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Fluid–Structure Coupling Model and Experimental Validation of Interaction Between Pneumatic Soft Actuator and Lower Limb

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Abstract

Pneumatic soft actuators (PSAs) are components that produce predesigned motion or force in different end-use devices. PSAs are lightweight, flexible, and compatible in human–machine interaction. The use of PSAs in compression therapy has proven promising in proactive pressure delivery with a wide range of dosages for treatment of chronic venous insufficiency and lymphedema. However, effective design and control of PSAs for dynamic pressure delivery have not been fully elaborated. The purpose of this study is to explore interactive working mechanisms between a PSA and lower limbs through establishing fluid–structure coupling models, an intermittent pneumatic compression (IPC) testing system, and conducting experimental validation. The developed IPC testing system consisted of a PSA unit (multichambered bladders laminated with an external textile shell), a pneumatic controller, and various real-time pressure monitoring sensors and accessory elements. The established coupling model characterized the dynamic response process with varying design parameters of the PSA unit, and demonstrated that the design of initial thickness, stiffness, and air mass flow of the PSA, as well as stiffness of limb tissues of the users, influenced PSA-lower limb interactions and resultant pressure dosages. The simulated results presented a favorable agreement with the experimental data collected by the IPC testing system. This study enhanced understanding of PSA-lower limb interactive working mechanisms and provided an evidence-based technical guidance for functional design of PSA. These results contribute to improving the efficacy of dynamic compression therapy for promotion of venous hemodynamics and user compliance in practice.

Keywords: pneumatic soft actuator, compression therapy, fluid–structure coupling model, experimental validation, lower limb

Introduction

SOFT ACTUATORS ARE an integral component of soft robotic systems. This includes diverse pneumatic soft actuators (PSAs) fabricated from linear or nonlinear soft materials to generate numerous predesigned motions or forces.

PSAs have been widely investigated in terms of bionic design (artificial muscles,^{1–4} wearable exoskeleton,⁵ robotic fish,⁶ and climbing robot⁷), material fabrication (textiles,⁸ soft composite material,^{9,10} silicone elastomers,¹¹ soft gel,⁹ hybrid soft–rigid material,¹² and dielectric elastomers¹³), prototype development (gripper,^{2,8,14–16} orthodontic application,¹⁷ minimally invasive surgery,^{12,18} variable stiffness endoskeleton,¹¹ and robotic fish^{2,6,13}), product modeling,^{2,19–22} movement control,^{2,5,23,24} and biomedical applications (artificial muscles,^{16,25} sur-

gery,^{12,26,27} and rehabilitation^{17,26,28–30}). The powered PSAs by pneumatic pressure present advantages of lightweight, easy to fabricate, and inherent environment compliance.

A number of studies have attempted to apply PSAs in human limb and joint treatment. For example, Belforte *et al.*²⁸ designed textile-based pneumatic artificial muscles for upper/lower limb recovery. Park *et al.*⁵ designed a PSA-powered controllable and wearable robotic device for ankle–foot rehabilitation. Li *et al.*^{29,31–33} investigated effects of polyvinyl chloride gel soft actuator-based wearable assistive garments on hip joint support in walking. Singh and Xiao^{34–37} designed a soft pneumatic interface between a crutch and user's forearm using a fiber-reinforced elastomeric enclosure to decrease wrist and palmar loads. However, these studies mainly focused on fabrication and experimental testing without theoretical

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models to demonstrate mechanical contacts between active garments and biological bodies.

Ghate *et al.*³⁸ designed and developed a bendable PSA prototype for surgical application and devised a mathematical model to characterize its mechanical behavior. However, this model is a fourth-degree polynomial approximation equation that does not incorporate specific physical connotations. Low *et al.*³⁹ developed a soft pneumatic sock as an alternative mechanical prophylaxis to assist a robot's ankle joint motion. However, this model cannot real-time detect effects of a pneumatic control (e.g., air mass flow) on joint mechanical function. Young and Ferris⁴⁰ critically reviewed the existing lower limb robotic exoskeletons, and indicated that rigorous quantitative evaluations on exoskeleton performance were rarely reported, which limited understanding on disadvantages and drawbacks of the tested devices.

In recent studies, researchers have further integrated numerical simulation and experimental tests to validate PSA prototype design in locomotion and grippers,¹⁶ robot-assisted ankle exercise,³⁵ and linear motion and bending.⁴¹ However, the aforementioned studies are irrelevant to the pneumatic compression therapy of lower extremities.

With the increase in the aging population and incidences of venous disorders, compression therapy has been widely applied for prophylaxis and treatment of vascular disorders (e.g., varicose veins, deep vein thrombosis, and lymphatic edema), wound management, and pain relief.⁴² The global compression

therapy market size was valued at USD 2.9 billion in 2016 and is expected to witness a lucrative compound annual growth rate of 5.2% between 2018 and 2025.⁴³ Dynamic compression therapy using PSAs powered by an intermittent electronic pump to control pressure dosage delivery to lower limbs has been demonstrated to reduce venous stasis,^{44,45} promote blood flow,^{46,47} stimulate fibrinolytic activity,^{48,49} and cure venous ulceration.^{50,51}

In recent years, pneumatic compression therapy has been recommended as an alternative to treat patients who could not use conservative measures (e.g., compression stockings or bandages) that offer sustained static pressures. The modalities of PSAs can be boots, sleeves, and other garment types, which mimic muscular contraction that occurs naturally when walking for hemodynamic promotion.

The girth and curvature of limb surface as well as stiffness of limb tissue influence pressure dosage delivery. In pneumatic compression therapy, rhythmic pressure is applied uniformly to the calf by either an inflated single-chambered (single-bladder) or multichambered PSA (multibladder) device for venous emptying.⁵² The PSA unit also can be constructed as either circumferential or noncircumferential ("asymmetric")⁵³ around lower limb. The circumferential bladders encompass limb tissue, which commonly requires larger and powerful pneumatic air pumps or slower inflation rates. Whereas the asymmetric bladders compress along part of the circumference of the limb (e.g., posterior aspect) requiring a lower pneumatic air input (Fig. 1). The PSA shape must be

FIG. 1. Schematic presentation of PSA-lower limb system. (a) PSA unit with circumferentially set multibladders to lower limb. (b) Biomechanical pressure by PSA delivered to lower limb tissue system for hemodynamic promotion. (c) Asymmetric PSA unit with single pneumatic bladder set at posterior limb. (d) Circumferential PSA unit with sequential gradient pneumatic bladders set around limb. PSA, pneumatic soft actuator. Color images are available online.

adaptable to the anatomy of the limb to minimize dead volumes that would affect the dynamic pressure function.⁵⁴

Till now, the nature of intermittent compression by PSAs and the sophisticated interaction with body system remain not fully understood, and its mechanical model has not been theoretically characterized.

Therefore, the purpose of this study was to explore interactive working mechanisms between PSAs and lower limbs through a mixed methodology of establishing fluid–structure coupling models, an intermittent pneumatic compression (IPC) testing system, and conducting experimental validation, to enhance understanding of PSA–lower limb system. The developed IPC testing system consisted of a PSA unit (multichambered pneumatic bladders laminated with an external textile shell), a pneumatic controller with a constant flow pump, various real-time pressure monitoring sensors, and accessory elements (air tubes and valves).

Essential factors influencing interactions between PSAs and lower limbs were characterized based on the integrative coupling model and experimental study. The essential factors included (1) pneumatic air mass flow governed by a pump controller, (2) initial thickness and stiffness of PSAs, (3) stiffness of soft tissues, and (4) contact surface area between a PSA and lower limb. The effects of each essential factor on mechanical performance of PSA were analyzed; and the simulation results of the coupling model were further validated against the data collected by the built IPC testing system. This study integrated theoretical models and experimental validation to provide an evidence-based guidance for ergonomic design and engineering of dynamic compression therapeutic devices, and laid a foundation for innovation of new pneumatic compression modalities in diverse end-uses.

PSA–Lower Limb Interaction System

Configuration and mechanism analysis of the PSA–lower limb system

Figure 2 illustrates the studied PSAs and their working condition when they were being mounted on lower limbs. Multiple inflatable air chambers (bladders) are built in the PSA, which is wrapped by an external textile shell and are supplied by a pneumatic pump system in inflation–deflation through air tubes. The interaction between a PSA and limb tissue is a complex, dynamic, and nonlinear process, as shown in Figure 3.

The pneumatic pressure (p_a) inside bladders increases with inflating (expanding) bladder powered by a pump controller. The inner wall of a bladder that contacts limb tissue generates surface contact pressure (p_c). With an increase in the pneumatic air input, p_a increases, which compresses soft tissue and results in p_c , and transfers p_c from the tissue surface to a deeper venous system, finally leading to vascular deformation and blood circulation. In dynamic compression therapy, the cycled inflation and deflation of bladders produce compression waves, dynamically propagating within soft tissues to enhance a veno-muscular pump and hemodynamics. Rationally controlling airflow inside bladder(s) and real-time monitoring the resultant p_a are crucial for ensuring the efficacy of pressure delivery (p_c) in a dynamic compression treatment.

Fluid–structural coupling model of PSA–lower limb system

To critically analyze multifactor interaction between a PSA and lower limb, a fluid–structural coupling model was developed. Appropriate simplification in the model is necessary to efficiently explore the key mechanisms. In this

FIG. 2. The studied PSA–lower limb system. (a) PSA with circumferential six airtight chambers (bladders). (b) Lower limb wrapped by PSA with bladders for proactive pressure delivery. (c) Working status of PSAs in use. (d) Inflated and deflated bladders in different views. (e) Hierarchical structure of the PSA–lower limb interaction system. Color images are available online.

FIG. 3. The interaction mechanisms of PSA-lower limb system. (a) Cross-sectional view of lower limb. (b) The side cross-sectional view of interactions among external textile shell, bladder, and lower limb tissue (note: red thick line is the contact surface between bladder(s) and limb tissue). Color images are available online.

Symbol	Unit	Physical significance
C_a	$\text{Pa}\cdot\text{s}^{-1}/\text{m}$	Damping coefficient of bladder
C_s	$\text{Pa}\cdot\text{s}^{-1}/\text{m}$	Damping coefficient of soft tissue
h_0	m	Initial position of bladder acting surface
K_a	Pa/m	Stiffness of bladder, Pa/m
K_s	Pa/m	Stiffness of soft tissue
K_{sh}	Pa/m	Stiffness of external shell
K	Pa/m	Composite stiffness of bladder and external shell, $K=(K_{sh}\cdot K_a)/(K_{sh}+K_a)$
p_a	Pa	Internal pneumatic pressure of bladder
p_c	Pa	Contact pressure between bladder and soft tissue
y	m	Displacement of interaction surface

study, it is assumed that pressure transmission initiated by the PSA occurs under a quasistatic condition, where the damping effects of external textile shell, pneumatic bladder, and soft tissue are eliminated. Furthermore, no clearance was observed between the lower limb and bladder during inflation and deflation cycles, and the stiffness of soft tissue, bladder, and external shell was constant. As illustrated in Figure 3, the external shell and bladder of PSA unit as well as the soft tissue of the lower limb were in a serial connection. No displacement occurs between the laminated bladder and external shell in dynamic inflation–deflation cycles. The inflation and deflation process in the bladder obeys the ideal gas law:

$$p_a V_a = QRT \quad (1)$$

where p_a is the pneumatic pressure inside a bladder; Q is the pneumatic air mass flow of the bladder; R represents an air constant; T denotes absolute temperature; and V_a is the bladder volume.

Based on the assumptions in the “Fluid–Structural Coupling Model of PSA-Lower Limb System” section, bladder volume can be expressed as follows:

$$V_a = A(h_0 + y) \quad (2)$$

where A is the contact area between bladder and soft tissue; h_0 is the initial thickness of the bladder; and y denotes the displacement of the contact surface with positive and negative values responding to inflation and deflation processes. By substituting Equation (2) into Equation (1), an expression of $\dot{p}_a$ is obtained as follows:

$$\dot{p}_a = \frac{(RTQ - p_a A \dot{y})}{A(h_0 + y)} \quad (3)$$

The pressure at the left side of contact surface (red line in Fig. 3b) can be expressed as follows:

$$p_c = p_a - Ky - C_a \dot{y} \quad (4)$$

where p_a is the internal pneumatic pressure of the bladder; y is displacement of the contact surface; C_a indicates the damping coefficient of bladder and is mainly determined by bladder materials and structures; $\dot{y}$ denotes the moving velocity of the

contact surface; and K is the composite stiffness of external textile shell and bladder. Considering the serial connection structure, K can be illustrated as follows:

$$K = \frac{K_{sh} K_a}{K_{sh} + K_a} \quad (5)$$

where K_{sh} varies with the shell thickness and material properties, and K_a varies with the bladder structure and material property.

The pressure at the right side of contact surface (red line in Fig. 3b) can be expressed as follows:

$$p_c = K_s y + C_s \dot{y} \quad (6)$$

By combining Equations (3–6), the control function of the PSA-lower limb interaction system is established as follows:

$$\begin{cases} \dot{p}_a = \frac{(RTQ - p_a A \dot{y})}{A(h_0 + y)} \\ p_c = p_a - Ky - C_a \dot{y} \\ y = \frac{p_c - C_s \dot{y}}{K_s} \\ \frac{1}{K} = \frac{1}{K_{sh}} + \frac{1}{K_a} \end{cases} \quad (7)$$

The fluid–structural coupling model [Eq. (7)] is an implicit differential equation group reflecting the fluid–structural coupling mechanism and illustrates the relationship among the aforementioned key factors, including the bladder pneumatic pressure (p_a), contact surface displacement (y), moving velocity of contact surface ($\dot{y}$), and the contact pressure (p_c) between the bladder and soft tissue. Equation (7) can be solved using ODE 15i in MATLAB once the air mass flow Q is obtained. Q can be calculated using the ISO 6358 Standard and experimental data obtained in the “Pneumatic Air Mass Flow Calculation” section.

Pneumatic air mass flow calculation

The pneumatic air mass flow (Q) critically determines both p_a and p_c . Figure 4 illustrates the testing setting of Q in inflation and deflation processes. An orifice valve was installed along the air supply channel. The pneumatic pressures recorded before and after the orifice valve are denoted by p_1 and p_2 , respectively.

FIG. 4. Schematic configuration of the test setting of air mass flow rate (Q) in (a) inflation (charge process) and (b) deflation (discharge process). Color images are available online.

It is assumed that the temperature inside the bladder during the inflation–deflation cycle is constant and isothermal, and the supplied air by the pneumatic pump is ideal gas, which obeys the ideal gas state equation. With this assumption, the pneumatic air mass flow Q can be calculated through Equation (8),⁵⁵

$$Q = C \rho_0 p_1 K_T \left[1 - \left(\frac{p_2}{p_1} \right)^{\frac{2}{1-b}} \right]^m \quad (8)$$

where C is the sonic conductance; ρ_0 is the mass density of air under standard reference atmosphere (1.29 kg/m^3); p_1 is the upstream stagnation pressure; p_2 is the downstream pressure; K_T is the air temperature coefficient; b is the critical back-pressure ratio; and m is the subsonic index. The sonic conductance C ($\text{m}^3/(\text{s Pa})$) can be derived from Equation (9).⁵⁶

$$C = \frac{\pi d^3}{20} \frac{1}{\sqrt{\frac{20L}{d^{3.1}} + 1}} \quad (9)$$

where d is the diameter of the valve orifice, and L represents the length of the valve orifice. To calculate the air mass flow Q , the critical back pressure ratio b and subsonic index m are calculated first in terms of Equation (8). The conductance ratio is defined as follows:

$$y_i = \frac{C_e}{C} \quad (10)$$

subject to

$$C_e = \pm \frac{V_a}{\rho_0 p_1 R \sqrt{T_0 T_a}} \frac{dp_a}{dt} \quad (11)$$

where V_a is the bladder volume, which is calculated by $A(h_0 + y)$; T_0 and T_a are the absolute temperature at standard reference atmosphere and absolute temperature inside the bladder at the start of deflation; “+” represents the inflation process, whereas “−” indicates the deflation process.

To determine b and m , the least-square method was used. By inputting the values of arbitrary b and m in Equation (12), the difference can be calculated as follows:

$$\delta_i = y_i - \left[1 - \left(\frac{x_i - b}{1 - b} \right)^2 \right]^m \quad (12)$$

Then, the least squared difference E can be obtained as follows:

$$E = \sum_{i=1}^n \delta_i^2 = \left\{ y_1 - \left[1 - \left(\frac{x_1 - b}{1 - b} \right)^2 \right]^m \right\}^2 + \left\{ y_2 - \left[1 - \left(\frac{x_2 - b}{1 - b} \right)^2 \right]^m \right\}^2 + \dots + \left\{ y_n - \left[1 - \left(\frac{x_n - b}{1 - b} \right)^2 \right]^m \right\}^2 \quad (13)$$

Figure 5 summarizes a flow chart to calculate parameters b and m . The sonic conductance C can be calculated using Equation (9) according to the bladder structural property. The conductance C_e is obtained based on the experimental pressure variation in a time domain using Equation (11). The initial values of both b and m are assumed as 0.5,⁵⁵ which are adjusted by E as illustrated in Equation (13). The values of b and m are determined once the minimum value of E is obtained. And then, the air mass flow (Q) can be further calculated by inputting b and m into Equation (8). Finally, all the physical parameters involved in the IPC system can be obtained by Equation (7) in the “Fluid–Structural Coupling Model of PSA-Lower Limb System” section, which is validated against experimental data in the “Model Validation” section.

Experimental Setup

Configuration of the PSA-lower limb testing system

Based on the aforementioned mechanism analysis, an IPC testing system was designed (Fig. 6a) for two purposes: (1) acquire pneumatic pressures (p_1 , p_2) and intermediate parameters (b , m) as described in the “Pneumatic Air Mass Flow Calculation” section, to obtain Q ; and (2) validate the fluid–structural coupling model constructed in the “Fluid–Structural Coupling Model of PSA-Lower Limb System” section. The IPC testing system comprises a PSA unit with six circumferential bladders (Fig. 2a) around an artificial lower limb, a data acquisition board with three real-time air pressure monitoring sensors, and a laptop displaying and recording the collected pressure signal data.

Figure 6b illustrates an operational IPC testing system, in which an artificial lower limb in a cylinder shape was fabricated using three-dimensional printing technology and soft

FIG. 5. A flow chart to calculate parameters b and m . Color images are available online.

gel materials. The morphology and internal geometric structure of the limb model were based on magnetic resonance imaging scanning and three-dimensional digital body scanning on a healthy female subject's lower limb. The diameter, length, and shore hardness of the limb model were 110 mm, 200 mm, and 5 HA, respectively. Two viscoelastic tubes (red) simulating superficial and deep veins were set at periphery and near center to form a more realistic lower limb model.

The PSA unit is regarded as the core of the developed IPC testing system and delivers a controllable pressure dosage to the lower limb. A 5-mm-diameter air inlet was set at the bladder shell of the PSA unit to allow pneumatic air supplied by the pneumatic pump to fill in the bladder. Three differential pressure sensors in type of MPX5100DP applied in the IPC testing system are piezoresistive transducers made by monolithic silicon (Freescale Semiconductor, Inc., Austin, TX). Their pressure testing range is 0–100 kPa, error range is 2.5% maximum error over 0°C to 85°C, and the accuracy, sensitivity, and response time are $\pm 2.5\% V_{FSS}$, 45 mV/kPa, and 1.0 ms, respectively.

The applied differential pressure sensors were sequentially connected with the air inlet tubes using tee joints (Fig. 6c), in which pressure sensors ① and ② were used to test the input pneumatic pressures p_1 and p_2 before and after the orifice, the valve 9, and pressure sensor ③ was used to detect pneumatic pressure p_a inside the bladder. The 1 mm diameter and 10 mm length of the orifice valve can be used to calculate sonic conductance C in terms of Equation (3). The difference between pneumatic pressures p_1 and p_2 detected by the orifice valve was used to determine the pneumatic air mass flow Q in terms of Equation (8).

The pneumatic pressure signals collected from the aforementioned three differential pressure sensors were transmitted

to the data acquisition card, which was installed with an analog to digital converter (AD7606) and data processing unit. The time domain signal was displayed on the screen of the laptop for real-time analysis. The contact pressure (p_c) between the PSA and the lower limb was tested using a piezoresistive sensor [Yubo intelligent technology (Hangzhou) Co. Ltd].

To reduce the influence of PSA setup procedure on the testing results, at the initial condition, the PSA unit was appropriately wrapped around the lower limb to conform to the limb circumference avoiding excessively squeezing or existing clearance between the bladder and the lower limb. Before data collection, several cycles of inflation and deflation of PSA unit were performed to allow the testing condition to be more reliable. In general, the initial pressure values were slightly higher owing to the uneven thrusts and frictions existing between the bladder and the lower limb. After several cycles of operation (i.e., three or four cycles), the pressure values became more stable and the effective data were collected to characterize the pressure variations.

The working modes (i.e., inflation–holding–deflation cycle) and control logic were governed by the air pump controller of the IPC testing system. Different compression cycles are applied in the IPC treatment in practice depending on the individuals' requirements. In this study, a mode of 20–10–8 s in one cycle sustaining 38 s was adopted as an example, which is a recommended treatment cycle by a commercial IPC device for daily home care of the lower limbs. This treatment cycle included three stages, that is, (1) inflation in the first 20 s, where the pneumatic pump controller initiates and charges the bladder with a constant pneumatic air mass flow; (2) holding from 21 to 30 s, where the solenoid valve closes to maintain pneumatic pressure inside bladder for 10 s; and (3) deflation in the last 8 s, where the solenoid valve opens to deflate.

System testing method

Pneumatic pressure (p_a) variation can be used to determine the pneumatic air mass flow under a certain inflation–deflation cycle, and to analyze the corresponding mechanism of the design parameter on PSA performance. The p_a variation can also be used to validate the established fluid–structural coupling model. Figure 7 depicts an example of the detected periodic working rhythms of the PSA using the three aforementioned pressure sensors (Fig. 6c). The variation profile and amplitude of p_a were governed by the pneumatic pump controller and solenoid valve. This profile was displayed real time on the screen of the laptop in the developed IPC testing system.

Model Validation

To validate the developed fluid–structural coupling model, the simulated and the experimental data are compared. Table 1 lists the physical parameters used in the developed coupling model.

The values of the pneumatic conductance (C) and contact area (A) are calculated using Equation 9 and the formula $A = 2\pi rL$ (Table 1), respectively. The values of air constant, air density, and temperature are constant. The critical back-pressure ratio (b) and subsonic index (m) can be obtained by

FIG. 6. IPC testing system design and construction. (a) Schematic diagram of the developed IPC testing system. (b) Engineering of an artificial lower limb model based on magnetic resonance scanning. (c) Experimental setup and testing components involved in the IPC testing system. IPC, intermittent pneumatic compression. Color images are available online.

FIG. 7. Detected pneumatic pressure in inflation–holding–deflation cycles by IPC testing system. Color images are available online.

calculation or by experimental test following the process illustrated in Figure 5.

The initial thickness of the bladder h_0 is tested using the Vernier caliper (Mitutoyo 150 mm Digital Caliper, resolution 0.01 mm, accuracy ± 0.02 mm; Kawasaki, Japan). The external shell stiffness K_{sh} can be determined by the experimental test as shown in the Supplementary Data (Supplementary Fig. S1). The stiffnesses of bladder and soft tissue can be determined from the reference.⁵⁶ The damping effects of both bladder and soft tissue are eliminated in the calculation, and hence, the bladder damping coefficient C_a and soft tissue damping coefficient C_s are 0 N•s/m, respectively. The inflation time, holding time, and deflation time are determined as 20, 10, and 8 s, respectively, which can be controlled by the pneumatic pump in the experiment of this study.

The simulation process using the coupling model to calculate physical parameters [e.g., pneumatic pressure (p_a), contact pressure (p_c), and contact surface displacement (y)] is presented as follows:

Step 1	Calculate sonic conductance (C) based on orifice structural parameters using Eq. (9) (e.g., diameter (d) and length (L)).
Step 2	Test and calculate conductance C_c based on Eq. (11); C_c in time-domain is presented in Figure 8a and b.
Step 3	Calculate intermediate parameters b and m using Eq. (13).
Step 4	Substitute the calculated sonic conductance (C), critical back-pressure ratio (b), and subsonic index (m) to Eq. (8) to acquire pneumatic air mass flow Q .
Step 5	Substitute the pneumatic air mass flow Q and parameters in Table 1 to Eq. (7), to obtain the key parameter values of the bladder pressure (p_a), surface contact pressure (p_c), and contact surface displacement (y).

Figure 9a indicates a favorable agreement between the simulated and the experimental results, which demonstrates an applicability of the developed coupling model in prediction of the pneumatic pressure (p_a) and its variation in inflation–deflation cycles of the PSA unit. The results calculated by the coupling model can be used to devise novel PSA designs for effective pressure delivery. The quantized error values of the pneumatic pressure p_a are shown in Figure 9b.

The difference between the simulated and the experimental data could have been caused by elimination of the damping effects of both bladders and soft tissues in the coupling model, as well as the impact of the dynamic stiffness variation of bladders during the inflation–holding–deflation cycles in practice. In the simulation modeling, the stiffness of K_{sh} (shell), K_a (bladder), and K_s (soft tissue) is assumed to be constant, while the practical stiffness of these three parameters is nonlinearly varying during the deflation process, which is the potential reason for sudden rise of relative errors in the deflation stage. Referring to the related studies,^{57,58} the relative errors less than 15% at the holding process are acceptable from an engineering perspective.

Results and Discussion

Figure 10a–f illustrates interactions among key parameters involved in the PSA-lower limb system. Effects of multiple factors (e.g., stiffness of bladder and external textile shell, stiffness of soft tissues, air mass flow, and contact area) on pneumatic pressure inside the bladder, contact surface pressure, and contact surface displacement are quantitatively analyzed based on the simulated and experimental results.

Effect of stiffness of the bladder and external shell

Figure 10a illustrates the stiffness effects of the external textile shell (K_{sh}) and bladder (K_a) on pneumatic pressure (p_a) inside the bladder, surface contact pressures (p_c), and contact surface displacement (y) in the inflation process (0–20 s). With increase in the pneumatic air in the bladder, both p_a and p_c increased. Bladder and external shell stiffness is largely influenced by material elastic moduli, bending rigidity, and thickness.

When stiffness (K_{sh} and K_a) was low (10^5 Pa/m), the bladder and shell were relatively thin and soft, which generated lower elastic potential energy in the pneumatic bladder. Consistent results were shown in the simulated and tested p_c and p_a . When stiffness (K_{sh} and K_a) was high (10^7 Pa/m), the bladder and shell were relatively thick and stiff, which induced high elastic potential energy to be stored in the bladder and textile shell. This results in the difference between the simulated and tested p_a and p_c , which increased with inflation time, especially at the later stage. The results indicated that the bladder and external shell with higher stiffness could simultaneously augment p_c and p_a , and p_a increased more rapidly than p_c .

Figure 10b illustrates varying contact surface displacement y with variation of stiffness K_a and K_{sh} . Here, y increased with inflation, demonstrated increased expansion of bladder, and resultant increased contact pressure at limb tissues. However, with the increase in bladder and shell stiffness, the contact surface displacement decreased with constant input of pneumatic air, which limited the volume expansion and deformation of the bladder, and reduced surface contact pressure p_c .

TABLE 1. PHYSICAL PARAMETERS USED IN FLUID–STRUCTURAL COUPLING MODEL

Parameters	Value	Notes
Pneumatic conductance, C	$3.8061 \times 10^{-12} \text{ m}^3/(\text{s} \cdot \text{Pa})$	Calculation [Eq. (9)]
Contact area, A ($A = 2\pi rL$)	0.069 m^2	Calculation
Air constant, R	$8.314 \text{ J}/(\text{mol} \cdot \text{K})$	Constant
Air density, ρ_0	$1.29 \text{ kg}/\text{m}^3$	Constant
Temperature, T and T_a	293 K	Constant
Critical back-pressure ratio, b	0.28 (inflation) 9.35 (deflation)	Test and calculation Test and calculation
Subsonic index, m	0.68 (inflation) 10 (deflation)	Test and calculation Test and calculation
Initial thickness of bladder, h_0	0.01 m	Experimental
External shell stiffness, K_{sh}	$5 \times 10^5 \text{ Pa}/\text{m}$	Experimental
Bladder stiffness, K_a	$5 \times 10^5 \text{ Pa}/\text{m}$	Yang <i>et al.</i> ⁵⁶
Soft tissue stiffness, K_s	$7 \times 10^6 \text{ Pa}/\text{m}$	Yang <i>et al.</i> ⁵⁶
Bladder damping coefficient, C_a	$0 \text{ N} \cdot \text{s}/\text{m}$	Assumption
Soft tissue damping coefficient, C_s	$0 \text{ N} \cdot \text{s}/\text{m}$	Assumption
Inflation time	20 s	Experimental
Pressure holding time	10 s	Experimental
Deflation time	8 s	Experimental

FIG. 8. Intermediate parameters C_e and x_i resulting from the calculation process of (a) inflation and (b) deflection processes. Color images are available online.

Effect of stiffness of limb tissues

Figure 10c illustrates the effects of stiffness of limb tissues on pneumatic pressure (p_a), contact pressure (p_c), and contact surface displacement (y). With the increase in tissue stiffness, both p_c and p_a increased with inflation, whereas their differences decreased gradually. Here, y decreased with time, which indicated that the stiffer tissue would counteract

volume expansion of the bladder during inflation. Thus, the lower limb with stiffer tissue would generate higher pressure dosage (p_a) than that with softer tissues, which implied that pressure treatment effects maybe varied among various end-users with different tissue properties (e.g., young adults or older adults, or athletes or nonathletes). Therefore, a customized PSA should be used, and the customized design should reflect users' biological and anatomic characteristics.

Effect of contact surface area

Figure 10d illustrates the variation of the contact area of the bladder with tissue surface under a constant air mass flow (Q) input and initial thickness of bladder (h_0). The contact surface area largely depends on the morphology of the PSA design. The increased bladder size of the PSA unit increased the contact area (A) between the bladder and lower limb.

The simulated results indicated that with increase in the bladder size, the surface contact pressure p_c , the pneumatic pressure inside bladder p_a and the contact surface displacement y decrease, which indicated that when the inflation capability of the air pump controller was determined, the morphologic design of the pneumatic bladder would directly influence the pneumatic pressure inside the bladder, interface pressure contacting with soft tissues, and bladder volume. For example, when the air pump size was fixed, the increased bladder size (i.e., surface contact area) would result in insufficient pressure dosages delivered to the affected lower limb, which can negatively influence compression therapeutic effects in practical treatment.

Effect of the initial thickness of the bladder

Figure 10e depicts the effects of the initial thickness of the bladder (h_0) on the contact surface pressure p_c , pneumatic pressure p_a , and contact surface displacement y . Here, h_0 is a sensitive indicator that reflects the initial volume of the bladder. Lower h_0 implies a smaller bladder volume, which would be inflated more rapidly to deliver pressure dosages to the target tissue zone; whereas higher h_0 would increase the bladder volume, which could require longer inflation time to fill the bladder chamber, thus delaying pressure achievement. In terms of Equation (1), when air mass flow Q , air constant R , and temperature T are constant, the enlarged bladder volume can be only equilibrated by a reduced initial pressure p_a . When h_0 increased, the p_a , p_c , and y are decreased,

FIG. 9. (a) Comparison on pneumatic pressure between the simulated and tested results in one compression cycle. (b) The quantized relative errors of pneumatic pressure at the three stages of one compression cycle. Color images are available online.

FIG. 10. Effect of stiffness K_{sh} and K_a on (a) surface pressure contact p_c and pneumatic pressure inside bladder p_a , and on (b) contact surface displacement y . (c) Effects of soft tissue stiffness K_s on p_c , p_a , and y . (d) Effects of contact area A on p_c , p_a , and y . (e) Effects of bladder initial thickness h_0 ($K_s = 1 \times 10^6$ Pa/m) on p_c , p_a , and y . (f) Effects of pneumatic air mass flow Q on p_c , p_a , and y . Color images are available online.

which is consistent with the modeling analysis in terms of Equation (7).

Effect of the pneumatic air mass flow

The pneumatic air mass flow Q is one of the most crucial parameters, which directly determines pressure dosage delivered in dynamic compression therapy. Figure 10f indicates that pneumatic pressure p_a and contact pressure p_c nonlinearly increase with the increase in the air mass flow Q (e.g., from 0 to 4.5×10^4 Pa). The contact surface displacement y increases

from 0 to 6 mm with increase in Q from 0 to 2×10^{-3} m³. The varying curves and interactions of each studied parameter would provide an important reference for designers and engineers in PSA design and application, including bladder materials and pump controller selection, dimensional determination, and end-user target.

Conclusion and Remarks

In this study, we established a fluid–structural coupling model and an IPC testing system to analyze interactions

between PSAs and lower limb, and to discuss factors that influence characteristics of PSAs in dynamic pressure delivery.

The developed coupling model demonstrated a favorable agreement with the experimental data, which indicated its applicability in predicting effects of varying parameter designs of a PSA on pneumatic air pressure, skin pressure dosage, and surface contact area on the lower limb. The analysis results indicated that the stiffness design of external shell and bladder, initial thickness, and morphology of the PSA, pump controller setting (the pneumatic air mass flow), and users' biological properties (e.g., limb tissue stiffness) influence pressure dosage delivery and fitting effect (contacting condition) of the PSA when it is applied on the lower limb in use.

The pneumatic pressure inside the bladder of the PSA unit can be augmented by increasing the pneumatic air mass flow, bladder stiffness, or reducing the contact surface area (i.e., bladder size or volume). The contact pressure delivered by the PSA can be increased by raising the stiffness of the bladder and the air mass flow input or reducing the initial thickness (i.e., volume) of bladders. The varied contact pressures (or pressure dosages) can transmit from the skin surface to the deeper tissues, and exert biomechanical function to the vascular system for promotion of fluid circulation (e.g., venous return or lymphatic movement).

This study presented an integrative modeling and experimental method and provided theoretical guidance on technical design of pneumatic compression devices. Its results provided a novel insight on quantitative relationships among multiple design parameters of the PSA-lower limb system, which contribute to creating more programmable and dynamic compression therapeutic devices for venous hemodynamic improvement and lower limb rehabilitation.

Author Disclosure Statement

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Supplementary Material

Supplementary Data
Supplementary Figure S1
Supplementary Figure S2

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