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Design of a Device to Ease and Improve the Diagnosis of Popliteal Artery Entrapment Syndrome

Popliteal artery entrapment syndrome (PAES) is a condition affecting blood flow in the back of the leg, which can have a significant impact on the patient's life. It is often misdiagnosed due to a lack of standardized procedures and quantifiable diagnostic criteria. To facilitate easier and more accurate diagnosis of this syndrome, we have designed and built an initial prototype of a device that provides adjustable resistance during plantar-flexion of the patient's ankle while quantifying force generated and ankle range of motion. The device will be used while the physician observes blood flow through the popliteal artery in the back of the knee using an ultrasound. The device provides a convenient and ergonomic solution for patients and physicians, which helps improve the accuracy of PAES diagnosis and allows physicians to further study this condition. [DOI: 10.1115/1.4065588]

Keywords: popliteal artery entrapment syndrome, PAES, plantar-flexion force and angle, diagnostic device

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1 Introduction

In patients with PAES, the popliteal artery that supplies blood to the lower leg is abnormally compressed by surrounding muscles, causing pain and cramping due to claudication in the back of the leg [1]. This condition is difficult to diagnose due to challenges provoking symptoms in a doctor's office setting and a lack of data correlating the onset of symptoms with occlusion of the vessel [2]. This paper lays out the design of a prototype that eases the doctor's ability to replicate movements that cause pain in patients with PAES on an examination table. Our device also collects useful patient data that can help characterize the syndrome and contribute to the ongoing research surrounding the condition.

2 Background

Popliteal Artery Entrapment Syndrome occurs when the popliteal vessels in the back of the knee, are abnormally compressed by the surrounding muscles and bones, leading to a reduction or complete blockage of blood flow. PAES causes severe calf pain, numbness, and coldness of the lower extremities when walking or running, and goes away with rest [3]. This condition is often observed in athletes with enlarged calf muscles, but there are also congenital cases where it's related to abnormal positioning of the artery in the knee [4]. It is estimated that PAES affects between 0.17% and 3.5% of the United States population, with the primary demographic being athletic patients under the age of 30 [5,6].

Treatment options for the condition are currently limited. Botox can be used as a noninvasive method of relaxing surrounding muscles and reducing compression on the artery. For some patients, this provides temporary relief [7,8]. However, some patients require invasive surgery where large pieces of muscle are removed from the back of the knee [1,2]. These surgeries take months to recover from and can significantly disrupt the patient's life. Thus, accurate PAES diagnosis is crucial in providing care to patients in pain and reducing un-necessary major surgeries.

Due to the difficulty of diagnosing PAES, patients may be misdiagnosed by physicians before securing the correct diagnosis and appropriate treatment, which can take years [9,10]. Current methods for the detection of artery occlusion include ultrasonography, computed tomography (CT), or magnetic resonance angiography [11,12]. PAES diagnosis can be challenging because it is a dynamic condition. Standard methods of evaluating blood flow often do not uncover any problems when the patient is at rest. This is due to the fact that occlusion of the artery and obstruction of blood flow are more likely to become apparent when the foot is flexed by the muscles that also are those that squeeze the artery [2]. Therefore, in order to provoke the patient's symptoms and properly diagnose the syndrome, activities analogous to walking, running, and jumping must be performed in the office.

Currently, there are a range of strategies used to provoke patient symptoms in the office. Some physicians have the patient run on a treadmill or perform calf raises to aggravate symptoms then measure blood flow through the artery [11,12]. However, without actively flexing the muscles during diagnosis, the mechanisms which compress the artery may not be apparent. Other clinics will use a hand, block of foam, or other basic resistance mechanism for the patient to push against. However, these methods do not measure the forces and angles at which a patient occludes, making it difficult to compare thresholds between patients and between the same patients on different days.

An additional challenge with current diagnostic methods is that many asymptomatic individuals will also experience occlusion of the popliteal artery under sufficient conditions [13]. Thus, quantitative research on the occlusion points of symptomatic and asymptomatic individuals should be compared in order to develop better diagnostic criteria.

For this project, we worked closely with Dr. A. Dowlatshahi at Beth Israel Deaconess Medical Center, who specializes in treating this condition and sees patients from across the country. He has found that a good way to diagnose PAES is to measure blood flow with triplex ultrasound in the popliteal artery while the patient actively plantar-flexes with varying resistance levels. Some patients occlude more readily than others and thus require different levels of resistance. However, this measurement is difficult and subjective because the physician has to use his hands and upper leg to resist the patient as they push against him, while simultaneously performing ultrasound, as shown in Fig. 1.

The current diagnosis procedure thus has multiple issues. First, there is currently no objective way to control and measure the stimulus required for a given patient to show symptoms. It would be beneficial for doctors to reliably quantify the force and angle needed to have a patient reach a threshold where the artery occludes. Additionally, these measurements would allow doctors to compare patient performance pre- and postoperation and contribute to a body of ongoing PAES research. The second issue is that it is challenging for the physician to both track the popliteal artery with the ultrasound and apply resistance for plantar flexion. Multitasking makes this procedure mentally and physically taxing for the physician. Finally, some patients require a large amount of resistance to display symptoms, which is difficult or impossible for the physician to apply manually.

We aim to make this diagnosis procedure easier for the doctor and the patient. In addition, we want to improve precision for accurate diagnosis, rehab, and research with an ergonomic, hands-free device that attaches to a doctor's office's examination bed and applies adjustable resistance. The device will measure and record the force and angle to characterize the variables that cause the patient to show symptoms.

This device is not attempting to replace the physician's manipulation of the ultrasound probe. Conversations with doctors and observations of the diagnosis procedure informed the team that it would be insufficient to simply strap an ultrasound device to the back of the patient's knee. The blood vessel moves around during plantar flexion, requiring visual tracking and control by the doctor, who has to adjust the ultrasound accordingly. Thus, automating the ultrasound screening procedure is currently outside the scope of our product development. Instead, we focused on simplifying the doctor's workflow and providing quantitative measurements to aid in diagnosis.

There are currently devices on the market that measure the range of motion of the ankle by quantifying angles and applying adjustable resistance, but our device is novel in its small footprint and having the patient in the correct position to diagnose PAES in a hospital setting. This device may be applicable to the diagnosis and rehabilitation of other conditions as well.

3 Design Section

3.1 Design Requirements. During the design process, our discussion with the physician helped us formulate key requirements that would provide a more convenient, reliable, and repeatable diagnosis process. The six primary functional requirements of our design are:

(1) **Provokes PAES by applying resistance at various angles:** Our device must cause popliteal artery occlusion through

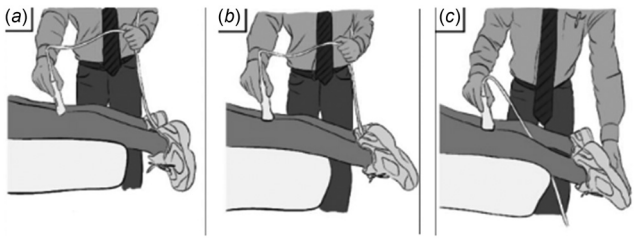


Fig. 1 Current diagnosis procedure: (*a*) physician examines blood flow in popliteal artery with patient prone on table and foot relaxed, (*b*) patient performs plantar flexion with no resistance, and (*c*) patient performs plantar flexion against the physician's hand while the artery is observed

different combinations of forces and angles, improving current methodologies of applying force manually. PAES occurs primarily in strong young athletes who can output large forces. We estimated that an athlete could resist around twice his or her body weight on one leg, based on data estimating forces in the legs while running [14]. Thus, the device was specified to withstand a range of 0–450 lbs (0–2000 N), in line with twice the average weight of an American adult male.

(2) **Measures and logs resistance force and angle of plantar flexion:** Quantitative measurements of the conditions that result in an ultrasound observation of the artery occlusion will be used to better characterize the syndrome for diagnosis and research purposes.
(3) **Does not obstruct blood flow:** The leg must not be compressed by the device to avoid decreasing blood flow and impeding ultrasound observation of the artery.
(4) **Leaves the back of the knee open for ultrasound diagnosis:** The back of the knee, where the artery is the closest to the skin and easiest for the doctor to observe with ultrasound, must remain clear and accessible.
(5) **Little input required from the doctor during ultrasound screening:** The doctor's hands are occupied maneuvering the ultrasound probe to track the artery during screening. The diagnosis device must not require excessive input from the doctor.
(6) **Comfortable for patients with a wide range of foot sizes:** The device must comfortably accommodate plantar-flexion motion while fitting many foot sizes.

The team worked under a tight development timeline. Therefore, the focus was to develop a minimal viable product that enables testing and data collection and fulfills these essential design requirements. However, the device should be versatile as physicians are still trying to understand the condition and might need additional capabilities to conduct the study effectively. Thus, in addition to the design requirements above, adaptability and the availability of multiple operation modes are desired.

3.2 Strategy and Concept Selection. Having the patient lie in the prone position on the bed, as in the current examination setup, was deemed the most suitable. It is the most ergonomic for the doctor due to accessibility of the patient's calf muscles and is comfortable for the patient. Handles and bars on the bed provide bracing to prevent the patient from sliding up the bed. The hospital beds also have adjustable height and angle, which can be used to study the condition at different inclinations. This was found to be of interest due to hydrostatic pressure causing arteries in the legs to enlarge when the patient is tilted upwards.

Other positions, such as standing, may require the doctor to bend down or the patient to perform calf raises on an elevated platform to access the back of the knee. The leg moving vertically during a calf raise would also make blood vessel tracking even more difficult. A wearable device attached to the patient's ankle like a brace was also considered, but this would require considerable compressive forces on the leg to resist plantar-flexion, restricting blood flow. Additionally, a device like this would be harder to clean and more difficult to fit to many foot sizes.

After considering multiple ways to mount the device, as shown in Fig. 2, the bed mounting method was selected over other methods such as cart, leg, or wall mounted. The bed provides a stable platform to attach the device to that can withstand large reaction forces. Additionally, it is easy to clean and doesn't restrict blood flow. The doctor mentioned that one bed would be specially set aside for diagnosing PAES, so permanent attachment of the device was not an issue. While portability and adaptability to many bed models would be part of the next iteration, these were not the main concerns of this design.

The hospital bed that our team designed the device for was the Stryker 0747 Transport Stretcher, shown in Fig. 3, with rolling

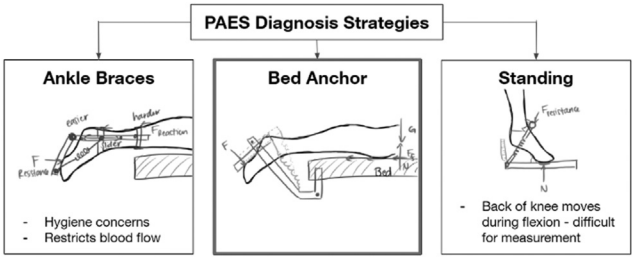
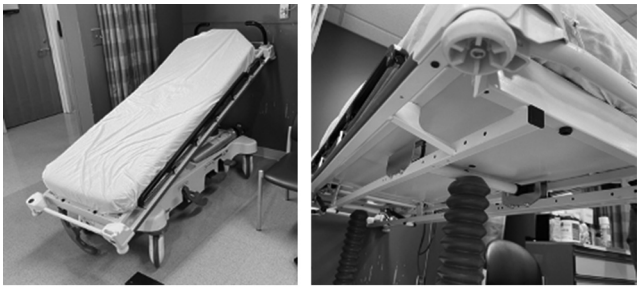


Fig. 2 Initial strategies



(*a*) (*b*)

Fig. 3 (*a*) Stryker 0747 hospital bed for mounting and (*b*) the device is mounted to the frames underneath

wheels and adjustable angles up to a 22-deg incline. The square hollow bars on the underside of the bed have four through holes on each side that our team used to mount the device. No permanent modification was made to the bed.

Once deciding to mount the device to the hospital bed, we came up with two concepts focused on ergonomics from the patient perspective. Both linear and rotary concepts in Fig. 4 were proposed, with the goal of finding the design that felt most natural to the patient.

Two mockups were built using 80-20 aluminum extrusions, linear guides, and rotating fixtures. Figure 5(*a*) depicts the linear mechanism formed using a foot plate and a linear bearing slide. The flat foot plate easily adjusts to accommodate different foot sizes, arches, and angles by sliding up to start flush with the sole of the foot. However, the measurement of the angle would be indirect and more complicated, achieved by measuring how far the toe travels vertically and horizontally during plantar flexion. Figure 6(*b*) depicts the rotational mechanism, which turns around a fixed pivot where a motor would be placed to provide resistance. Angle and force would be directly measured with the motor, but the adjustment of the device for different foot sizes may be more difficult since the pivot point would have to move to coincide with the natural pivot of the ankle.

After testing, it was found that the linear mechanism felt more ergonomic, and the rotary mechanism had a more limited range of

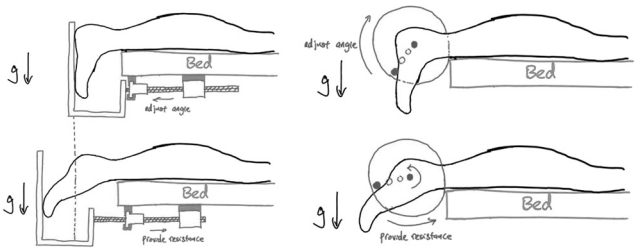


Fig. 4 Left: linear resistance concept. Right: rotational resistance concept.

(*a*) (*b*)

Fig. 5 (*a*) Linear prototype which incorporates a linear bushing slider and (*b*) rotational prototype which uses a fixed pivot point

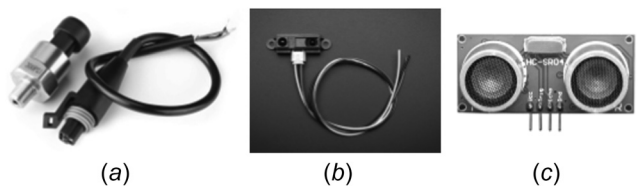
motion. Therefore, the linear mechanism was chosen by the team and Dr. Dowlatshahi as the final concept.

3.3 System Design. The linear system setup required four subsystems: (1) linear actuation mechanism to provide adjustable resistance in the horizontal direction, (2) vertical sliding footplate to allow the toes to naturally rise as the foot is flexed, (3) sensing system to determine force output and angle, and (4) mount to attach it to the hospital bed.

In light of the limited development timeline, the team wished to rapidly create a minimum viable product that would provide our physician with a tool to understand occlusion behavior and receive user feedback for subsequent development. For our adjustable linear resistance system, we considered both a servomotor actuated ball-spline-screw mechanism and a pneumatic piston. Due to ease of implementation and off the shelf availability, a pneumatic double-acting piston was selected as the linear actuation mechanism (McMaster-Carr, 6648K182). A double-acting cylinder allowed us to pressurize both sides of a piston, giving options for a wider range of control modes than a single sided piston. The pneumatic system uses the compressed air supply currently present in most hospital rooms, which is normally kept at 50 PSI, but can be increased to around 80 PSI. When the patient flexes, the cylinder rod is pushed outwards, compressing the gas in one chamber of the double acting piston and expanding the gas in the other.

In addition to the horizontal linear resistance, a passive vertical sliding footplate was needed to accommodate the rise of the toes as the ankle is flexed. A footplate is attached to two parallel linear ball bearing carriages on guide rails, creating a wide base for the patient to press against without creating large moments on the bearings. The flat plate easily adapts to any foot size. Analytical calculations and FEA were performed to ensure the selected rails could withstand the necessary forces and moments.

The force resisted by the patient is calculated by directly measuring the pressures in both sides of the piston. The pressure sensor is a 300 PSI, 5 V DC sensor (Zerone, ZERONE1SQINA-BR6E-05), selected to strike a balance of sensitivity and maximum pressure. Sensing of the angle is done indirectly through the measurement of two distances: the piston extension distance and distance vertically traveled by the foot. One ultrasonic distance sensor (range 2–400 cm) was placed at the bottom of the guide rails pointing upwards to record vertical displacement. An infrared distance sensor (range 10–80 cm) was placed on top of the cylinder facing the footplate carriage to record horizontal displacement.



(*a*) (*b*) (*c*)

Fig. 6 (*a*) Pressure transducer sensor, (*b*) infrared distance sensor, and (*c*) ultrasonic distance sensor

Sensor readout is done using an Arduino Uno and powered by a USB A port. The different sensors used are shown in Fig. 6.

The angle of flexion and Jacobian for angle sensitivity are calculated as shown in Fig. 7 and Eqs. 1 and 2. We found that our angle resolution would be around 9 deg at expected x and y displacements given resolution in position measurements of 1 cm. This angle sensitivity is sufficient for our purposes

$$\varphi = \frac{\pi}{2} - \tan^{-1}\left(\frac{y - y_i}{x - x_i}\right)$$
$$\theta = \pi - 2\varphi = 2\tan^{-1}\left(\frac{y - y_i}{x - x_i}\right) \tag{1}$$

Calculation of angle the foot moves through given sensed changes in X and Y position.

$$J_\theta = \left[\frac{\partial\theta}{\partial x}\ \frac{\partial\theta}{\partial y}\right] = \left[\frac{-2(y - y_i)}{(x - x_i)^2 + (y - y_i)^2}\ \frac{2(x - x_i)}{(x - x_i)^2 + (y - y_i)^2}\right]$$
$$d\theta = \frac{\partial\theta}{\partial x}dx + \frac{\partial\theta}{\partial y}dy \tag{2}$$

Jacobian to estimate sensitivity.

The final step in electronics implementation was the creation of a GUI (Guided User Interface) that displays the foot angle and forces values to the surgeon while he is taking the ultrasound. The GUI was created in processing and communicated with the Arduino via Serial communication. When the "Start" Button is pressed on the GUI, it displays the current pressure value, in psi, the corresponding force, in lbs, the distance of the footplate from its initial position, in mm, and the angle which the foot is at. The "Find Flexion" button is used to find the full length of a patient's foot so that the angle can be accurately calculated using the x-distance. The GUI also allows the doctor to save the full stream of data collected during the test, using the "Save" button. Figure 8 shows a schematic diagram of the Serial communication, and Fig. 9 shows an image of the GUI.

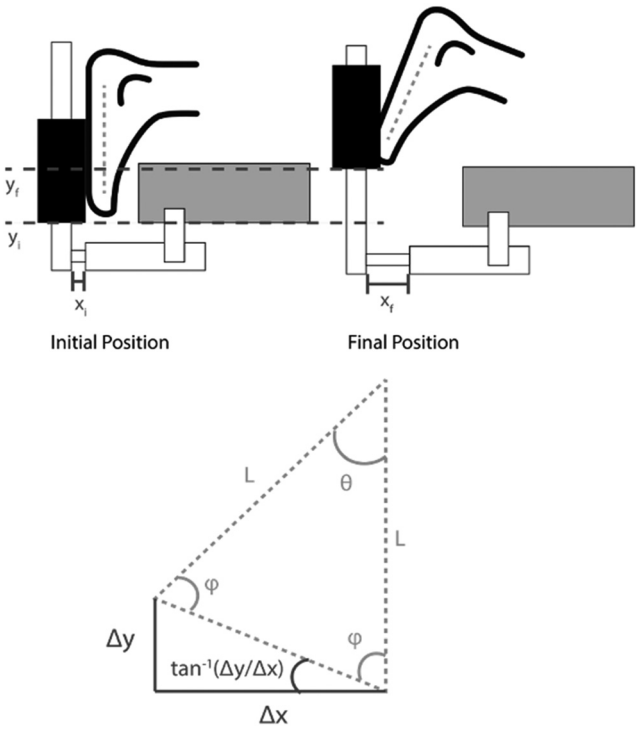


Fig. 7 Geometrical depiction of relationship linear motion and angle

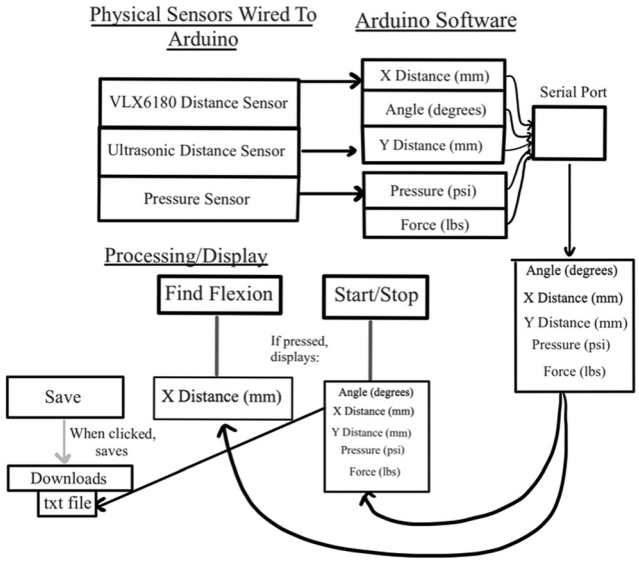


Fig. 8 Sensor and GUI system diagram

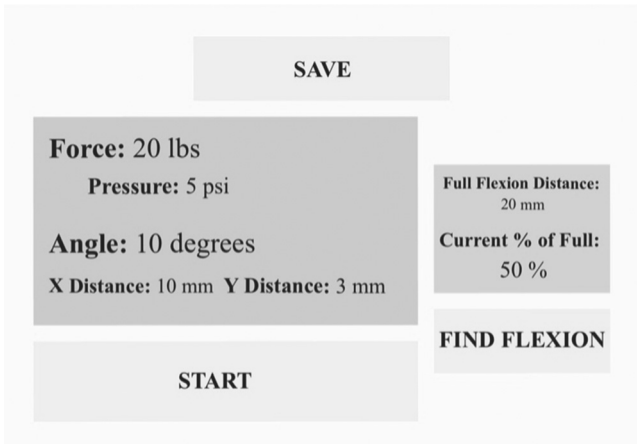


Fig. 9 GUI

Rather than develop a universal mounting system to fit any hospital bed, for this prototype, we focused on the model in Dr. Dowlatshahi's office. We designed an attachment system using a plate and several L-shaped brackets. The cylinder was placed on a $^3/_8''$ thick 6061-T6 aluminum plate, sized for sufficient torsional stiffness. This plate interfaces with the bed frame through L-brackets that can be adjusted to move the plate forward or backward. The mechanical system is mounted centered on the bed so both left and right feet can be comfortably tested without moving the device. Figure 10 shows the overview of the system mounted below the hospital bed.

Hand calculations of stresses followed by computer numerical methods were employed on each element of the system to determine the specifications of components that were needed to withstand a maximum of 450 lbs of resistance. The selected pneumatic cylinder shown in Fig. 10(*a*) is double-acting, single-sided with two parallel rods. Parallel rods are arranged vertically to provide maximum bending resistance.

3.4 Pneumatics. Since this is a research device and it is currently unclear what combinations of force and angle cause PAES patients' arteries to occlude, we designed our device with multiple operating modes by using a double-acting pneumatic

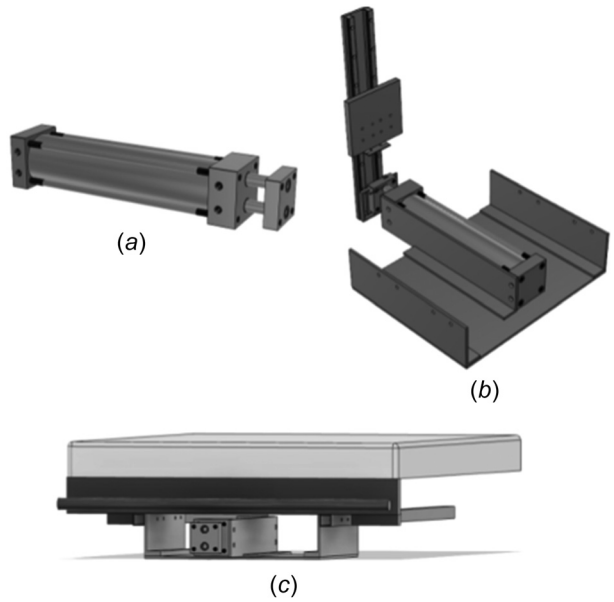


Fig. 10 CAD of prototype setup: (*a*) nonrotating NFPA tie rod air cylinder (double acting, 2-1/2″ bore size, 3″ wide, 10″ stroke length, 0.63″ rod diameter, smaller piston area = 2.746 in^2), (*b*) top view of the mount attached to the cylinder with an L-bracket, and (*c*) view of the cylinder mounted under the hospital bed

cylinder. A diagram of the four different operation modes is shown in Fig. 11.

The first, "Constant Force," mode maintains a steady pressure in the cylinder as it is compressed by using a relief valve. This provides a relatively constant force during the entire range of motion. Its behavior manifests on the force-angle graph as horizontal lines, which change in resistance magnitude with changes in pressure setting. The piston area of 2.746 in^2 minus the rod area of 0.623 in^2 gives an effective piston area of 2.12 in^2. With a maximum pressure

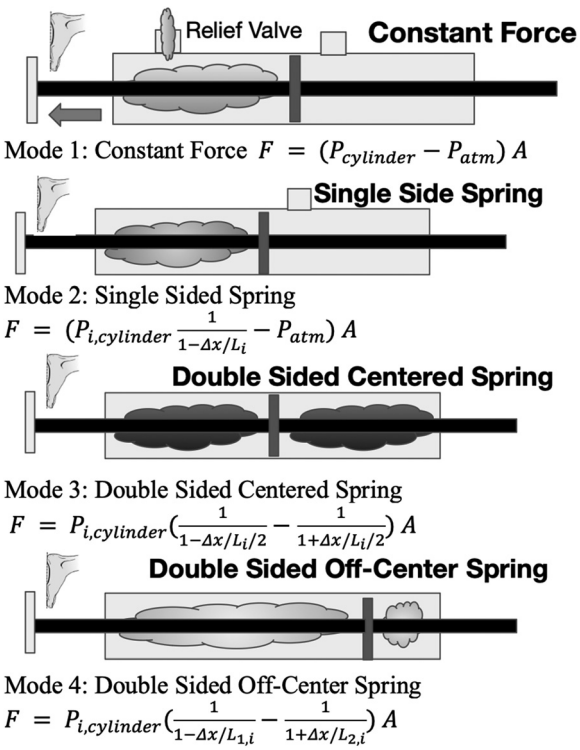


Fig. 11 Double-acting piston modes

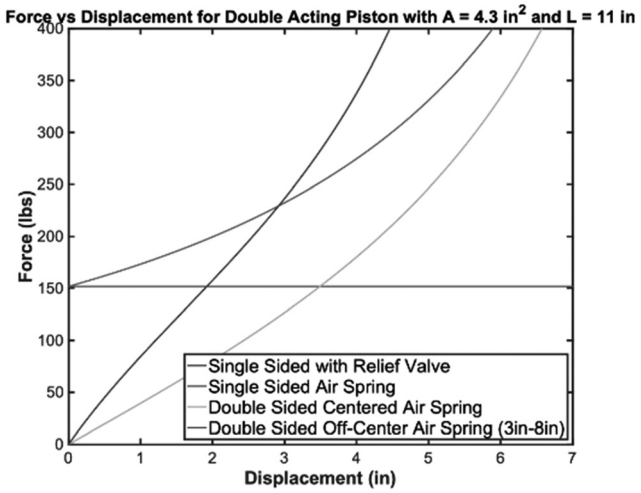


Fig. 12 Four operating modes for the cylinder at a pressure of 50 PSI

of 80 PSI from the hospital compressed air, this constant force mode is theoretically able to operate up to 393 pounds (1748 N).

The second mode of operation is the "Single Side Spring," which requires one side of the piston to be first pressurized and then closed off such that the gas will be trapped and compressed when the patient plantar flexes. This theoretically provides up to infinite resistance as the gas is compressed to near-zero volume. Spring modes may be particularly useful to the doctor and the patient because the patient can quickly pulse their ankle back and forth without the system having to react to changes in pressure. This may allow for increased blood flow to the area and allow for a useful "warm up" to provoke symptoms, which is a common practice [13]. Additionally, this operating mode can reach higher resistances than achievable from just the wall pressure supply.

These will likely be the main operating modes, however, a third "Double Sided Centered Spring" mode may also be useful if it is determined that having the resistance start close to zero would make it easier for the patient to reach larger angles without having to battle large forces. This mode utilizes the double-acting cylinder by pressurizing both sides such that the starting pressures balance the force on the piston. A downside of this mode is a slower increase in force and large displacements needed to achieve higher forces.

The final operating mode, "Double Sided Off-Center Spring," pressurizes the two sides to the same value but with an off-center starting point. This mode allows the force to start at zero, but the force curve approaches that of a single-sided spring at larger displacements, allowing larger forces to be reached. Resistances were calculated as follows for each operating mode, assuming isothermal compression, and plotted in Fig. 12.

These operating modes were achieved using the pneumatic circuit represented in Fig. 13. The hospital wall supplies compressed air through the NPT-DISS (Diameter Index Safety System) adapter, which is then split into two branches. Pressure reducing regulators are used to independently regulate downstream pressure in each branch (between 7 and 123 PSI), allowing physicians to set appropriate pressure levels. Each branch is then connected to one of the air inlets on the double-acting cylinder through a ball valve, which can be set to open or closed position after the chamber is pressurized. Pressure sensors and needle valves are incorporated at the cylinder's inlets to monitor the line pressure and vent the chamber's air into the atmosphere as needed.

Push-to-connect adaptors are used to enable rapid changes to the system configurations for prototyping purposes. The entire pneumatic control system is mounted on a panel that allows for convenient control and modification. While only one branch is currently required for the constant pressure and single-sided spring operation modes, the second branch allows for potential experimentations of double-sided spring operations. All components are rated for at least 140 PSI, far beyond the hospital's air supply capability, to ensure safe operation and accommodate potential higher pressure supply systems.

An error in pressure reading exists due to the friction in the seals of the piston. The patient must overcome both the pressure in the chambers and this static or kinetic friction. Thus, when the patient is in the motion of plantar flexion, the pressure measurement is an underestimate since kinetic friction is also being overcome. When the patient is holding the foot in the fully plantar-flexed position, the pressure measurement is an overestimate since static friction is helping to resist motion. These friction values were estimated using a force gauge to be 7.3 lbs for kinetic friction and 12.8 lbs for static friction.

4 Building and Testing

Figure 14 shows the system at the Orthopedics department of Beth Israel Deaconess Medical Center for testing with Dr. Dowlatshahi.

Initial ergonomics testing showed promising results. The pneumatic system was able to firmly apply resistance against the patient's foot and return to its original position after plantar flexion. The sliding footplate system provided smooth motion and allowed for comfortable and natural positioning of the foot during testing.

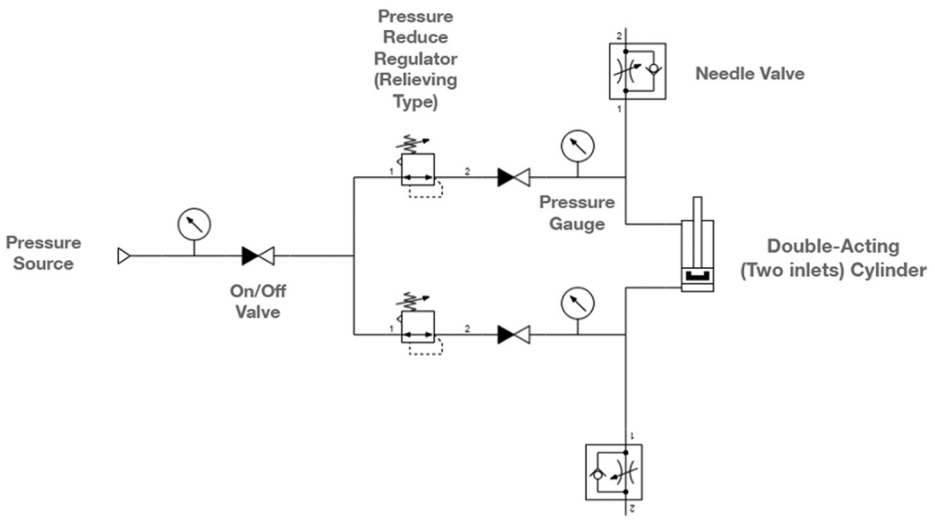


Fig. 13 Pneumatic circuit

The cylinder's stroke and foot plate's length provided sufficient travel distances that can accommodate a wide range of foot sizes.

We tested the device on ourselves and one consenting patient who had symptoms of PAES. A photo of testing is shown in Fig. 15. Data were collected on two asymptomatic females, one asymptomatic male, and one symptomatic female. Results are summarized in Table 1. These trials were conducted in constant force mode. In all trials, a baseline examination of blood flow through the artery during plantar flexion was conducted with no resistance. Participants were instructed to plantar-flex to their maximum angle. Then, pressure was increased to 5 psi and the examination was repeated. Pressure was increased in increments of approximately 5 psi until the patient occluded or was no longer able to plantar flex under the resistance. Dr. Dowlatshahi observed the popliteal artery with an ultrasound probe. In all participants, occlusion percentage increased with increased plantar flexion angle. Occlusion force was marked as the force when full flexion led to lack of blood flow through the artery. Forces reported below were adjusted to add kinetic friction.

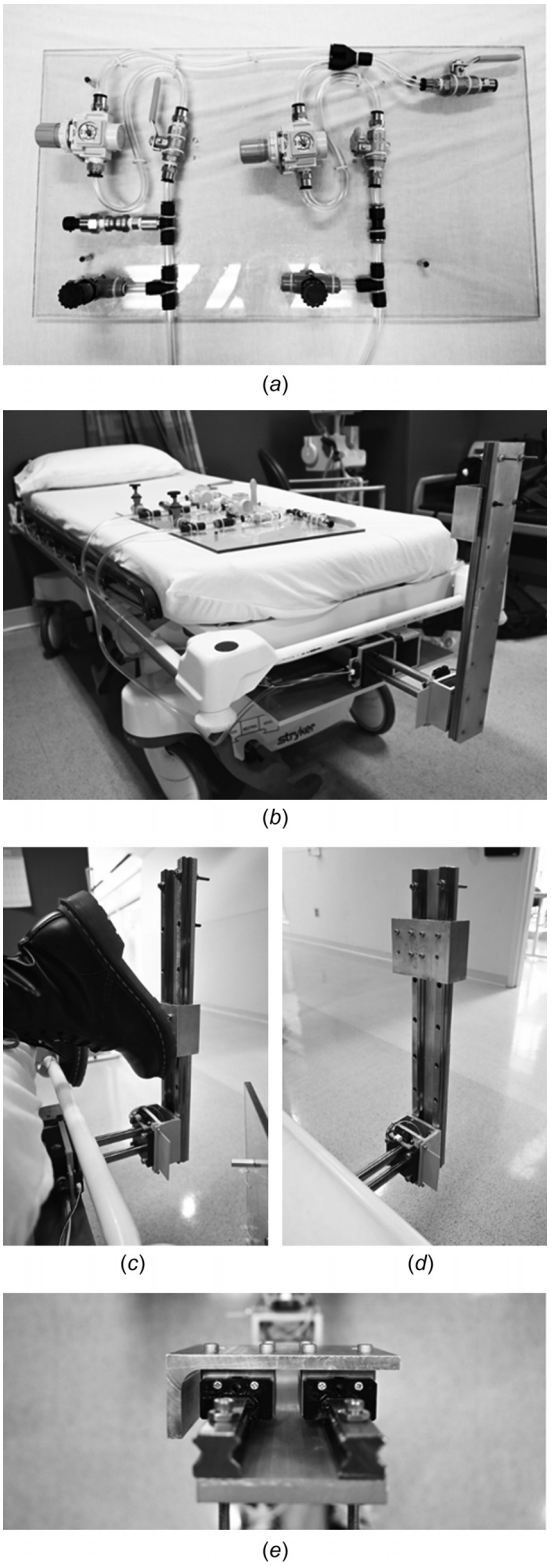


Fig. 14 Final assembly: (*a*) pneumatic circuit, (*b*) full setup on hospital bed, (*c*) author trying out the device, (*d*) vertical slide, and (*e*) close up of linear carriage system

We found that even healthy patients who do not have symptoms of PAES still occlude at high angles and forces. Therefore, comparing average occlusion angle and resistance in patients with the syndrome may allow for quantitative guidelines for diagnosis to be developed. This observation has also been made by Barrett and Carreira et al., who observed that false positive rates may be reduced by examining patients in a standing position [13]. Thus, it may be effective for this device to be used with the bed at a tilt in order to increase blood flow.

Importantly, the device allowed for the accommodation of different experimental designs, such as applying force without plantar flexion or varying force while the foot was flexed. Our tests showed that the artery did not occlude in the reported participants unless there was plantar flexion, suggesting that the angle of plantar flexion is key for artery occlusion. The customizable settings of the device will help Dr. Dowlatshahi determine the significant parameters for PAES diagnosis. These results indicate that the device will be important in improving the diagnosis of PAES by standardizing procedures and quantifying occlusion criteria. However, more extensive testing is desirable to determine the best practices for PAES diagnosis.

5 Future Improvements

The current iteration meets many of the original objectives. Namely, this system is comfortable to use and able to generate adjustable and repeatable resistance for plantar flexion motion. The pressure in the cylinder and displacements of the foot in horizontal and vertical directions are able to be measured and recorded with an Arduino and GUI. This allows the physician to focus on performing the ultrasound diagnosis.

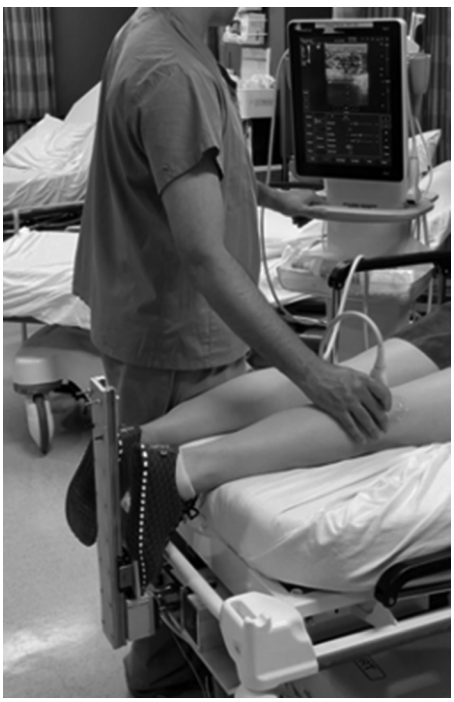


Fig. 15 Prototype testing

Table 1 Testing results

	Age	Force at occlusion (left) (lbs)	Force at occlusion (right) (lbs)	Notes
Symptomatic female	26	43[a]	43[a]	Had botox treatment 1 week prior
Asymptomatic female 1	23	28	28	—
Asymptomatic female 2	21	39[a]	39[a]	—
Asymptomatic male 1	23	18	30	Left leg noticeably more muscle

[a]Did not fully occlude but narrowed.

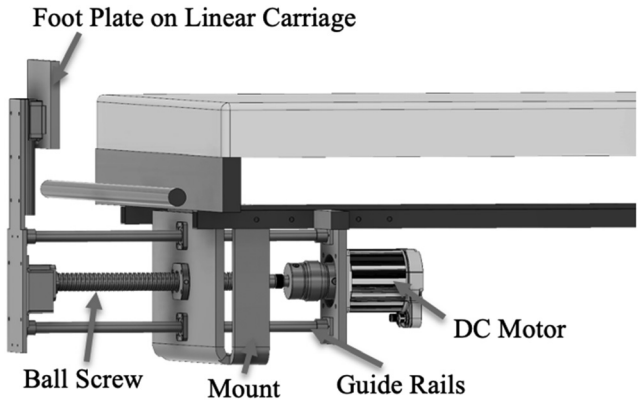


Fig. 16 Concept of ball screw and motor device system

One problem with the system is that the piston experiences friction during its movement. This is caused by the seals that make the chamber air-tight and isolate both sides of the chamber from each other. Thus, a patient needs to provide a higher initial pushing force to overcome the static friction. In order to mitigate this issue, both sides of the piston can start with slightly different pressures, with the differential amount being used to offset frictional force. A spring element can also be attached to the cylinder's rod to provide initial preload.

We chose a manual pneumatic circuit to provide resistance because it was cost-effective and easier to implement, but it gave us less precise control than a servomotor and ball screw spline system, which would eliminate the cylinder's sealing friction by utilizing rolling elements. Additionally, an electronic system would not rely on access to a compressed air supply and, thus, may be easier to implement in smaller doctor's offices without a central air line. This design is in the process of being developed and would have the benefits of better-integrated hardware and software systems, fewer components, and a digital control input. This would simplify operations for practitioners and improve accuracy of measurements. A diagram of the proposed ball screw and motor system is shown in Fig. 16.

Another diagnostic tool that the team explored was a Doppler ultrasound to measure the blood flow near the ankle. The detected blood flow at the ankle was able to be correlated to the ultrasound imagery. Previous to this device, Dr. Dowlatshahi had difficulty using multiple probes during diagnosis since resistance to the patient flexion had to be provided by his free hand. In the future, it may be beneficial for the physician to also use a Doppler probe or attach a Doppler ultrasound probe at the approximate region of the artery on the ankle. This may provide an additional diagnostic measure to sense if blood flow to the lower leg is being cut off during the examination.

6 Conclusion

This prototype was successful in allowing us to determine that the device concept is viable and valuable to the physician before investing more time and money into a more complex system. Dr. Dowlatshahi is working to conduct a study with PAES patients at Beth Israel to collect more data and determine future directions of the project. We look forward to continuing to make improvements on this prototype to allow for the better study and diagnosis of PAES.

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We want to thank Dr. Dowlatshahi for working with us and helping us understand the current procedure for diagnosing PAES and its current shortcomings. We also want to thank the Medical Device Design class staff, including Nevan Hanumara, Jay Connor, and Anthony Pennes, for their help during the process. They have supported us throughout this development process.

Data Availability Statement

The authors attest that all data for this study are included in the paper.

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