THE MAGNABOOT

FOOT RESCUE: A NEW APPROACH TO COMPRESSION THERAPY

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INTRODUCTION

Of the 246 million diabetics currently diagnosed globally, nearly 45% are expected to suffer from atherosclerosis after 20 years duration of the disease [1]. In addition, limb ischemia is observed in nearly 30% of all patients. Physiologically, the effects of arterial wall thickening in the peripheral limbs of diabetic patients is compounded by two conditions: vasculopathy and neuropathy. Vasculopathy refers to inflammatory destruction of blood vessels, including both veins and arteries. Neuropathy involves damage to the peripheral nervous system, which translates to reduced sensation in the limb. While these conditions can lead to a range of symptoms throughout the entire body, their effects are most profoundly observed in the feet. This is not surprising considering the daily stress from walking, running, sports activity, and improper footwear can aggravate a weakened tissue maintenance system. This condition, referred to as Critical Limb Ischemia (CLI), starts with an occlusion in the femoral artery decreasing blood flow to the foot. High blood glucose concentrations interrupt numerous biochemical reaction pathways including ECM deposition, antioxidant defense against reactive oxygen species, and leukocyte migration to name only a few [2]. Together, these events destroy nerve tissue and blood vessels. Inadequate circulation then leads to dry skin that can crack and develop into a wound. Poor sensation allows these sores to go undetected and a compromised immune response contributes to the high likelihood of bacterial infection.

Revascularization is one surgical treatment method to stave off amputation. This procedure uses the autologous vein to bypass the arterial blockage. Although limb salvage rates are greater than 80% (depending on location of occlusion), the therapy also carries considerable risks as patients are immobile after the operation and mortality rates range from 0.97-2.0% [3]. The lack of a popular non-invasive treatment method which could restore sufficient blood flow with minimal risk was the primary

motivation of this research project. Because of the paucity of health coverage for disease treatments, we also sought an affordable therapy for all classes of patients. A review of alternative treatment methods which satisfied these criteria led to an examination of Intermittent Pneumatic Compression (IPC). In this therapy, a patient's leg is placed in a boot insulated with air pockets that rapidly inflate and deflate, the purpose being to relax hardened arteries and improve leg blood inflow. The device extends up to the knee and treatment is carried out in a clinic. Definitive studies from the Mayo Clinic have proven the effectiveness of IPC, as three 2-hour sessions each day resulted in a 41% higher limb salvage rate in the treatment group compared with control. Patients were assessed after 18-months of treatment and limb salvage was defined as the avoidance of amputation [4]. A comprehensive review of literature revealed positive therapeutic results with inflation pressure ranging from 55 mmHg [5] up to 120 mmHg [6]. In order to minimize the force requirement for compression, we chose to design a boot at the low end of the spectrum (approx 55 mmHg).

In the Mayo clinic study, compression therapy was delivered via the ArterialFlow device. Another study by Labropoulos and colleagues used a device called ArtAssist [7]. Unfortunately, neither company complied with inquiries of cost and design. Rental of the equipment was limited to residents in close proximity of either company, which were in the southern United States. This was true for many of the manufacturers of similar devices. The lack of home use of comparable devices is a direct consequence of the devices bulky design and their requirement of constant monitoring by trained personnel. Boots are often composed of a large rigid outer plastic attached to noisy air compressors. Therefore, our aim was to design a portable, user-friendly pressure delivery system. The device is intended for home use and does not require additional expert operating assistance. In addition, a review of literature revealed the advantage of timing the compression with the diastole of the heartbeat. This feature increases blood flow velocity in the lower limbs and has not been incorporated into current

market available models [8,9]. During class presentations, there were numerous concerns about the risk of venous backflow caused by compression. A thorough literature review has found no cases of this occurring, as the venous valves are able to resist the pressure from IPC therapy. Although development of an exact prototype was not possible due to cost limitations, we sought to thoroughly prove the design potential by demonstrating its physical impact using a computer model of the foot, mathematically describing the size and magnetic strength required to rapidly generate 55 mmHg, and identifying materials involved in construction of the device. Combined, these elements would provide the necessary blueprint to build, what we have come to refer to as **The MagnaBoot**.

PROJECT OBJECTIVES

1. To design a compact and cost efficient device that is more effective than current devices on the market.*
2. To model the effect of our IPC device on leg venous/arterial blood circulation.
3. To build a simple prototype demonstrating the mechanics of our pressure change device as a proof of concept.

* The success of the design and accuracy of the circuit modeling of blood flow can be verified by a Doppler ultrasound done on the femoral artery of the leg. This test evaluates the blood flow through the vessels and should demonstrate an increased circulation of blood, matching rates predicted by the model after initial use of the device [10].

DESIGN PROGRESS AND RESULTS

I. Design overview

The device (shown in Figure 1) consists of the following three components:

1. Compression boot
2. Heart cycle monitor
3. Microcontroller & user interface

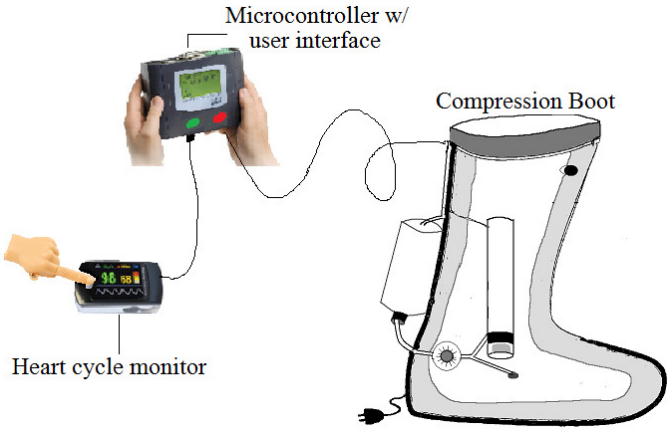

Figure 1. Three Principal Interacting Components of the MagnaBoot.

The heart cycle monitor (pulse oximeter) transfers data to the microcontroller via a USB port. The user interface has a START and STOP button to turn on/off the device. The electromagnet and electric pump on the boot are powered through an AC to DC converter (120Vac to 12Vdc) plugged into a power outlet. The microcontroller is wired to the electric pump and the electromagnet to control the rate of inflation. A pressure gauge is present on the air line connecting the pump to the inlet hole. Pressure readings obtained are fed back to the microcontroller. A pressure release valve at the top of the boot allows the internal air bag to be deflated after usage.

The components of the compression boot are shown in Figure 2 below. The rigid outer casing contains the inflatable internal air bag and provides an attachment surface for the pressurizing electromagnet and power source. The flow of air within the air chamber is controlled by an electromagnet. On passing current through the coils of the electromagnet, the material becomes magnetized thus attracting the armature plate to the bottom of the chamber. This causes air to be compressed into the airbag thereby increasing the pressure on the leg (see calculations in Appendix A). On the cessation of current flow, the electromagnet is demagnetized causing the armature to rise because

of the internal pressure within the airbag. The microcontroller synchronizes the switch circuit required to turn on/off the electromagnet at a rate timed with the heart cycle readings, as described in section II.

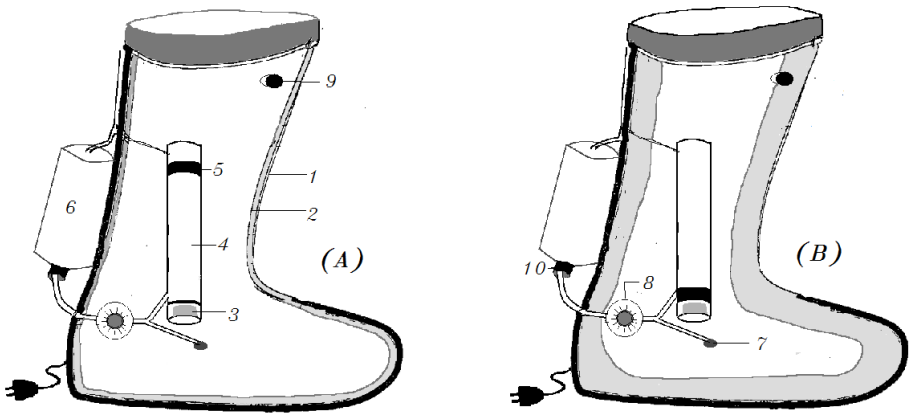

Figure 2. MagnaBoot components depicting (A) deflation stage and (B) inflation stage: 1- Rigid Outer Casing; 2- Inner Air Bag; 3- DC Electromagnet; 4- Air Chamber; 5- Armature plate; 6- Electric Air Pump; 7- Sealed Input; 8- Pressure Gauge; 9- Pressure Release Valve; 10- Pump Inlet Valve

II. Functional overview

A key component of the system is the microcontroller, which processes inputs from the user, pressure gauge, and pulse oximeter, and sends out signals to the magnet and pump, as shown in Appendix B. Importantly, the microcontroller user interface is extremely user-friendly, with very few options, mainly consisting of start and stop commands.

The microcontroller functionality can be divided into two main parts: an algorithm for initial pressurization, and an algorithm for generating pressure pulses. The initial pressurization algorithm is designed to activate the pump until the pressure in the air bag reaches 55 mmHg. The pressure pulses algorithm processes the real-time cardiac cycle signal received from the pulse oximeter. First, a high pass filter is used to remove background noise and motion artifacts. Afterwards, a special algorithm taking into account the time delay of pulse propagation is used to find the diastole onset in the cardiac

cycle signal [11]. The diastole onset then triggers magnet activation, ultimately producing increased pressure in the air bag.

III. Materials & rationale

1. **Compression Boot**
   a. The **rigid outer surface** will be made of fiberglass as it is strong, inexpensive and has a high surface area to weight ratio. This composite is made of epoxy polymer laced with glass fibers (tensile strength = 50 000psi [12])
   b. The **inner air bag** will be made of urethane coated nylon (material used in blood pressure cuffs), as it resists wear form repeated inflation and deflation.
   c. The **electromagnet** chosen based on system power requirements and the minimum 9.2N force requirement as calculated in Appendix A, is made by Storch Circular, part no. E001-0489-016 [13]. The electromagnet will be shielded from surroundings with a plastic casing.
2. The **Heart Cycle Monitor** for the device will be a pulse oximeter, given the low price and ease of use (does not involve electrodes like ECG machines or complicated user interfaces). The model made by LongfianScitech Co was chosen for small volume and weight [14]. The device also contains a USB interface, which is integral for communication with the Microcontroller, discussed below.
3. The chosen **Microcontroller** is the C2000^{TM} 32-bit Real-time MCU produced by Texas Instruments [15]. This chip offers real-time control applications, necessary for the integration of data from the pulse oximeter.

IV. Blood flow modelling

In order to gauge the effect of timed compressions on blood flow in the lower limbs, the lower body and foot region was modelled as a lumped electrical circuit in MATLAB [16]. The circuit model

allowed us to determine how timed compressions would affect a diabetic foot compared to a non-diabetic foot. The objective of the model was to match the output blood volume of the diabetic and non-diabetic foot. The electrical and fluid dynamic analogues were defined as follows:

Fluid quantity	Relationship	Electrical quantity	Relationship
Pressure	P	Voltage	V
Flow rate	Q	Current	I
Compliance	Q = C(dP/dt)	Capacitance	i = C(dv/dt)
Inertia	P = L(dQ/dt)	Inductance	v = L(di/dt)
Resistance	P = QR	Resistance	v = iR

Table 1. . Electrical and Fluid Dynamic Analogues Used for MATLAB Lower Limb Modeling.

The model used was a simplified model of the cardiovascular system in the leg, with one resistor, inductor, and capacitor for the arterial component and the venous component. The diode represents the function of the vein valve, which allows blood to flow in the forward direction only.

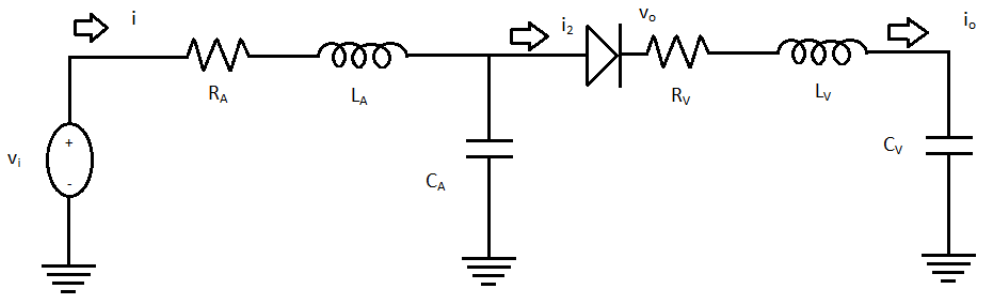

Figure 3. Circuit Diagram for a Lumped Model of the Arterial and Venous System of the Leg.

Continuous and discrete time analysis of this circuit is included in Appendix C, as well as input and output waveforms for a normal leg, diabetic leg with neuropathy, and a diabetic leg with neuropathy using the MagnaBoot. The simulation shows that in diabetic neuropathy, an increase in pressure and decrease in flow rate occurs, while during the use of external compression,

synchronized increases in both pressure and flow rate occur, forcing blood in the leg back to the heart, thus improving circulation.

CHALLENGES AND RISKS

The following are the foreseen challenges and risks that may arise with the device:

1. The electromagnet may not demagnetize at a fast enough rate to allow the air bag to be fully de-pressurised. This would depend on the choice of material for the electromagnet and the hysteresis loop of the chosen material.
2. Due to the high strength of the electromagnet, power may be dissipated as heat and cause local heating of the boot in the area surrounding the magnet. Care should be taken to ensure that the material chosen for the cylindrical air chamber and the outer casing of the boot can withstand these temperatures; fibreglass can easily withstand such temperatures [17].
3. Due to the improved blood flow brought about by the boot in the blood vessels, there was concern of an increased risk of embolism in diabetic patients. Intermittent Pneumatic Compression therapy has been proven effective in decreasing the risk of proximal and deep vein thrombosis [18]. A review of literature found no cases where IPC therapy exacerbated pre-existing conditions. However, patients are encouraged to consult a physician before the proceeding with a therapy regime.
4. Ruptures in the inner air bag could lead to escape of air after pressurisation and hence a reduction in the compression pressure applied to the foot over the treatment period. Replacement airbags will be made available in this situation.
5. The device may cut off arterial blood flow to the leg for patients suffering from tachycardia (resting heart rate > 100 bpm). This is because the increased heart rate may exceed the maximum

magnetisation/demagnetisation time of the electromagnet and hence non-diastole timed compressions could impede blood flow into the femoral artery. A safety threshold for heart rate will be incorporated into the microcontroller algorithm, triggering device shutdown for resting heart rates above 100 bpm.

6. Rapidly moving mechanical parts could undergo wear and tear which would ultimately reduce the durability of the device. This will be minimized by thorough stress testing prior to commercialization.
7. Extreme shoe sizes may not be accommodated within the boot design. The manufacturing of different boot sizes outside of a small, medium and large range for adults could increase manufacturing costs.
8. To address hygienic concerns the inner bag is detachable to allow cleaning and disinfection.

FUTURE WORK

1. The pulse oximeter could be integrated into the hand held user interface to increase user-friendliness of the device.
2. Modifications to the inner air bag so as to allow for the inclusion of an antibiotic solution or therapeutic salts that hasten the healing of foot wounds/ulcers.

CONCLUSION AND IMPACT

The MagnaBoot offers a compact and early-treatment solution for patients suffering from CLI. The design differs from comparable technology in its emphasis on providing compressions synchronised to the heart beat to allow maximal arteriole inflow into the leg. A simple and intuitive user interface,

noise free mechanics and the ability to use the device with no medical assistance make the MagnaBoot ideal for home usage.

As device fabrication and clinical trials were outside the scope of our research, we sought to determine physiological effectiveness through lower limb modelling. ANSYS engineering software was considered in the original proposal but the circuit representation was more appropriately analyzed using MATLAB. The results support the predicted blood flow improvement in the lower limb. Although approximate cost estimates of individual components and the entire device were sought, much of the raw material cost (i.e. fibreglass, nylon) is highly dependant on quantity, importing costs, etc. Thus, a cost estimate was not obtained. The advised treatment of 2 hours daily should provide noticeable and quantifiable results as demonstrated by the fluid flow modelling algorithms. Surgical alternative treatments make this non-invasive therapy extremely appealing. Therefore, we believe there exists a significant niche within the diabetic community which would embrace the MagnaBoot.

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APPENDIX A

Mathematical derivations:

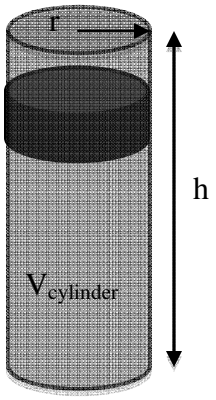
State 1 is defined as atmospheric pressure before compression, and state 2 is defined as 55 mmHg after compression and pressurization of the bag.
Assuming isothermal compression, temperature remains constant. The pressures are:

$$P_1V_1 = P_2V_2$$
$$P_2 = 55mmHg(gauge)$$
$$= 7.36kPa + 101.325kPa$$
$$= 108.685kPa$$
$$P_1 = 101.325kPa$$

Volume of air in the bag when fully inflated, V_2, will be 2 L as specified in the design parameters. V_1 can be found as the volume of air required in the bag and cylinder to depressurize the bag.

$$V_2 = 2L$$
$$V_1 = \frac{P_2V_2}{P_1}$$
$$V_1 = 2.145L$$
$$V_{cylinder} = V_1 - V_2 = 0.145L$$

Therefore 145 mL is the required cylinder volume to pressurize the bag from 0 to 7.36 kPa (gauge).



$$V_{cylinder} = \pi r^2 h$$
$$r = 0.02m$$
$$V_{cylinder} = 1.45 \times 10^{-4} m^3$$
$$h = \frac{V_{cylinder}}{\pi r^2}$$
$$h = 0.115m$$
$$= 11.5cm$$

Therefore assuming a radius of 2 cm, the required cylinder height is 11.5 cm. The minimum force required to pressurize the bag within the boot, assuming that the piston applies a constant force against constant maximum pressure is 9.2 N:

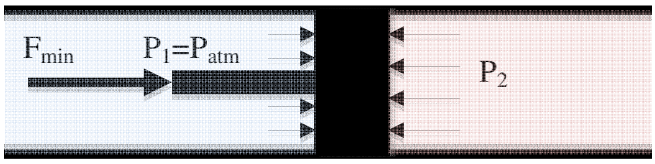
$F_{net} = F_{\min} - (P_2 - P_1)A$

$A = \pi r^2$

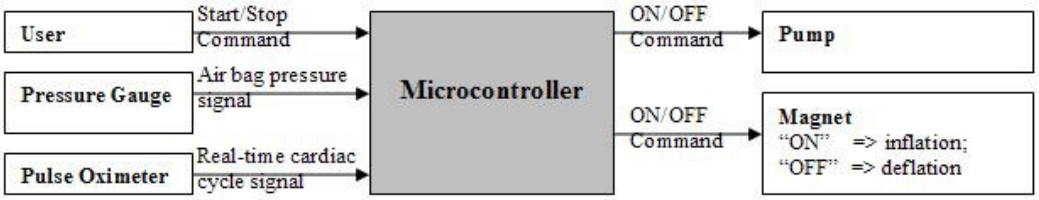
$F_{net} = 0$

$F_{\min} = (P_2 - P_1)A$

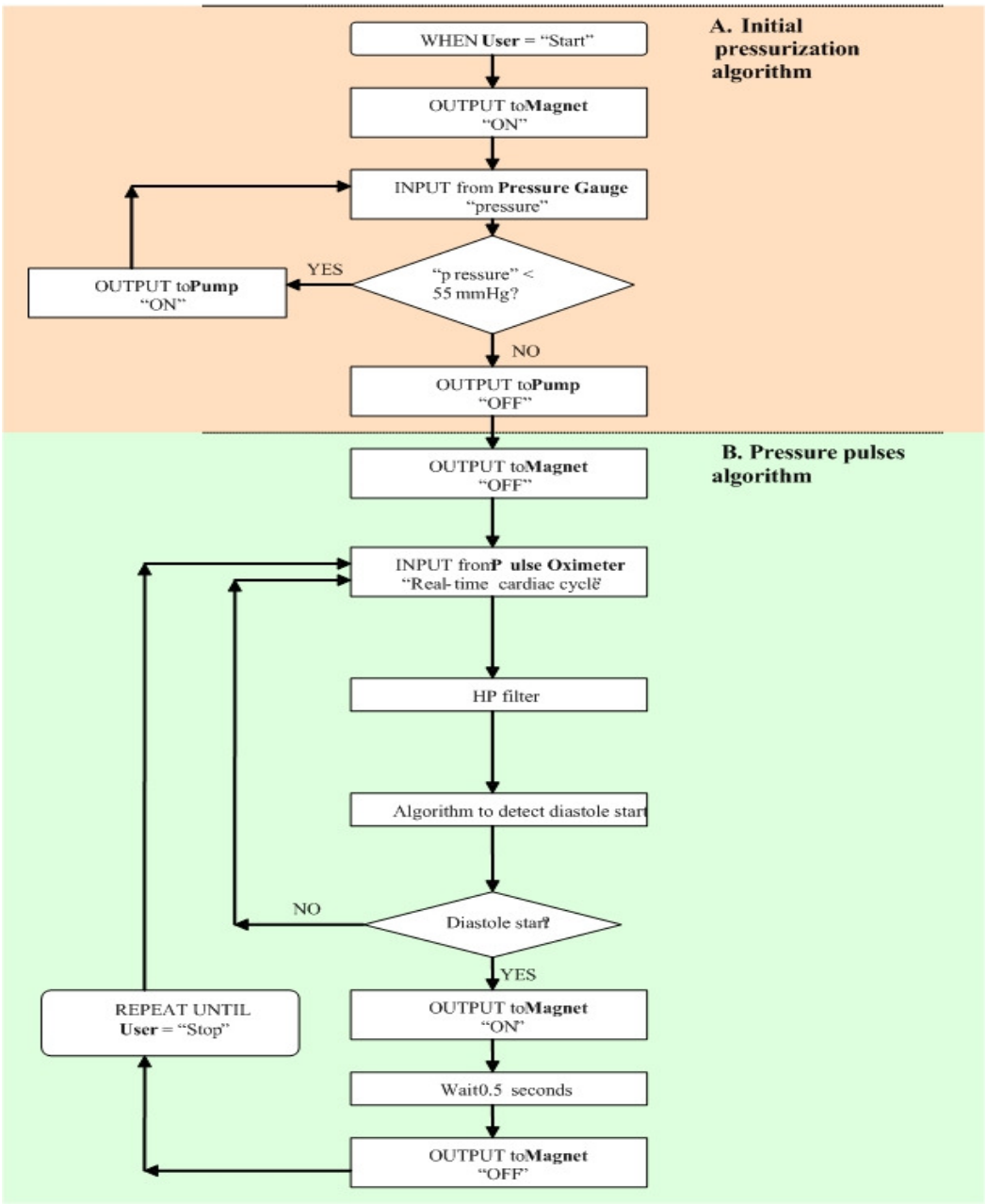
$F_{\min} = 9.2N$



APPENDIX B



Supplementary Figure 1. Microcontroller Inputs and Outputs .



Supplementary Figure 2. Microcontroller Functional Schematic.

APPENDIX C

MATLAB Equations and Figures:

Relation between mechanical properties of cardiovascular system and their equivalent electrical elements:

1 mmHg = 1 volt (pressure - voltage)
1 ml/s = 1A (volume - charge)

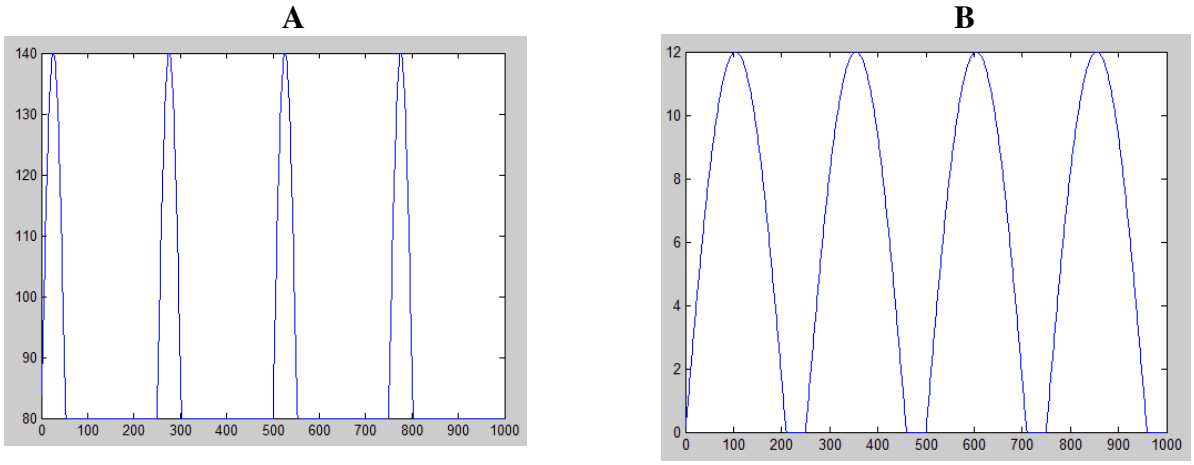
Continuous time equations for this circuit are:

$i_2 = i + R_A C_A(di/dt) + L_A C_A(d^2i/dt^2) - C_A(dv_i/dt)$
$i_o = r(i_2)$
$v_o = i_o R_V + L_V(di_o/dt) + (1/C_V)\int i_o dt$

Discrete time equations for this circuit using a time step of n=1 are:

$i_2[n] = i[n] + R_A[n]C_A[n](i[n] - i[n-1]) + L_A[n]C_A[n](i[n] - 2i[n-1] + i[n-2]) - C_A(v_i[n] - v_i[n-1])$
$i_o[n] = \max(0, i_2[n])$
$v_o[n] = i_o[n]R_V[n] + L_V[n](i_o[n] - i_o[n-1]) + (i_o[n] + i_o[n-1])/(2C_V[n])$

Input and output waveforms



Supplementary Figure 2. Y-axis: A. Input Pressure (mm Hg), B. input flow rate (mL/s). X-axis: Time (samples)

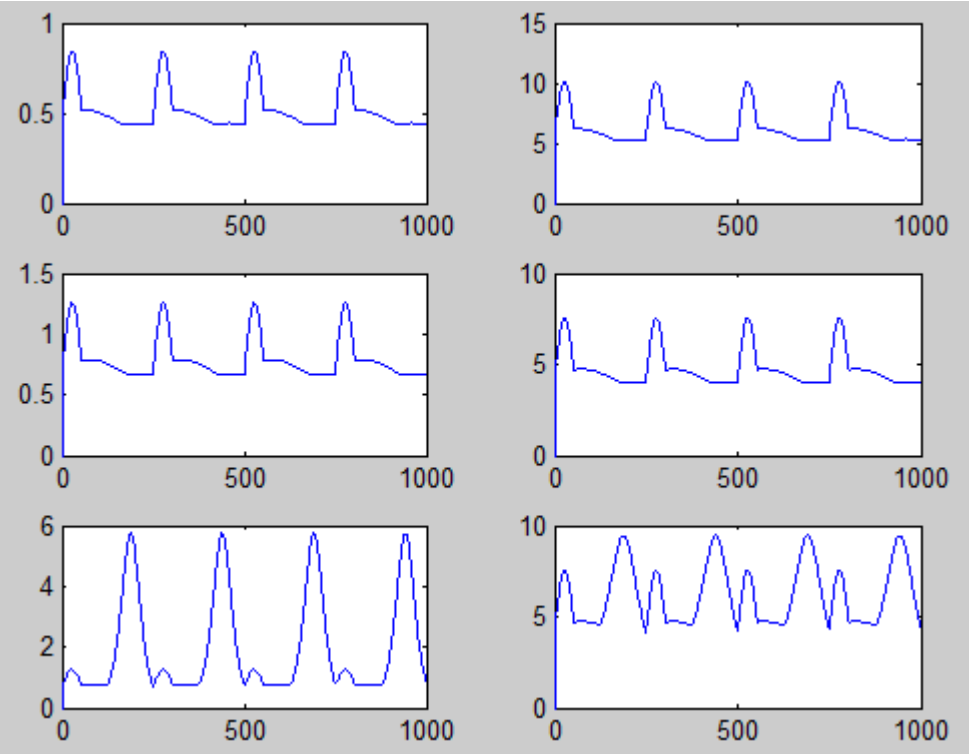
Circuit element values and parameters (justification for these parameters can be found in [16]):

	Non-diabetic	Diabetic neuropathy	Diabetic neuropathy with pump
R (artery) (kΩ)	115	1.1 x non-diabetic	Diabetic / r^4[n]
L (artery) (μH)	90	1.05 x non-diabetic	Diabetic / r^2[n]
C (artery) (μF)	0.05	0.5 x non-diabetic	Diabetic x r^3[n]
R (vein) (kΩ)	0	1.1 x non-diabetic	Diabetic / r^4[n]
L (vein) (μH)	0	1.05 x non-diabetic	Diabetic / r^2[n]
C (vein) (μF)	1.2	0.5 x non-diabetic	Diabetic x r^3[n]

Supplementary Table 1. Parameters Used for Modeling Equations.

Where r (the average radius) is estimated to vary according to the following equation:
r = 1+min(0,0.3*sin(0.025*t)); % t = sampling rate of 250Hz

Output pressure and flow rate:



Supplementary Figure 3. Output Pressure (Left) and Flow Rates (Right) of Three Different Model Limbs.

The left column shows (from top to bottom) the output pressure of a non-diabetic leg, a diabetic leg, and a pumped leg. The right column shows (from top to bottom) the output flow rate in a non-diabetic leg, a diabetic leg, and a pumped leg.