OPTIMIZATION OF INTERMITTENT PNEUMATIC COMPRESSION FOR LOWER EXTREMITIES, COMPUTATIONAL RESULTS

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OPTIMIZATION OF INTERMITTENT PNEUMATIC COMPRESSION FOR LOWER EXTREMITIES, COMPUTATIONAL RESULTS

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Thesis

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CHAPTER I

INTRODUCTION

Introduction to Deep Venous Thrombosis

Deep venous thrombosis (DVT) is a medical condition characterized by development of an intravascular mass of red blood cells and fibrin within the deep veins of the leg (Hirsh, 1996). This mass, or thrombus, compromises the health of the patient as it can cause inflammation, pain, and edema. Moreover, a pulmonary embolism (PE) will develop should the thrombus become dislodged from the deep leg vein and relocate to the blood vessels in the lungs, severely disrupting or completely blocking circulation. Emboli are of tremendous concern as they prove more times than not fatal, if not diagnosed and treated in a timely manner. DVT and PE are collectively grouped into venous thromboembolism (VTE).

The annual incidence of VTE in the United States has reached 600,000 cases, causing up to 200,000 related deaths (Hirsh, 1996 and Anderson, 1991). DVT is highly prevalent among post-operative patients. Moreover, with the number of surgical patients increasing, especially with the rise of elective surgeries, the number of DVT cases is increasing as well. Anderson indicates that VTE is the number one case of unexpected hospital–related deaths.
Post-operative patients are predisposed to VTE because movement of their lower extremities may be difficult and/or discouraged (Labropoulos, 2000). This reduction in movement causes a reduction in the level of musculovenous pump activity. In a healthy individual, this pump functions as a peripheral heart, providing a counteracting force to the sizable hydrostatic pressure that venous blood flow must overcome to return to the heart. Normal muscle activity provides enough force to overcome this hydrostatic pressure, allowing appropriate venous return. For example, the muscular contractions generated during walking provide a pressure of approximately 100mmHg, and at maximal muscular contraction, up to 250mmHg.

Reduced musculovenous pumping, and lessened resultant pressures compromise venous return of postoperative patients. Blood flow in the lower extremities slows to allow pooling, and potentially coagulation. Development and progression of venous thromboembolism is then instigated.

**External Compression as a DVT Prophylaxis**

As originally described by Virchow, thrombus formation is initiated by an inflammatory response to a vessel lesion, venous stasis, and/or an increase in blood’s coagulation tendency.

Traditional DVT prophylaxis includes a pharmaceutical regimen aimed at anti-coagulation therapy. Physicians have administered heparin and warfarin to decrease blood’s coagulation tendency by altering its chemical composition. However, because many DVT-prone individuals are also surgical patients, complications involving hemorrhage and bleeding have occurred.
Other approaches have been mechanical solutions, aiming to alter the hemodynamics of vascular blood flow in the lower extremities and eliminate venous stasis. Compression stockings, electrical stimulation, and external compression are used (Cotton, 1977) in both the clinical and home setting, as less supervision is required.

One method of external compression involves usage of an intermittent pneumatic compression (IPC) device. The intention of IPC is to provide a substitute for a sluggish musculovenous pump, ultimately changing the venous blood flow characteristic of a DVT patient. An IPC device generally consists of a pneumatic pump, tube assembly, and removable cuff(s). The cuff(s) connect to the pump via the tubes, allowing the cuffs to inflate and deflate automatically. During treatment, the cuff is secured circumferentially around the lower extremity, interfacing directly with the skin. When the cuff inflates, it applies pressure to the section of the extremity over which it covers. This pressure compresses the tissue against the blood vessels, forcing blood out of the legs, toward the heart.

IPC devices vary greatly, from construction, material, interface pressure, number of cuffs, cuff segmentation, compression mode, including inflation sequencing and gradation, and recommended use. Three device features have been considered by researchers to be significant in DVT prevention: (1) cuff design; (2) compression mode; and (3) interface pressure.

Cuffs of an IPC device are designed to cover a patient’s lower extremity, yet different design options are available. Some devices provide only foot compression, whereas others provide calf or thigh compression. Still other devices provide a combination of foot, calf, and thigh compression. The amount of coverage that a cuff
provides to a lower extremity has been clinically demonstrated to affect venous blood flow.

Compression modes describe the ways in which an IPC device inflates (Kamm, 1982). Current devices generally operate by one of three (3) compression modes: uniform, graded, and sequential or wavelike. Uniform compression applies a single pressure over the entire area simultaneously. Graded compression applies a non-uniform pressure – highest pressure at the most distal leg segment and lowest pressure at the most proximal – over the entire area simultaneously. Sequential compression applies a uniform pressure to the entire area in a progressive manner, beginning at the most distal leg segment and ending at the most proximal (Kamm, 1982). Researchers suggest that the hemodynamic effect of a specific device is partly controlled by mode.

Interface pressure of a device is controlled by the level of cuff inflation. Pressure widely varies between devices from 40mmHg to 160mmHg. Increasing the level of cuff inflation increases interface pressure. Clinical studies have shown a positive correlation between interface pressure and lower leg vein hemodynamics.

Several IPC devices are commercially available, including ArtAssist 1000 (ACI-Medical, San Marcos, CA); Arterio-Venous Impulse (Novamedix); WizAir (Medical Compression Systems Inc, Ltd, Or-Akiva, Israel); and VenaFlow (AirCast Inc, Summit, NJ). Individual device parameters are detailed in Chapter II.

The efficacy of IPC devices in the clinical setting has been well-documented for DVT patients (Chen, 2001). According to clinical studies, the instance of DVT can be reduced with IPC treatment to the lower extremities. This prophylactic method not only has proven to reduce morbidity and mortality, but also provide a low-cost and more
A conservative solution compared with surgical intervention and drug therapy. One example is illustrated in a study conducted on 500 surgical patients using various DVT prophylactic methods. The incidence of DVT in the group treated with IPC was only 11.5%, compared to the control group at 35.6%. Other methods, such as heparin treatment and the use of elastic compression stockings, also proved to have higher incidence of DVT than IPC, 25.2%, and 14.2%, respectively. (Borow, 1983)

Although IPC devices have proven effective at preventing DVT, there is still a need to understand how IPC devices interact with the lower extremity blood flow, in order to optimize their design and operation (Labropoulos, 2000). The purpose of the present investigation is to address this need.

**Goal of Thesis**

The purpose of this thesis is to

1. develop a computational model that aims at determining optimal IPC parameters;
2. and evaluate the efficacy of various compression parameters (mode, rise time, etc.)
CHAPTER II
LITERATURE REVIEW

A MEDLINE search was conducted to identify all English-language articles and reviews (1977-present). The search retrieved all articles that were indexed with the MeSH “pneumatic compression” and at least one of the following: intermittent compression; external compression; deep venous thrombosis; computational model; venous hemodynamics; lower extremity. References were also cross-checked for all reports.

Several computational and clinical studies have been conducted to attempt determination of optimal IPC parameters, ideally providing the most antithrombotic hemodynamic effect in the lower extremities.

**Computational Studies**

A lumped parameter model of the leg venous system was developed by Kamm, 1977, to study hemodynamic changes induced by IPC. His goal was to predict venous flow by changing the IPC modes and pressure. Several conclusions were reached including the finding that sequential compression causes greater blood flow velocity than uniform compression, and that sequential compression can reduce the time to empty the venous system to 1-2 seconds.
Kamm furthered his work in 1982 with the development of a model involving a continuous system of vessels, allowing detailed discrimination between IPC modes, or inflation schemes. The study resolved that graded and sequential compression provided the most rapid and complete emptying of vessels. Suggested optimal parameters included a gradation change of 5-10 mmHg and a sequencing change of 0-0.5 seconds.

Under Kamm’s guidance, Dai, 2001, developed a finite element model of the lower extremity to predict venous blood flow and pressure distributions when subject to IPC. This study aimed to evaluate the difference between asymmetric versus symmetric compression, circumferentially around the lower extremity. Results suggested that at low pressure, symmetric compression produced greater hemodynamic effects, yet at high pressures, asymmetric compression proved more effective.

Fragomeni, et. al., 2008, developed a lumped parameter, electrical analogue model of the venous tree of the lower limbs with nonlinear parameters. Although this model was aimed to study possible treatments for chronic venous insufficiency, compression to the limb is applied and therefore can be analyzed in context of this study. Each venous segment was described by and RC circuit, separated by ideal diodes, which represent venous valves. At each segment, the blood flow was computed from the pressure drop across the conduit resistance. Limited data were provided but agreement was indicated between simulation of a Valsalva maneuver and its physical manifestation.

Narracott, et. al., 2009, developed and validated a finite element model of calf compression during IPC. Calf geometry was acquired from MRI data of seven (7) healthy subjects. These data were reconstructed to build 7 individual finite element models. IPC simulations were then run on the models to study tissue deformation. The
simulated results were compared against physical compressions, also imaged by MR. Qualitative agreement was obtained between the two methods, yet errors in the study prohibited conclusive quantitative agreement. However, it was determined that calf compression caused consistent deep vessel collapse. No data was presented for suggested IPC parameters.

Avril et. al, 2010, used MRI data to construct a finite element model of the calf undergoing external compression. This compression was static, however, and not intermittent. Blood flow analysis was achieved using computational fluid dynamics (CFD).

Wang et. al, 2011, furthered Avril’s modeling work, in which CFD via MRI data was employed to again analyze blood flow of calves subject to static external compression. This compression, based on an average of 10 healthy subjects, caused venous flow rates to decrease, but the decrease in cross-sectional area of the vessel was significant enough to increase blood velocity. Wall shear stress also increased 4-fold in some vessels. Although Avril’s and Wang’s studies are not performed with IPC devices, knowledge can still be extracted from the results.

Clinical Studies

In addition to Kamm’s modeling work, clinical studies were also performed. In Kamm, et. al., 1986, a study is described whereby 23 healthy subjects undergo radionuclide-gated imaging during 10 different pressurization cycles to the calf. Results indicated that graded compression, specifically 5-10mmHg, and sequencing, from 0-0.5 seconds, provided optimal IPC conditions.
Flam, et. al, 1995, enrolled 26 healthy subjects to test a uniform compression, calf IPC device (Flowtron DVT-10 and AC Pump, HNE Healthcare, Manalapan, NJ) and a thigh-high, sequential IPC device (SCD 5320, Thigh-Hi Sleeve 5330, Kendall Co., Mansfield, Mass.). The compression cycles were similar between the two devices. The maximum pressure applied with the latter device was 40mmHg; the applied pressure was not given for the former. Duplex ultrasonography was used to measure blood velocity. Overall, the calf IPC provided 107% increase in velocity, compared to the 77% increase provided by the thigh-high system.

Christen, et. al., 1997, compared a high-pressure foot compression system (A-V Impulse System, Novamedix, Andover, UK) to low-pressure, whole-leg compression (Turbo-Puls Systems AB, Uppsala, Sweden) on 10 healthy subjects. Duplex ultrasound scanning was used to measure venous blood velocity. The pressure difference of 140mmHg was significant in increasing venous velocity, supporting a high-pressure IPC device.

Malone et. al., 1999, studied 22 healthy lower extremities and 11 post-thrombotic lower extremities for optimal IPC. Using duplex ultrasound scanning, Malone determined that high-pressure, rapid inflation compression increased venous velocity compared to traditional low-pressure, slow-inflation devices. High pressure ranged from 120-160 mmHg, whereas low pressure ranged from 40-50 mmHg. Rapid inflation time was defined as 1-2 seconds, and slow inflation was defined as 11-12 seconds.

Delis, et. al., 2000, conducted a clinical study using the ArtAssist 1000 device (ACI Medical Inc., San Marcos, CA) applied to the foot, calf, and foot/calf, with frequency combinations of 2, 3, and 4, impulses/minute, applied pressures of 60, 80, 100,
120, and 140 mmHg, and – for the foot/calf – IPC proximal inflate delay times of 0.0.5, and 1 second. Six (6) healthy subjects were tested for direct venous pressure measurements. Ultimately, Delis suggested wavelike IPC applied to the foot and calf, using 120-140mmHg of pressure, applied at 3-4 impulses/second, at a 1 second delay.

Labropoulos et. al, 2000, studied 30 healthy lower limbs for venous velocity change with the application of one of two IPC devices. The first device, SCD 5325 (Kendall), applied 45mmHg of pressure sequentially over 6 chambers. The second device, VenaAssist (ACI Medical) applied 80mmHg of pressure over 3 cuffs: foot, ankle, and calf. Duplex scanning was used to determine that the VenaAssist generated a higher peak venous velocity than SCD.

Lurie, et. al., 2002, studied the hemodynamic effects of venous blood flow on 12 healthy subjects using ALP Pump System (Healthcare Service and Supply, Tustin, CA). Three (3) different compression modes were applied: foot at 80 mmHg, calf at 40 mmHg, and calf/thigh at 40 mmHg; all at a 12 second inflation time. Ultrasound scanning was used to determine that calf IPC provides the maximum increase in volume flow and flow velocity through the deep leg veins.

Morris, et. al., 2006, studied blood flow velocity of 20 healthy volunteers using two different IPC devices. The first device had two chambers; Chamber A rapidly inflated to 73mHg and then stabilized at 52mmHg and Chamber B rapidly inflated 0.3 seconds after the first to 60mmHg, stabilizing at 40mmHg. The second device had one pressure chamber which slowly inflated to 40mmHg within 2 seconds. As determined by a Doppler frequency spectrum analysis system, the first device increased peak velocity approximately 17cm/s more than the second device.
John, Narracott, Morris, et. al., 2007, presented experimental findings in addition to their computational studies. Four (4) calf IPC devices, each reaching 40mmHg of applied pressure, were evaluated on 10 healthy subjects. Interface pressure between the cuff and skin of the subject was measured using a pressure monitor, and determined to vary with position on the skin and also from the applied pressure. The highest interface pressure was directly under the air chamber of the cuff.

Lurie, et. al., 2008, studied the hemodynamic effects of venous blood flow on five (5) healthy subjects using two calf compression devices: WizAir (Medical Compression Systems, Inc., Ltd., Or-Akiva, Israel) and VenaFlow (AirCast Inc., Summit, NJ). No findings were published concerning differences in venous blood velocity between the two devices. However, interface pressure between the two devices was significant, both in amount and spatial distribution. Lurie suggested that the spatial distribution of interface pressure will affect the deformation and ultimately compression of the calf’s venous system.

Nose, et. al, 2010, compared two devices: a sequential foot and calf IPC system (Veno Stream 601-J, Tokyo, Japan) and an impulse foot IPC system (AV impulse, Kobayashi Medical, Osaka, Japan). The former system had four chambers that inflated in 10 seconds to 50mmHg, at a frequency of 1 cycle per minute. The latter system applied 130mmHg within 1 second, providing 3 cycles per second. A linear probe measured venous blood velocity, indicating that the foot and calf system provided a greater increase than the foot system, both for healthy subjects and DVT-prone patients.

Although clinical studies provide valid results, the studies vary widely, making comparisons and comprehensive conclusions challenging. Not only are the study
parameters different, but venous blood flow is variable because of natural fluctuations, compounding the search for a solution (Morris 2004). Additionally, the studies are difficult to conduct, in terms of cost, subject recruitment, logistics, and variable selection. A model of IPC for DVT prophylaxis will provide a cost-effective means of testing many variables in a short time frame. Further computational results of IPC devices and treatment parameters will provide a stepping stone for future clinical studies.

**Marketed Devices**

There are several commercially-available IPC devices (See Table 2.1). Just as the clinical studies, the marketed devices vary widely in style and functionality. Again, optimization based on computational results should provide advanced treatment for DVT.
Table 2.1. Marketed IPC devices and their related parameters

<table>
<thead>
<tr>
<th>Device Name</th>
<th>ArtAssist 1000</th>
<th>Arterio-Venous Impulse</th>
<th>Active Care</th>
<th>VenaFlow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>ACI Medical Inc., San Marcos, CA</td>
<td>Novamedix, Andover, UK</td>
<td>Medical Compression Systems, Inc., Ltd., Or-Akiva, Israel</td>
<td>AirCast Inc., Summit, NJ</td>
</tr>
<tr>
<td>Foot/Calf/Thigh</td>
<td>1 foot cuff 1 calf cuff</td>
<td>1 foot cuff</td>
<td>1 foot cuff 1 calf cuff 1 thigh cuff</td>
<td>1 foot cuff 1 calf cuff 1 thigh cuff</td>
</tr>
<tr>
<td>IPC Mode</td>
<td>Individual or simultaneous compression</td>
<td>Uniform compression</td>
<td>Sequential compression</td>
<td>Graded, sequential compression</td>
</tr>
<tr>
<td>Pressure Range</td>
<td>50-140mmHg 130mmHg (default)</td>
<td>60-200mmHg 130mmHg (default)</td>
<td>Foot: 130mmHg (default) Calf: 50mmHg (default) Thigh: 50mmHg (default)</td>
<td>Calf: 45-52mmHg</td>
</tr>
</tbody>
</table>
CHAPTER III
DEVELOPMENT OF ELECTRICAL-ANALOG MODEL

Anatomy of the Lower Leg Circulatory System

The lower extremities principally consist of the upper and lower legs and feet. Blood flow to the lower extremities originates at the femoral arteries. From there, it branches into smaller arteries, and subsequently arterioles and capillaries. Blood then drains into the venules, which funnel into small veins, and then ultimately into the femoral veins. These femoral veins carry the blood back to the inferior vena cava, allowing appropriate venous return to the heart.

The lower leg deep venous system includes three major vessels: anterior tibial vein, posterior tibial vein, and peroneal vein. Each vein is responsible for draining deoxygenated blood from different parts of the foot.

Blood flow through the arteries and arterioles is achieved primarily by pressure created from the pumping of the heart and major arteries. Blood flow through these three veins, however, primarily relies on external pressure applied from skeletal muscle compression – the musculovenous pump. Because veins are far more distensible than arteries, valves aid in prevention of back-flow and pooling of blood.
Computational Model of the Lower Leg Circulatory System

A computational model has been developed to aid in understanding hemodynamic effect of varying IPC parameters, such as applied pressure, and inflation timing. To evaluate IPC parameters, this model enables prediction of blood flow rate through vessels under the conditions of external pressure as applied by the IPC device.

Specifically, the model described here is an electrical analog to the circulatory system. For example, the drop in pressure along a blood vessel is analogous to drop in voltage across a resistor. Other effects, such as the valve mechanism in the veins, dilation and contraction of blood vessels, and the external pressure applied by the IPC device can also be modeled in this way (Reddy, 2009). Circuit components and corresponding circulatory system features are listed in Table 3.1.

The electrical analog model was constructed to consist of leg arteries, arterioles, capillaries, venules, and three leg vein segments. Various properties and dimensions of each type of blood vessel are accounted for, and external pressure from the IPC device is incorporated. The model schematic is shown in Figure 3.1.

As can be seen from the schematic, each blood vessel has a corresponding resistive component. The resistances were calculated from Equation 1:

\[ R = \frac{8\mu l}{\pi r^4} \]

where \( R \) is the resistance, \( \mu \) is the viscosity, \( l \) is vessel length, and \( r \) is the vessel radius. The resistance of all of one type of blood vessel in the lower leg (i.e. the combined resistance of all of the arterioles in the lower leg), \( R_{total} \), was added in parallel using Equation 2:
Table 3.1. Circuit components and corresponding circulatory system features

<table>
<thead>
<tr>
<th>Electric Circuit</th>
<th>Circulatory System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>Blood flow rate</td>
</tr>
<tr>
<td>Voltage drop across resistor</td>
<td>Pressure drop along vessel</td>
</tr>
<tr>
<td>Electrical resistance</td>
<td>Resistance to blood flow</td>
</tr>
<tr>
<td>Inductance</td>
<td>Inertial effect of blood flow</td>
</tr>
<tr>
<td>Capacitance</td>
<td>Vessel compliance</td>
</tr>
<tr>
<td>Voltage source</td>
<td>IPC pressure or arterial blood pressure</td>
</tr>
<tr>
<td>Diode</td>
<td>Venous valve</td>
</tr>
</tbody>
</table>
Figure 3.1. Electrical analog model of the lower extremities with IPC. CSV1, CSV2, CSV3, RSV1, RSV2, RSV3 are the capacitances and resistances, respectively, of the three small vein sections; CV and RV are the capacitance and resistance, respectively, of the venule; RC is capillary resistance; CA and RA are the capacitance and resistance, respectively, of the arteriole; and CSA and RSA are the capacitance and resistance, respectively, of the artery.
where \( N \) is the total number of blood vessels of one particular type in the lower portion of the leg.

The capacitance, \( C \), of each vessel was determined from the Equation 3:

\[
C = \frac{rV_0}{hE}
\]

where \( r \) is the vessel radius, \( V_0 \) is the initial volume of an individual vessel, \( h \) is vessel wall thickness, and \( E \) is the vessel modulus of elasticity. The combined capacitance, \( C_{\text{total}} \), of all of one type of blood vessel in the lower leg was added in parallel using Equation 4:

\[
C_{\text{total}} = CN
\]

Each type of blood vessel includes capacitance except for the capillaries, which experience negligible changes in volume with respect to pressure. The number of each type of blood vessel was determined by dividing the initial total volume of the combined blood vessel type by the initial volume of one individual blood vessel.

The resistance and capacitance parameters used in this model are listed in Table 3.2. All vessel descriptors are given in the Appendix. Most of the resistance in the system is encountered within the smallest diameters (see Eqn. 1). Four parallel vessels of the distal vein segment were assumed, as well as two parallel vessels of the middle vein segment, one vessel of the proximal vein segment, and four parallel vessels of the artery. The radius of the proximal vein segment used in this model is 0.546cm, which agrees with Hitos, et. al., 2007.
Table 3.2. Blood vessel parameters for simulation

<table>
<thead>
<tr>
<th>Vessel (subscript)</th>
<th>Resistance (gm/cm$^4$/s)</th>
<th>Capacitance (cm$^4$·s/gm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artery (sa)</td>
<td>284.9</td>
<td>5.73 * 10^{-5}</td>
</tr>
<tr>
<td>Arteriole (a)</td>
<td>2279.5</td>
<td>8.19 * 10^{-7}</td>
</tr>
<tr>
<td>Capillary (sc)</td>
<td>2873.1</td>
<td>n/a</td>
</tr>
<tr>
<td>Venule (v)</td>
<td>518.1</td>
<td>5.40 * 10^{-5}</td>
</tr>
<tr>
<td>Distal Vein Segment 1 (sv1)</td>
<td>77.6</td>
<td>4.58 * 10^{-4}</td>
</tr>
<tr>
<td>Middle Vein Segment 2 (sv2)</td>
<td>19.4</td>
<td>4.58 * 10^{-4}</td>
</tr>
<tr>
<td>Proximal Vein Segment 3 (sv3)</td>
<td>8.6</td>
<td>4.58 * 10^{-4}</td>
</tr>
</tbody>
</table>
Changes in resistivity and capacitance of the arteries and arterioles, due to hormonal, metabolic and neurogenic contraction and dilation of those vessels, are not taken into account. Inertance (inductance) is not included in this model as it is very low in each component blood vessel when compared with their resistances. The valves of the small leg veins that allow flow in only one direction are modeled as diodes. Three valves were included in the model as studies have shown that there are 3-5 valves in sections of the femoral vein, and that the number of valves is not related to vein length (M CG, 1999; Liu 1985). The IPC device in this model applies to three general vein segments of the lower extremities: distal, middle, and proximal. The external applied pressures, $P_{ext}$, are modeled as external voltage sources acting upon the capacitor components of these leg vein segments.

Using the electrical analog, Figure 1, the following equations were generated (Equations 5-17):

\[
Q_{sa} = \frac{P_{in} - P_{sa}}{R_{sa}} \quad Q_a = \frac{P_{sa} - P_a}{R_a} \quad Q_v = \frac{P_a - P_v}{R_v + R_{sc}}
\]

\[
Q_{sv1} = \frac{P_v - P_{sv1}}{R_{sv1}} \quad Q_{sv2} = \frac{P_{sv1} - P_{sv2}}{R_{sv2}} \quad Q_{sv3} = \frac{P_{sv2} - P_{sv3}}{R_{sv3}}
\]

\[
P_{sa} = \frac{1}{C_{sa}} \int (Q_{sa} - Q_a) dt + P_{ext} \quad P_a = \frac{1}{C_a} \int (Q_a - Q_v) dt + P_{ext}
\]
where \( Q \) is the blood flow (mL/s), \( P \) is the pressure drop across the vessel, and \( P_{\text{ext}} \) is the external pressure applied to the leg by the IPC device.

The blood pressure is the input pressure to the model. This pressure was derived from an electrical analog model of the heart. The simulated arterial blood pressure is illustrated in Figure 3.2.

**Performance Indices**

The prevention of DVT dictates that the lower extremity veins be emptied as rapidly and completely as possible (Kamm, 1982). Therefore, for the sake of this study, and as many others have described in the past, optimal IPC treatment parameters for DVT, including compression mode and cuff design, will be achieved with the maximization of emptying lower extremity veins. To compare these three compression modes, one must examine the flow rates that these modes generate in the leg veins; the quicker the flow rate, the more effective the compression mode. Furthermore, one must assure that all the veins experience a high degree of flow. In other words, pooling of blood in a particular vein segment should be avoided. In this model, comparison among the three compression modes will be made by comparing the peak flow rates of all three vein segments.
Figure 3.2. Simulated arterial blood pressure
CHAPTER IV
SIMULATION RESULTS

The model was built using MATLAB software in the Simulink environment (MathWorks, Natick, MA). The following test cases were simulated on the model to study the effects of parameter variation:

(1) Variation in cuff pressure, as applied to the lower extremity
(2) Variation in rise time of cuff inflation
(3) Change in venous properties

The first two test cases included variation of IPC mode, in addition to the parameter being studied. This information will further the search for optimum IPC conditions. The third test case provides insight into the potential merit of this model for different patient conditions, such as those patients with changes in compliance of arteries and/or veins.

To determine the most effective IPC, flow in the small veins was recorded and analyzed for each test case, with the understanding that greater flow rates move more blood volume back, aiding venous return. The compression method that proves to expel blood most rapidly and completely out of the lower leg will provide the greatest therapeutic value.
Effect of Parameter 1: Level of Cuff Pressure

In the first test case, different levels of cuff pressure were applied to the lower extremity circulatory system model. Low pressure of 50mmHg to high pressure of 140mmHg was tested to study how the model reacted to the pressure variation. All other variables remained constant, detailed in Table 4.1.

Effect of Parameter 2: Rise Time Length for Cuff Inflation

In the second test case, different rise times to maximum cuff inflation were tested on the model. A short rise time of one (1) second to a long rise time of 12 seconds was studied to determine the highest level of venous blood flow. All other variables remained constant, detailed in Table 4.2.

Effect of Parameter 3: Change in Venous Properties

In the third test case, three simulations were run that included varying venous compliance and resistance. All other variables remained constant, detailed in Table 4.3.
Table 4.1. Compression parameters for simulation in Test Case 1

<table>
<thead>
<tr>
<th>Compression</th>
<th>Time to Max ( P_{\text{ext}} ) (s)</th>
<th>Total Compression time (s)</th>
<th>Deflation Time (s)</th>
<th>Total Relaxation Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>Graded</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>Wavelike</td>
<td>1-7</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
</tbody>
</table>
Figure 4.1: Effect of 50mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of uniform compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.2: Effect of 20-50mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of graded compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.3: Effect of 50mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of wavelike compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.4: Effect of 140mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of uniform compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.5: Effect of 110-140mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of graded compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.6: Effect of 140mmHg cuff pressure on venous blood flow (mL/s) through the vein segments during application of wavelike compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Table 4.2: Peak (max) blood flow and time average blood flow rates for IPC modes during Test Case 1

<table>
<thead>
<tr>
<th>IPC Mode</th>
<th>Blood Flow @ 50mmHg External Pressure</th>
<th>Blood Flow @ 140mmHg External Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform</td>
<td>0.63 mL/s (0.98 max)</td>
<td>0.55 mL/s (1.13 max)</td>
</tr>
<tr>
<td>Graded</td>
<td>0.77 mL/s (5.89 max)</td>
<td>0.62 mL/s (7.73 max)</td>
</tr>
<tr>
<td>Wavelike</td>
<td>0.72 mL/s (7.77 max)</td>
<td>1.05 mL/s (15.0 max)</td>
</tr>
</tbody>
</table>
Table 4.3: Compression parameters for simulation for Test Case 2

<table>
<thead>
<tr>
<th>Compression</th>
<th>$P_{\text{ext}}$ (mmHg)</th>
<th>Total Compression time (s)</th>
<th>Deflation Time (s)</th>
<th>Total Relaxation Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform</td>
<td>100</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>Graded</td>
<td>70-100</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>Wavelike</td>
<td>100</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>1sec Rise Time of External Pressure: Uniform Compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**External Pressure vs. Time**

- **Figure 4.7**: Effect of 1s rise time on venous blood flow (mL/s) through the vein segments during application of 100mmHg of uniform compression. Pink - proximal segment (sv1); light blue - middle segment (sv2); dark blue - distal segment (sv3).

**Blood Flow vs. Time**

- 0 8 16
Figure 4.8: Effect of 1sec rise time on venous blood flow (mL/s) through the vein segments during application of 70-100mmHg of graded compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.9: Effect of 1s rise time on venous blood flow (mL/s) through the vein segments during application of 100mmHg of wavelike compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.10: Effect of 12s rise time on venous blood flow (mL/s) through the vein segments during application of 100mmHg of uniform compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.11: Effect of 12s rise time on venous blood flow (mL/s) through the vein segments during application of 70-100mmHg of graded compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.12: Effect of 12s rise time on venous blood flow (mL/s) through the vein segments during application of 100mmHg of wavelike compression. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Table 4.4: Peak (max) blood flow and time average blood flow rates for IPC modes during Test Case 2

<table>
<thead>
<tr>
<th>IPC Mode</th>
<th>Blood Flow @ 1sec Rise Time</th>
<th>Blood Flow @ 12sec Rise Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform</td>
<td>0.57 mL/s (1.05 max)</td>
<td>0.56 mL/s (1.13 max)</td>
</tr>
<tr>
<td>Graded</td>
<td>0.64 mL/s (7.74 max)</td>
<td>0.59 mL/s (1.47 max)</td>
</tr>
<tr>
<td>Wavelike</td>
<td>0.91 mL/s (10.95 max)</td>
<td>0.64 mL/s (1.46 max)</td>
</tr>
</tbody>
</table>
Table 4.5: Compression parameters for simulation during Test Case 3

<table>
<thead>
<tr>
<th>Compression</th>
<th>$P_{\text{ext}}$ (mmHg)</th>
<th>Rise Time (s)</th>
<th>Total Compression time (s)</th>
<th>Deflation Time (s)</th>
<th>Total Relaxation Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform</td>
<td>100</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>45</td>
</tr>
</tbody>
</table>
Figure 4.13: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous compliance of $10^{-2}$ cm$^4$/s/gm. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.14: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous compliance of $10^{-3}$ cm$^4$/s/gm. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.15: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous compliance of $10^{-4}$ cm$^4$s/gm. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.16: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous resistance of $10^1$ gm/cm$^4$/s. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.17: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous resistance of $10^2$gm/cm$^4$/s. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Figure 4.18: Blood flow (mL/s) through the vein segments caused by application of uniform external pressure and venous resistance of $10^3$ gm/cm$^4$/s. Pink- proximal segment (sv1); light blue- middle segment (sv2); dark blue- distal segment (sv3).
Table 4.6: Blood flow rates during Test Case 3, changing venous compliance

<table>
<thead>
<tr>
<th>Level of Venous Compliance</th>
<th>Blood Flow @ 100mmHg External Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10^{-2}$ cm$^4$/s/gm</td>
<td>0.36 mL/s (0.78 max)</td>
</tr>
<tr>
<td>$10^{-3}$ cm$^4$/s/gm</td>
<td>0.41 mL/s (0.84 max)</td>
</tr>
<tr>
<td>$10^{-4}$ cm$^4$/s/gm</td>
<td>0.57 mL/s (1.05 max)</td>
</tr>
</tbody>
</table>
Table 4.7: Blood flow rates during Test Case 3, changing venous resistance

<table>
<thead>
<tr>
<th>Level of Venous Resistance</th>
<th>Blood Flow @ 100mmHg External Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10^1$ gm/cm$^4$/s</td>
<td>0.57 mL/s (1.05 max)</td>
</tr>
<tr>
<td>$10^2$ gm/cm$^4$/s</td>
<td>0.55 mL/s (0.95 max)</td>
</tr>
<tr>
<td>$10^3$ gm/cm$^4$/s</td>
<td>0.39 mL/s (0.79 max)</td>
</tr>
</tbody>
</table>
CHAPTER V
DISCUSSION

According to Kamm (1982), there are many criteria for preventing DVT, such as clearing valve sinuses and increased flow velocity. However, all identified parameters fall under the dictum that the entire length of the veins should be emptied as fully and rapidly as possible. Therefore, the compression method that most effectively achieves this physiological state will provide the greatest level of protection for the patient population (Kamm, 1982).

In order to determine optimal compression, a computational model of the lower leg circulatory system was developed using MATLAB software. The pressure from IPC was simulated and imposed on the model to predict flow rates through blood vessels. Three different parameters were changed to evaluate the hemodynamic effect: cuff pressure, rise time, and vessel resistance and compliance. In addition, several different IPC compression modes were simulated, including uniform, graded, and wavelike. Peak flow and time-averaged blood flow values were recorded for analysis.

In the present study, the level of cuff pressure was studied in all three compression modes. Uniform compression at 50mmHg and 140mmHg provides a peak flow rate of 0.98mL/s and 1.13mL/s, respectively, in the small vein segments (Table 4.2). Although the flow rates between the vein segments are fairly uniform, as illustrated by
Figures 4.1 and 4.4, the rates are significantly lower than those provided by graded or wavelike compression. Kamm, et al. (1982) suggests that with application of uniform external pressure, the vessel collapses near the proximal (knee) end forming a constrictive throat that moves distally with time, prohibiting blood to flow out of the leg veins easily. Uniform application of compression may severely compromise a patient’s ability to prevent DVT.

The application of graded pressure, with a maximum compression of 50mmHg and 140mmHg, to a lower leg provides a peak flow rate of 5.89mL/s and 7.73mL/s, respectively (Table 4.2). The peak flow rate in the distal vein segment was low in comparison to the flow rates in the other two vein segments (Figures 4.2 & 4.5). This indicates that there is some pooling in the distal vein segment. The main advantage of graded compression is that the vessel collapses more uniformly than during uniform compression, meaning that the flow is not limited by a constrictive throat.

The peak flow rate achieved by wavelike compression is 15.0mL/s, when compression reaches 140mmHg (Table 4.2 & Figures 4.3 & 4.6). The peak flow rate is greater than that provided by graded compression. According to Kamm’s theory, the vessel collapse follows the motion of the wavelike compression, pushing blood out of the veins (Kamm 1982). The peak flow rate in wavelike compression nearly doubles when the pressure increases from 50mmHg to 140mmHg. Compared to other compression modes, wavelike compression causes the greatest difference in flow rate when the level of cuff pressure changes. Wavelike compression can cause over a 10 fold increase in peak blood flow rate.
The rise time for cuff inflation plays an important role. The effect of rise time was studied in all three compression modes. During uniform, graded, and wavelike compression, the peak flow rates for a 12s rise time are 1.13, 1.47, and 1.46mL/s, respectively (Table 4.4 & Figures 4.10 – 4.12). All compression modes exhibit an almost equally low blood flow rate. When the rise time is shortened to 1s, peak flow rates change to 1.05, 7.74, and 10.95mL/s, respectively (Table 4.4 & Figures 4.7 – 4.9).

Excluding uniform compression mode, when the rise time decreases, the peak flow rate increases greatly. These flow rates suggest that graded and wavelike compression with a short rise time cause more rapid clearance of blood from the lower extremities. Rise time appears to be a more influential factor for IPC than level of cuff pressure.

However, the opposite trend is observed in uniform compression: when the rise time shortens, the peak flow rate decreases. Kamm’s theory of a constrictive throat can be used to explain this phenomenon. A shorter rise time may cause the proximal blood vessel to collapse more quickly, thereby restricting blood flow. When the rise time is lengthened, more blood can flow through the vessel before it collapses proximally.

Blood flow during IPC was also analyzed when venous compliance and resistance were changed. For example, a patient may suffer from a disease that manifests in an increased venous resistance. The parameters in the model can be changed to determine how flow rate changes with the same IPC method, and ultimately, the IPC that will most benefit this patient. For the sake of this study, IPC was held constant to determine how a change in venous properties would alter flow rate.

When venous compliance decreases, flow rate increases during 100mmHg uniform compression with a 1s rise time (Figures 4.13 – 4.15). Venous compliance
indicates the ability of a blood vessel to distend and increase volume with increasing pressure. Therefore, with a decrease in venous compliance, the blood vessel will not distend as much during IPC and blood cannot pool as effectively. The blood, then, must displace, causing an increase in flow rate. According to simulation, decreasing venous compliance by 10-fold, can increase peak flow rate up to 1.25 times (Table 4.6). To achieve a higher flow rate at a higher venous compliance, the level of cuff pressure could be increased or the rise time could be decreased.

Presence of clots in the vein leads to increased viscosity and larger resistance. When venous resistance increases, flow rate decreases during 100mmHg uniform compression with a 1s rise time (Figures 4.16 – 4.18 & Table 4.7). This trend agrees with the fact that more resistance to blood flow within a vessel will decrease the amount of blood that can flow through it. To achieve the same level of blood flow with more venous resistance, either the level of cuff pressure could be increased or the rise time could be decreased.

The present study represents the first comprehensive investigation of the efficacy of the IPC device on venous outflow. The results revealed that the following parameters should be observed to achieve increased blood flow:

- high pressure
- wavelike compression
- quick rise time

Individually, these parameters provide the more venous return when compared to their counterpart (i.e. low pressure; uniform compression; slow rise time). (See Tables 4.2 &
The model, although simple, presents a clear distinction between the compression modes, cuff pressure, and inflation rise time.

The simulated results agree with prior studies. For example, Morris, et. al., 2006, studied two different IPC devices. The device with a higher cuff pressure and shorter rise time increased peak velocity approximately 17 cm/s more than the second device, with a lower cuff pressure and a longer rise time. Malone et. al., 1999, also agreed that high-pressure, rapid inflation compression increased venous velocity compared to traditional low-pressure, slow-inflation devices. For the devices he studied, high pressure ranged from 120-160 mmHg, and low pressure ranged from 40-50 mmHg. Rapid inflation time was defined as 1-2 seconds, and slow inflation was defined as 11-12 seconds.

This model can also be adapted to individual patients. For example, aging DVT patients will have increased vascular resistance, compared to younger patients. Therefore, the model parameters can be changed to account for higher resistance, and IPC for an aging patient can be optimized. Other parameters can be changed as well to further classify the patient and contribute to a higher degree of IPC optimization.

It should be noted that other definitions of “optimization” have been suggested. Several groups have suggested that the optimal IPC device will be the one that is deemed most patient-compliant. Others have suggested that maximization of venous blood velocity is not necessary to reduce the instance of DVT, but an increase in fibrinolytic activity is crucial. Yet these propositions are outside the scope of this study; further clinical investigations are warranted to evaluate these hypotheses.

In the present model, there was no transluminal fluid flow out of capillaries. The present study did not include the lymphatic clearance of interstitial fluid (Reddy, 1986;
Reddy and Patel, 1995). Reddy et al (1977) developed a multi-scale model of the lymphatic systems considering the interstitial fluid dynamics, fluid absorption by the terminal lymphatics, and lymph propulsion through the micro and macro lymphatic vessels. Perhaps, the present model can be integrated with a model of the lymphatic circulation proposed by Reddy et al (1977) to provide a more comprehensive analysis of the intermittent compression.

Nevertheless, use of the this model provides an efficient and cost-effective means of allowing physicians and researchers to identify factors that contribute to DVT prevention that then can be further clarified with clinical studies. Theoretical models of lower leg extremity pumping will provide greater insight to the nature of blood flow in the leg, ultimately offering patients greater protection from DVT.
CHAPTER VI
CONCLUSION

The incidence of DVT is increasing with the number of surgical patients. Considering that the primary cause of hospital-related deaths is DVT, treatment and prevention is crucial. Physicians and surgeons are moving beyond traditional DVT prophylaxis, anti-coagulants, as they can cause harmful side effects. Mechanical methods, such as IPC devices have proved to be a viable alternative, however, the physiological effect of IPC application is not entirely classified. The wide range of clinical studies and marketed devices complicates holistic understanding of hemodynamic response to extremity compression. Computational models of the lower leg circulatory system and simulations with applied intermittent pressure aids in more complete understanding, and therefore improved treatment methods.

A computational model of the lower leg circulatory system was developed using MATLAB software. IPC parameters were changed for each simulation, and resulting hemodynamic responses were recorded. The most efficient blood clearance from blood vessels was deemed ideal. Optimal compression parameters were then identified.

The study concludes that wavelike compression, quick rise time, and high pressure application are parameters that are most effective to be used in extremity pumping.
Wavelike compression can cause over a 10 fold increase in peak blood flow rate. All parameters studied, including cuff pressure, rise time, and compression mode, influence blood flow rates. Rise time appears to be a more influential factor for IPC than level of cuff pressure. However, the compression mode will dictate the rise time for cuff inflation.

The salience of this model is that it can be adapted to individual patients. Two studies were conducted to illustrate this feature: changing venous compliance and changing venous resistance. Perhaps a patient has a higher venous compliance or lower venous resistance. Simulation results conclude that the level of cuff pressure should be increased or rise time decreased to achieve a higher blood flow rate during uniform compression.

Future studies using this model would be to refine parameters such as rise time and cuff pressure in wavelike compression mode to further IPC optimization. Other future studies could be conducted with a more complex model. Additional vein segments could be accounted for, supplying the research community with a more holistic view of the blood clearance and hemodynamic events associated with application of an IPC device to a patient. A limitation of this model is that it averages number of vessels and properties of vessels in a human lower leg; the model could be altered to account for different patient types (i.e. a patient with failing vein valves).

Modifying model parameters will offer a higher degree of IPC optimization, and ultimately customized treatment. This and other theoretical models give greater insight to the nature of blood flow, providing patients greater protection from DVT.


### APPENDIX

#### BLOOD VESSEL PARAMETERS

<table>
<thead>
<tr>
<th>Vessel</th>
<th>Diameter (cm)</th>
<th>Wall Thickness (cm)</th>
<th>Length (cm)</th>
<th>Young’s Modulus (gm/cm/s²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artery</td>
<td>0.424</td>
<td>0.1822</td>
<td>30</td>
<td>343000</td>
</tr>
<tr>
<td>Arteriole</td>
<td>0.002</td>
<td>0.0015</td>
<td>0.2</td>
<td>4000000</td>
</tr>
<tr>
<td>Capillary</td>
<td>0.0005</td>
<td>0.0001</td>
<td>0.055</td>
<td>n/a</td>
</tr>
<tr>
<td>Venule</td>
<td>0.002</td>
<td>0.0002</td>
<td>0.2</td>
<td>2000000</td>
</tr>
<tr>
<td>Distal Vein Segment 1</td>
<td>0.446</td>
<td>0.0177</td>
<td>10</td>
<td>172000</td>
</tr>
<tr>
<td>Middle Vein Segment 2</td>
<td>0.750</td>
<td>0.0420</td>
<td>10</td>
<td>172000</td>
</tr>
<tr>
<td>Proximal Vein Segment 3</td>
<td>1.092</td>
<td>0.0649</td>
<td>10</td>
<td>172000</td>
</tr>
</tbody>
</table>

Vessel diameter and wall thicknesses were derived from Barrett 2009; McDonald 1974, Hitos 2007. Vessel lengths were derived from Sibbald 2002; Engelson 1985. Young’s modulus values were derived from Sipkema 1989; Lundkvist 1998; Klabunde 2011.