



Smart medical stocking using memory polymer for chronic venous disorders



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ABSTRACT

Proper level of pressure or compression generated by medical stocking or hosiery is the key element for successful treatment or management of chronic venous disorders such as oedema, leg ulcers, etc. However achieving the recommended compression level and, more importantly, sustaining it using stockings has been a major challenge to the health practitioners supervising the treatment. This work aims to investigate and design a smart compression stocking using shape-memory polymer that allows externally controlling the pressure level in the wrapped position on the leg. Based on thermodynamical rubber theories, we first derived several criteria that have to be satisfied simultaneously in order to achieve the controlled pressure adjustment using external heat stimuli. We then presented a case where such a stocking is developed using a blend yarn consists of selected shape-memory polyurethane and nylon filaments. Extensive experimental work has also been conducted to demonstrate the feasibility and explore the influencing factors involved.

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1. Introduction

Patients suffering from chronic venous disorders, such as leg ulcers, oedema, venous stasis, venous hypertension, etc., are known to have poor quality of life due to continuous discomfort or pain, limited mobility and long recovery time, in addition to a rigorous management plan and thus the financial cost involved [1,2]. Compression therapy is the cornerstone in the conservative treatment of such disorders since ancient times. Herein, external compression is provided to the affected leg by applying medical stockings or bandages to accelerate venous blood circulation, and finally decrease the venous pressure. The success of this treatment depends to a great degree on the level of pressure at the affected portion on the limb, and the sustenance of this pressure during the course of treatment [3,4]. This interface pressure has to be applied quite accurately within certain limits and should not be either below or above the prescribed level, or certain complications will occur [5,6].

In practice, selection of the stockings with proper sizing and fitting has always been a contest for both health practitioners and

manufacturers, for better patient's compliance and more effective treatment [7]. Different class of stockings are required to provide light (Class I, 14–17 mmHg), medium (Class II, 18–24 mmHg) and strong (Class III, 25–35 mmHg) levels of compression depending on the severity of the disease [8]. However in practice it is difficult to achieve the targeted pressure level due to various reasons, including mainly the different leg attributes (shape or size) among patients, and difference in material (including both stockings and the legs) properties (time and temperature dependence). Moreover, pressure drop over time is also a major concern due to the time dependence of the system behaviours [9]. For instance, experimental studies have showed that the pressure decreases over time due to reduction in swelling [10]. Also, many compression products displays initial pressure drop just after their application [4,11], as they are made of polymeric materials (cotton, viscose, PET, etc.), to which stress relaxation is an inherent attribute, although stockings containing elastomeric yarns can alleviate the problem. As pressure drop is inevitable for almost all available stockings, and re-installment or replacement of the stocking is needed once the pressure falls below the targeted level. Another reason for changing the stocking is for patient comfort, as there is often the need during night the stocking be removed so it will not interfere with the sleep [12]. Clearly, the aforesaid inadequacies of the conventional approaches demonstrate a compelling demand for a novel smart

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stocking system in compression management that allows modulating the compression level via external control to easily change or readjust pressure whenever needed.

In this work, based on some theoretical considerations, we first derived several criteria that have to be satisfied simultaneously in order to achieve the controlled pressure adjustment using external heat stimuli. We then proposed the use of shape memory polymers for the development of a smart compression stocking. Shape memory polymers (SMPs) are the smart material that can memorize the original shape so that they can recover from a temporary deformed shape, upon exposure to an external stimulus, e.g., heat, light, water, etc. [13]. SMPs have gained practical significance over the last 10 years in developing many potentially innovative products for biomedical applications such as clot removal devices, aneurysm occlusion devices, vascular stents, orthodontics, tissue engineering, etc. [14–28]. In the field of compression management, shape-memory polymer based film actuator has been proposed by Ahmad et al. (2012) for pressure bandage application. They have used temperature-responsive SMP strips attached to fabrics to control the compression by an external heat source. The use of SMP film actuators may significantly obstruct the moisture transmission and the permeability of the compression system, and therefore not a viable solution for providing improved comfort to the patients. Moreover, the use of shape memory alloy based compression bandage as proposed by Moein and Menon (2014) is also not an effective method as there exists challenges in the integration of shape memory alloy wires with the textile yarns.

A thermal sensitive SMP has the potential to adjust the internal stress in its structure via external heating [29–31] and this characteristic is the key for the present case to obtain smart compression management as suggested by Laplace's law [32–34]. We will investigate in this paper the fundamental relationship between the extra pressure and the recovery stress generated by the stocking. We will then present a case where such a stocking is actually developed using a blend yarn consists of selected shape-memory polyurethane and nylon filaments. Extensive experimental work has also been conducted to demonstrate the feasibility and explore the influencing factors involved.

2. Working principle and material determination

Before proceeding with the stocking design, there are a couple of theoretical issues to be examined to provide guidance in selection of desirable material.

2.1. Leg, stocking and generated pressure

The pressure developed in the leg by wearing a stocking depends on the shape, size and the particular position of the leg. Once the stocking is applied to the leg, a tensile strain in the stocking, ϵ , is generated and can be calculated as,

$$\epsilon = \frac{C_l - C_s}{C_s} \quad (1)$$

Where C_l and C_s are the original circumferences of the leg and the stocking, respectively, and $C_l > C_s$. In other words, for a given leg size C_l , this strain value is determined, exclusively, by the stocking size C_s , if we ignore the minimal effect of the stocking thickness. The corresponding stress σ in the stocking can be obtained simply as

$$\sigma = E \times \epsilon \quad (2)$$

where E is the tensile modulus of the stocking. Combining Eqs. (1) and (2) and according to Laplace's law [34], an internal radial

pressure P will be exerted by the tensioned stocking on to the leg as

$$P = \frac{\sigma w}{r} = \frac{E \epsilon w}{r} = 2\pi E w \frac{C_l - C_s}{C_l C_s} \quad (3)$$

where $r = C_l/2\pi$ is the radius of the leg and w is thickness of the stocking. So our problem of applying a proper level of pressure P to the leg of size C_l via a stocking appears to be a simple matter of selecting a stocking size C_s based on Eq. (3). However there are several factors that complicate the process:

- Most importantly, the stocking materials are viscoelastic **whose properties are time and temperature sensitive**. Similar concern exists to the material nature of the human body that is made of mostly biopolymers as well. This means that due to the stress relaxation or strain creep in such materials, both strain and stress developed in the system are going to fade away with time. So even we selected a stocking size C_s to achieve the desired pressure level P to the leg using Eq. (3) initially, the initial tensile strain ϵ developed will diminish gradually with time because of the creep, leading to the decline of the pressure level.
- The tensile modulus E of the stocking and its equivalent counterpart of the leg are both **heat sensitive** and will also alter with the interfacial temperature between the leg and the ambient.
- To make the matter worse, our leg is not a single sized solid cylinder but with different circumferences at different locations, and often **different pressure levels are needed at different locations of the leg**. A gradient pressure with high pressure at ankle and low at knee is frequently required [35]. This demands a proper size fitting or customized stocking to a particular leg.
- **Varying shape or size of legs for different patients** increases the complexities at manufacturing level as different choices for stocking size should be available to the clinicians for different patients. This further adds confusion to nurses in the selection process and also increases the cost to the manufacturers.
- In addition, **different compression is required at different stage of venous disease**. For example, 14–17 mmHg is required at the stage of varicose veins while 25–35 mmHg is usually recommended at the stage of venous ulcers. This means we need different stocking sizes even for the same leg depending on the pressure requirement.
- A lesser but worthy point is about the nonlinear influence of change stocking size C_s on the resulted pressure level P for a fixed leg size C_l . If we rearrange Eq. (3) into

$$\frac{P}{2\pi E w} = \left(\frac{C_l - C_s}{C_l C_s} \right) \quad (3b)$$

and plot it in Fig. 1 where leg size $C_l = 40$ cm.

That is, even at a fixed temperature level so the tensile modulus E remains constant, **the relationship between the pressure P and stocking size C_s is not linear**, revealing why it takes some training and practice for a nurse to get even the initial pressure right.

To conclude, giving the complexities discussed above, it is difficult if possible to achieve and maintain a desirable pressure level in treating chronic venous disease using the existing stockings. If looking at Eq. (3) more closely however, the key factor causing the diminishing pressure P is the relaxed stress σ in the stocking. If we can find a material whose internal stress σ can be easily adjusted in such that it can compensate the deviations of the pressure from the initially designated level, we can then sustain the desired pressure on the leg. Furthermore, we can even modulate the internal stress σ so as to eliminate the need of multiple stocking sizes in achieving targeted pressures, i.e., a smart stocking!

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