

**Original article**

**Is “Smart Pressure Monitored Suits” “smarter” than Conventional Garment in clinical application?**

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Running title: A comparison of effect of the smart pressure monitored suits (SPMS) and the conventional pressure garment for patients with Varicose Veins: its effect on standardisation of pressure therapy techniques

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This study was conducted in regional hospitals of Hong Kong which reflected the local data on the interventions provided. Also, the method introduced for pressure therapy interventions were commonly used in occupational therapy practice in Hong Kong. Thus, the results of the study could reflect the needs of local clinical practice.

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## **Abstract**

There is still no standardized regime to prescribe pressure garments with quantifiable pressure dosage to patients with different medical conditions. The present study aimed to examine the efficacy of a newly developed system-Smart Pressure Monitored Suits (SPMS) for pressure intervention when compared to the conventional method of pressure garment production (CG). The SPMS is designed with a set of standard methods of measurements and a computerized pattern drafting software (YUKA) to adjust the pressure range through computation of the percentage of strain directly on the drafted pattern. The conventional pressure garment was fabricated by occupational therapist in the clinical settings. A selected group of patients who required pressure therapy intervention was recruited through convenience sampling. They were provided with both the SPMS and CG, each to be worn for one month. The interface pressure levels of both garments were measured prior to the implementation. Patients' feedback was collected using a standardized questionnaire on the comfort of wear, elasticity and durability of the garments. There was a significant difference in the deterioration of pressure between SPMS and CG ( $p < 0.05$ ) before and after 1 month of wear. The satisfaction on overall efficacy of SPMS was significantly higher than that of CG ( $p < 0.05$ ). In conclusion, this standardized system using SPMS appeared to provide a more accurate and consistent pressure range and long lasting effect to the patients. It also appeared to be more efficient and effective in terms of production and fabrication.

**Keywords:** compression stocking, pressure therapy, rehabilitation

## **Introduction**

Pressure therapy is usually prescribed in forms of pressure garments in the management of post-burn hypertrophic scars, varicose veins and lymphoedema (Bradley, 2001; Korpan et al., 2011; Ripper et al., 2009). Pressure garments can be made in-house by occupational therapists in the hospital or burns units; or they can be ordered through commercial companies (Macintyre & Baird, 2006). These elastic garments can either be tailor-made based on individual's body dimension measurements and specific requirements, or be purchased at different fixed sizes already produced by the companies. The pattern design for garment fabrication and the fitting of pressure garments mainly depend on the experiences of the therapists or in some cases, by nurses or other allied health disciplines. The interface pressure produced by these pressure garments were seldom measured and monitored in the clinical situation (Lai & Li-Tsang, 2009; Macintyre, 2007; Macintyre & Baird, 2006; Mann et al., 1997). Therefore, whether these garments are therapeutically effective remain a question. Until recently, there is still no standardized regime to prescribe pressure garments with quantifiable pressure dosage to patients with different medical conditions.

In light of the drawbacks mentioned above, the Smart Pressure Monitored Suits (SPMS) (Fig 1) was invented by Li's research team, aiming to standardize the therapeutic intervention of pressure therapy through a self-developed computerized YUKA system (Li-Tsang, 2009). The YUKA software was developed to generate patterns with different percentage of strain based on the individual's body dimension. After measuring the body dimensions, therapists can simply input the data and the desirable pressure range into the YUKA software. The pattern of garment will be automatically drafted for each patient based on the pressure range needed to control the medical condition. The production of the pressure garment will become more effective and

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4 efficient. A standard fabric, which was tested on its durability, elasticity and permeability, was  
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6 adopted in the fabrication the SPMS in order to increase the comfort of wear. To test the end  
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8 result of pressure range generated by the SPMS, the Pliance X system which is a valid pressure  
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10 monitoring machine, is employed to measure and monitor the interface pressure (Lai & Li-Tsang,  
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12 2009).  
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16 In order to prove the effectiveness of this new method of producing pressure garment, a clinical  
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18 comparative study was conducted. The aim of this study was to examine the efficacy of the  
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20 SPMS for pressure intervention when compared to the conventional method of production. A  
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22 group of patients who required pressure therapy intervention was selected to participate in the  
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24 study using the method of convenient sampling. They were provided with both the SPMS and  
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26 conventional garments (CG), each to be worn for one month. The interface pressure values of  
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28 both types of garments were measured prior to the implementation of the pressure intervention.  
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30 Patients' feedback was collected regarding the comfort of wear, elasticity and durability of the  
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32 garments.  
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## **Materials and methods**

### *Study design*

An experimental pretest-posttest design was employed in this study. Participants recruited in the study were randomly assigned into two groups. One group of the subjects was given the CG for one month followed by prescription of SPMS for the next month, while the second group would be given the SPMS for one month and then the CG for another month. All participants were asked to fill in the questionnaire at the end of two months after they finished wearing both garments. They were blind to the types of garment they were prescribed.

Ethics approval was obtained from both the Hong Kong Polytechnic University and the hospitals involved in this study.

### *Sampling*

A total of 26 subjects with varicose veins (clinically rated as mild to moderate) who required pressure therapy were recruited in the department of occupational therapy in two regional hospitals in Hong Kong. The inclusion criteria of the participants were: 1) 18 years old or above in age; 2) with previous record of good compliance in pressure therapy (including tubigrip, conventional garments and ready-made garments, etc.); 3) recognized by the therapists as having good compliance to pressure therapy. Those who had difficulties in filling in the questionnaires or in attending the follow-up assessment sessions in the study were excluded from the study. All participants were asked to sign a written consent form before engaging in the study.

### *Pressure garment prescription*

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4 For either type of garments, two sets of pressure garments were given to the participants. All  
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6 participants were given only one type of pressure garments, e.g. CG or SPMS within one-  
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8 month's time. The first type of garment (2 sets) was named as No.1 and No.2; and the second  
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10 type (2 sets) was named as No.3 and No.4. The sequence of types of garment was randomized at  
11  
12 the very beginning of participant sampling. The two types of garments were being sewed to look  
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14 very similar to ensure effective blindness while the two sets of the same type of garments were  
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16 required to be used on alternate days. The instruction for wearing regime of garments was given  
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18 emphasizing the garment set number. The same handling regime was instructed for both types of  
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20 garments, hand wash and dry in the air every day. Participants were asked to keep a diary on  
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22 garment wearing and caring so as to monitor their compliance.  
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### 31 Assessment procedures

#### 32 *Objective measurement of interface pressure exerted by pressure garments*

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34 The Pliance X system was used in the study for measuring the interface pressure exerted by the  
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36 two types of pressure garments, so as to compare their ability to provide pressure and sustain  
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38 pressure. Figure 2 shows the Pliance X system used for pressure measurement. Lai and Li-Tsang  
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40 (2009) have validated the application of the Pliance X system to provide an objective and  
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42 quantitative measurement of the interface pressure generated by pressure garments.  
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#### 50 *Patients' feedback on the two types of pressure garments*

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52 A questionnaire was adopted to assess the properties of both types of pressure garments. The  
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54 content of questionnaire on patient compliance factors were adopted based on previous studies  
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56 (Johnson et al., 1994). An expert panel with three experienced occupational therapists, two  
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4 undergraduates from the Institute of Textile and Clothing, two undergraduates from School of  
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6 Nursing and one pressure garment user was formed for reviewing the validity of this self-  
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8 administered questionnaire which is composed of 14 questions.  
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11 The properties of the garment mainly contain the following aspects, namely, 1) appearance of the  
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13 garment; 2) comfort of wear of the garment; 3) joint mobility and movement when wearing the  
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15 garment; 4) ability to retain the elasticity of the garment; 5) ease of garment handling.  
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19 The first 6 questions in the questionnaire were to collect the demographic information of the  
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21 participants. Questions 7 and 8 were about the style of pressure garments and the time of  
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23 garment wearing. Questions 9 to 12 were to compare the differences of the garment properties  
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25 between SPMS and CG. Questions 9 and 10 employed a five-point scale (“1” indicated very  
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27 dissatisfied while “5” represented very satisfied) to assess the satisfaction level of garment users  
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29 towards the two types of pressure garments. Question 11 aimed to compare the displacement  
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31 tendency of both types of garments. Question 12 concerned the perceived elasticity of the  
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33 garments after wearing for one month’s time using a five-point scale where “1” indicated very  
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35 low and “5” meant very high. The last two questions sought opinions from the participants in  
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37 terms of the overall grading of SPMS versus CG.  
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#### 45 Therapists’ feedback on SPMS system

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48 A focus group discussion with the occupational therapists who joined the study was conducted  
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50 after the completion of the data collection to collect their feedbacks.  
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#### 54 Statistical analysis

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4 Paired t test was used to find out the differences in the interface pressure levels generated by  
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6 each type of garments before and after wearing for one month. Independent t test was employed  
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9 to compare the pressure sustainability of the two types of garments. Mann-Whitney U test was  
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11 employed to analyze the items in the self-administered questionnaire for the comparison of  
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13 SPMS and CG ( $P < 0.05$  indicated significant differences). All the statistical analysis was  
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15 performed using SPSS 17.0.  
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## **Results**

### *Demographic information*

A total of 26 subjects were recruited in the study. The mean age was  $56.0 \pm 9.68$  years. Most of them were female (N=23) and 3 of them were male. All the subjects received pressure therapy for prevention and management of varicose veins. The types of garments prescribed are mainly socks and pants.

### *Sustainability of pressure*

Significant differences were found in the interface pressure levels generated by both types of pressure garments before and after wearing for one month. After 1-month of continuous wearing, the pressure values of both SPMS and CG were reduced compared with initial measurements. However, there was a significant difference in terms of the pressure deterioration between SPMS and CG ( $t=2.71$ ,  $p=0.042$ ). SPMS demonstrated a better pressure sustainability than CG (Fig 3).

### *Patients' feedback*

From the descriptive statistics, subjects gave higher scores for SPMS than CG in 7 out of the 13 items on garment properties. Three out of 13 items got the same score for both garments. SPMS obtained lower scores than CG in the rest three items (Table 1). However, from the t-test score, there were no significant differences found between the two types of pressure garments.

For the displacement tendency, 88.5% of the subjects (23/26) agreed that SPMS had satisfactory performance in garment displacement tendency (no displacement or only slight displacement under large movements); compared with that of 73% (19/26) for CG (Table 2). Similarly, 27% (7/26) rated unsatisfactory displacement (significant or slight displacement under even small

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4 movements) for CG, compared with that of 11% (3/26) for SPMS. There was a significant  
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6 difference in the percentage of subjects who recognized the garment's performance in  
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8 displacement tendency for SPMS versus CG (Chi-square=1.981,  $p<0.05$ ).  
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12 The satisfaction level rated by subjects on overall efficacy of SPMS was significantly higher than  
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14 that of CG (Table 3). SPMS got higher satisfaction in overall evaluation than CG.  
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### 17 18 19 Therapists' feedback

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23 After the completion of data collection from the patients, 4 occupational therapists involved in  
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25 this study were invited to join a focus group discussion. Subjective feedbacks on the comparison  
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27 of the two systems for prescribing pressure garment were collected. The therapists felt the SPMS  
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29 system could save their time for pattern drafting. With the computerized system, the patterns can  
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31 be kept and archived in a better way and be easily transferred to other therapists when needed.  
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33 The time spent to fabricate the garment patterns was much reduced with the help of the YUKA  
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35 system. However, they also commented that initially they had to take some time to familiarize  
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37 the software system. It also appeared that for those therapists who are less experienced in  
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39 drafting patterns of garment would prefer to use the YUKA system when compared to those who  
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41 are more experienced. Most of them agreed that the SPMS had better appearance and more  
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43 acceptable by the patients. It was more durable and comfortable. However, the SPMS system  
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45 will require the installation of the computerized program (YUKA) to a computer and a printer  
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47 which need to be set up properly at the department. Therapists also commented that they took  
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49 some time to learn the YUKA software and the methods of measurement, which was different  
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51 from the conventional methods of measurement. In view of the daily clinical workloads, some  
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53 experienced therapists would prefer using their own ways of fabricating the pressure garment but  
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4 then, it would require adjustment and trimming by the assistants.  
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## Discussion

The effectiveness of pressure therapy has largely relied on the optimal pressure dosage prescribed and the sustainability of pressure during the treatment process (Atiyeh, 2007; Cheng et al., 1996; Lai & Li-Tsang, 2009). It is therefore of crucial significance to ensure enough and effective pressure exerted onto patients through prescribing appropriate pressure garments. In the present study, the initial pressure generated by both CG and SPMS was around 15 mmHg, which echoed the recommended pressure range commonly applied in clinical practice (Linares et al., 1993; Van den Kerckhove et al., 2005). After wearing for one month, the interface pressure of both types of garments had decreased but the SPMS managed to retain the pressure better than the CG. The SPMS showed a 35% decline of pressure after 1 month of usage, compared with a 62% deterioration of pressure in CG which was almost twice the pressure loss in SPMS. SPMS demonstrated a more favourable performance in maintaining the interface pressure than conventional garments. Our results may also indicate that a higher range of initial pressure could be employed onto patients in order to achieve a target range of pressure magnitude when needed, taking into account the deterioration of pressure over time.

Considering the loss of pressure over a month's time, this study also justified a need to check and monitor the pressure on a regular basis rather than prescription from the counter or from a store. It is important to monitor the pressure deterioration over time such that appropriate adjustments could be made to ensure a consistency of pressure generated to control the medical conditions such as varicose vein or scar formation, in accord with the suggestion of previous research (Lai et al., 2010). This study further confirmed the importance of using the objective pressure measurement method, namely, the Pliance X system, in the prescription of effective pressure therapy intervention (Lai & Li-Tsang, 2009).

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4 Patients' feedback was also more positive on SPMS with a higher scoring on satisfaction of  
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6 garment properties, including the level of itchiness, softness, colour, joint mobility, smell,  
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8 tightness and elasticity maintenance after washing. The level of comfort during wear is a critical  
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10 determinant for patients' good compliance with the pressure therapy (Cheng et al., 1996; Ripper  
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12 et al., 2009). Subjects in this study felt that SPMS was more comfortable to wear. They reported  
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14 less itchy sensation during wearing and that the materials were softer when compared to the CG.  
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18 The appearance and smell of SPMS were also more acceptable than those of CG.  
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22 Allowing normal joint mobilization activities when wearing pressure garment is also a  
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24 consideration for patients. Any discomfort and limitation in range of motion aroused may  
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26 probably lead to discontinuation of the pressure treatment (Ward et al., 1992). Participants  
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28 seemed to rate higher satisfactory level in joint mobility when wearing SPMS, compared with  
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30 that of CG. However, no statistically significant difference was found. Furthermore, elasticity  
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32 and durability of a garment are the priorities for clients or clinicians when choosing a garment  
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34 product for pressure therapy (Ng & Hui, 2001; Ripper et al., 2009). Our results showed that  
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36 SPMS had higher rating scores for items of tightness after one month's use and elasticity  
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38 maintenance after washing, in contrast with CG, though the differences did not achieve statistical  
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40 significance level. As for the garment displacement aspect, SPMS seemed to have a better  
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42 quality to restrict displacement during wearing. A significantly higher percentage of subjects  
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44 reported satisfactory displacement tendency during wearing (with little or no displacement) for  
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46 SPMS, compared with that for CG.  
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54 Although there were no significant difference found in the sub-scores of the questionnaire,  
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56 participants had a preference to wear SPMS rather than CG. The garment users in the present  
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58 study rated a significantly higher score for SPMS than CG in terms of the overall efficacy of the  
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4 pressure garments ( $p < 0.05$ ). SPMS appeared to be a more acceptable choice by patients in  
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6 clinical practice.  
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9 Besides, with a computerized program, this new standardized system of SPMS would allow the  
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11 users to adjust the required pressure level and style of the garment pattern conveniently by  
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13 simply making changes in the pattern plotting program in the computer. Unlike the conventional  
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15 garments in which the pattern was measured and drafted by therapists manually, the whole  
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17 process of fabrication of SPMS was operated more smoothly through a standard method of  
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19 measurement, input of data into the YUKA system and then pattern would be generated through  
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21 adjustment of percentage strain. Most importantly, it helps to reduce the time of therapists in  
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23 pattern drafting, fabrication and fitting of garment.  
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29 The new fabric used in the SPMS system also got better texture and durability. The computer  
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31 system also helped better record keeping but the related computer skills needed extra training  
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33 and technical supports. Generally speaking, the younger therapists tend to favour the usage of  
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35 SPMS system.  
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#### 38 39 40 Limitation of study

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43 The cross-over study design of the current study may probably induce some carry-over effects on  
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45 the intervention, especially having no washing period due to ethical concerns. However, the  
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47 current study mainly focused on objective data on interface pressure of the pressure garments &  
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49 subjective feedbacks from patients and therapists. While the subjective feedback of the same  
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51 individual on both types of pressure garments was collected, the between-subject variances in  
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53 subjective feelings were actually eliminated. The potential carry-over effects on the outcome  
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55 measures were also minimal since the condition of varicose veins maintained in a stable status  
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4 without exacerbation throughout this study. The potential bias has further diminished by random  
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6 allocation of subjects to start different treatment first.  
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9 However, since the current study only included limited clinical outcomes and the feedbacks from  
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11 the therapists were collected qualitatively, the statistical analyses on the clinical effects of the  
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13 intervention and its cost-effectiveness could not be preformed. Thus, to understand the clinical  
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15 efficacy of the new SPMS system, further research would be warranted.  
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## **Conclusion**

This study aimed to verify the use of a recently developed system–SPMS, to construct pressure garments and provide pressure-monitored therapeutic treatment. In this study, SPMS was found to have a better ability to sustain the interface pressure efficacy of the pressure garments; participants had a preference towards wearing SPMS than CG. The SPMS also had an advantage to provide a standardized procedure to objectively generate the pattern for garment fabrication by using a computerized program.

To summarize, this set of standardized system using SPMS to provide pressure intervention, together with a carefully pressure monitoring appeared to be a suitable option for use in clinical practice. With proper training on the system usage and further researches to prove the clinical effectiveness, this new method of pressure therapy prescription could possibly facilitate the therapists' intervention both in terms of time and efficiency when in future, there are less therapists skilful in tailoring and pattern drafting.

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Table 1 Rating of Satisfactory Level on Garment Properties

Items	CG	SPMS
Level of itchiness	3.7±0.95	4.1±1.46
Level of softness	4.2±0.98	4.4±0.54
Ease of cleaning	4.6±0.54	4.6±0.79
Ease of drying	4.7±0.49	4.4±0.79
Ease of donning and doffing	4.6±0.55	4.6±0.79
Colour	4.6±0.54	4.7±0.49
Neatness of sewing connection	4.6±0.54	4.1±0.70
Cutting	4.6±0.54	4.6±0.54
Joint mobility	4.4±0.54	4.7±0.49
Smell	4.7±0.76	4.9±0.38
Permeability after sweating	4.3±0.76	4.1±1.07
Tightness after one-month use	3.4±1.27	4.1±0.69
Elasticity maintenance after washing	3.9±0.90	4.3±0.95

Table 2

Performance		No. of	Votes (out of 26)
		CG	SPMS
Unsatisfactory :	Significant displacement under small movements	2	2
	Slight displacement under small movements	5	1
Subtotal		7	3
Satisfactory :	Slight displacement under large movements	7	9
	No displacement	12	14
Subtotal		19*	23*

\* represents  $P < 0.05$ , comparing CG and SPMS.

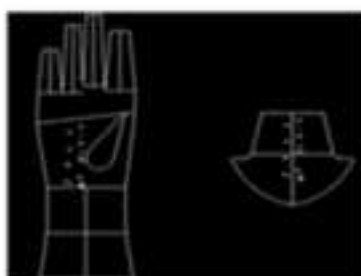
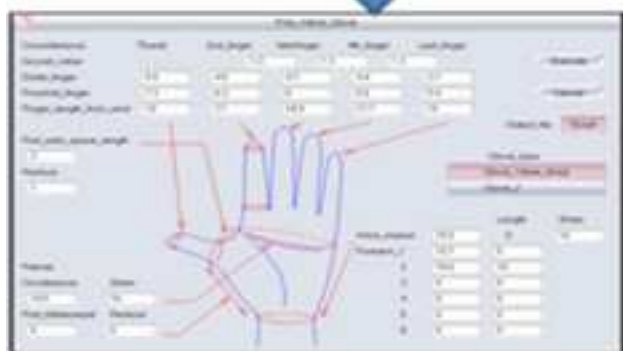
Table 3 Rating of Satisfactory Level on Overall Evaluation of CG and SPMS

Items	CG	SPMS
Overall efficacy	3.4±0.98*	4.0±0.58*
Overall rating	7.0±2.31	8.3±1.50

\* same as above.



Figure  
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Figure

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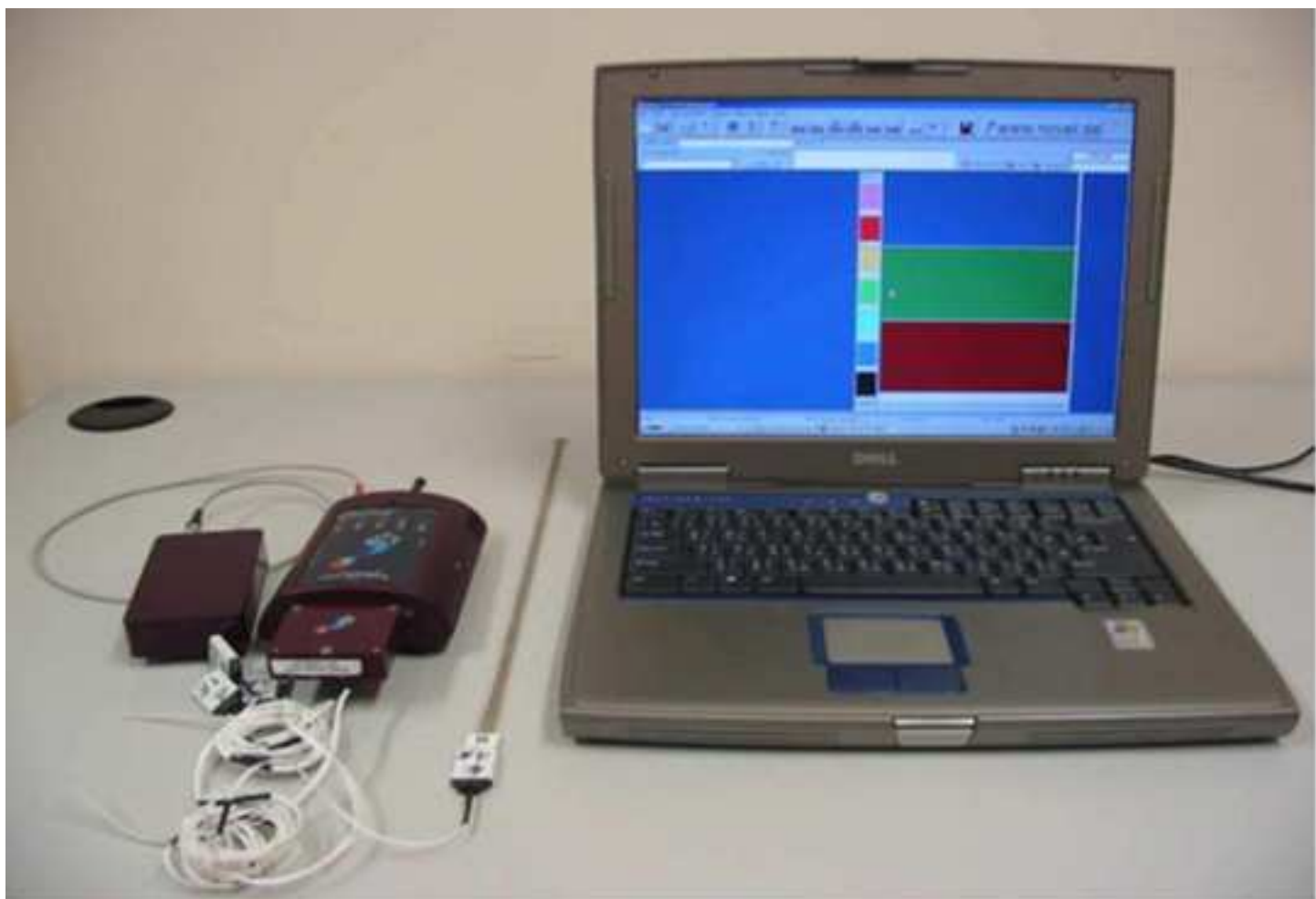


Figure  
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