment over sensitive areas.

4.2.2 Future Plans

A future goal is to advance this silicone sleeve prototype into a fully functioning clinical device through advanced research instrumentation and human research studies. Under RIT, GMU and Walter Reed Military Medical Hospital's guidance (who recently demonstrated interest in furthering my prototype), I will continue to advance my prosthetic prototype, utilizing advanced 3D Medical Applications Center and expert guidance. After speaking with military amputee volunteers who expressed the essential need for a comfortable device and silicone sleeve, I plan to further collaborate with amputee patients for their input and advice to innovate and serve societal needs.

References:

Ahmadizadeh, C., Pousett, B., & Menon, C. (2020). Towards management of residual limb volume: Monitoring the prosthetic interface pressure to detect volume fluctuations—A feasibility study. Applied Sciences, 10(19), 6841. https://doi.org/10.3390/app10196841

Baldock, M., Pickard, N., Prince, M., Kirkwood, S., Chadwell, A., Howard, D., Dickinson, A., Kenney, L., Gill, N., & Curtin, S. (2023). Adjustable prosthetic sockets: A systematic review of industrial and research design characteristics and their justifications. Journal of NeuroEngineering and Rehabilitation, 20, Article 147. https://doi.org/10.1186/s12984-023-01270-0

Biddiss, E., & Chau, T. (2007). Upper-limb prosthetics: Critical factors in device abandonment. American Journal of Physical Medicine & Rehabilitation, 86(12), 977–987. https://doi.org/10.1097/PHM.0b013e3181587f6c

Cagle, J. C., Hafner, B. J., & Sanders, J. E. (2018). Characterization of prosthetic liner products for people with transtibial amputation. Journal of Prosthetics and Orthotics, 30(4), 187–199. https://doi.org/10.1097/JPO.0000000000000205

CostHelper Health. (n.d.). How much does a prosthetic arm cost? Retrieved November 6, 2025, from https://health.costhelper.com/prosthetic-arms.html

Gaber, T. A., Gardner, C. M., & Kirker, S. G. (2001). Silicone roll-on suspension for upper limb prostheses: Users' views. Prosthetics and Orthotics International, 25(2), 113–118. https://doi.org/10.1080/03093640108726584

Lamers, H. B., West, D. W., & Lantzas, B. (1999, August). Experience with custom silicone suspension sleeves for self-suspending trans-humeral and trans-radial prostheses. In Proceedings of the 1999 MyoElectric Controls/Powered Prosthetics Symposium (MEC 99) (pp. 35–40). University of New Brunswick. https://hdl.handle.net/10161/4910

Lee, K.-H., Heo, H.-S., Kim, J., Cho, J. H., Kim, K. T., Hur, J.-Y., Kim, J. H., & Lee, Y. (2024). A pneumatically controlled prosthetic socket for transfemoral amputees. Sensors, 24(1), 133. https://doi.org/10.3390/s24010133

Orthotics Limited. (n.d.). The cost of prosthetic limbs. Retrieved November 6, 2025, from https://orthoticslimited.com/blog/cost-of-prosthetic-limbs

Polytek. (n.d.). Smith's theatrical prosthetic deadener. Retrieved November 6, 2025, from https://polytek.com/products/smiths-theatrical-prosthetic-deadener