

NARA Socks Project Aimed at Dissemination of Compression Therapy and Revival of Local Industry

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ABSTRACT

Rationale: Currently, Nara Prefecture is home to major producers of socks in Japan. Approximately 40% of all socks sold in Japan are manufactured in Nara. We cooperated with a sock manufacturer in Nara to produce and market knee-high compression stockings. We aimed to evaluate the effectiveness of the compression stockings. We performed a series of activities under the “NARA Socks Project” to promote the increased use of compression therapy over the previous year.

Objective: We investigated changes in the circumference of the leg below the knee and improvements in blood circulation of the legs before and after using compression stockings. We also performed a survey of users' impressions while wearing the stockings.

Results: The test results of below-knee leg circumference before/after wearing of stockings were showed $P = 0.343$ in the standing position and $P = 0.05$ in the supine position, and there was no significant difference in the circumference diameter of the leg. However, the mean VD of the popliteal vein decreased significantly from 8.65 mm (before wearing) to 8.48 mm (20 minutes after wearing the stockings) and 8.39 mm (40 minutes after wearing the stockings). In addition, the mean PV of the popliteal vein increased significantly from 4.65 cm/s (before wearing) to 5.62 cm/s (20 minutes) and 5.51 cm/s (40 minutes) ($P < 0.008$).

Conclusion: The test stockings appear to be useful in stimulating venous blood circulation of the leg. On the basis of these results, we plan to devise concrete campaigns and actions that focus on reviving the local industry and increasing the use of compression therapy across the country.

Keywords

Compression stockings, Compression therapy, Deep venous thrombosis, Pressure gradient, Venous return.

Introduction

Nara Prefecture is leading in Japan in terms of production of socks, accounting for 37.4% of all socks produced in this country. The socks industry in this prefecture has a long history, dating back to 1871 when a sock knitting machine was imported from the USA, and production of socks made of the locally produced Yamato cotton was started [1]. In recent years, however, low-cost socks imported from South Asian countries have been prevailing in the Japanese market, and the quantity of socks produced in Japan has decreased markedly to approximately 20% of the peak production level [2].

The quantity of socks currently produced in Nara Prefecture is approximately 10% of the peak level. With this tendency toward business deterioration, the question of how to continue operating has become a serious issue for socks manufacturing companies in this prefecture. Under these circumstances, we considered exploring a way of helping to restore this region's competitiveness in the socks market, including its brand based on historical background and skills.

Recently, challenges related to preventive medicine have developed. Elastic stockings, which can be easily used routinely, might provide a valid means of preventing edema in healthy individuals and also preventing deep-seated venous thrombosis in an emergency. With the cooperation of a local socks manufacturer,

we recently attempted to manufacture knee-high compression stockings to increase the use of compression therapy and revive the local socks industry. These manufactured stockings were worn by the subjects of this study, and data of the changes in below-knee leg circumference, effects in increasing blood circulation through the legs, and impression of users after wearing the stockings were analyzed.

Subjects and Methods

Between January and March 2017, 16 healthy subjects with no history of venous failure were enrolled (8 men and 8 women; mean age 36.4 [25-57]) in this study after providing consent (Table 1). The protocol, including the objectives and design, of this study was reviewed and approved at Nishinokyo hospital's ethics committee in advance.

n	16			
Age	36.4±9.3			
Sex	Male 8 / Female 8			
Height	166.5 cm			
Weight	60.4kg			
BMI	21.7			
Occupation	Doctor 2 / Nurse 5 / Medical technologist 3 / Pharmacist 1 / Medical clark 3 / Clerical staff 2			
Stocking size	S10 / M5 / L1			
*BMI : Body Mass Index				
Subjects	20' s	30' s	40' s	50' s
Male	2	3	2	1
Female	3	3	2	0

Table 1: Sixteen healthy volunteers participated in this study.

The test socks were made of 300 denier Nylon and polyurethane (mixture ratio = 88:12) (Figure 1), knitted by circular knitting. The below-knee compressive pressure was measured by AMI3037-10 (AMI Techno Co., Ltd.). The washing test was conducted 10 times on each test sample, revealing that the mean dummy compressive force at the ankle/sural region remained unchanged, i.e., 24.4/12.3 (SD: 1.4) mmHg before washing and 24.1/12.6 (SD: 1.6) mmHg after washing (Figure 2).



Figure 1: The stocking was designed by local college student in the design department.

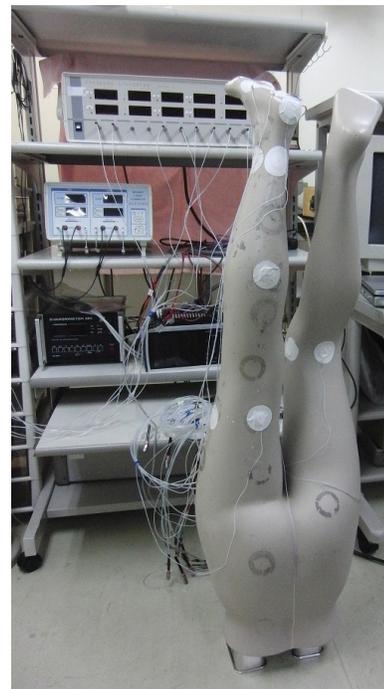


Figure 2: Pressure measurements were made with mannequin.

The measurements of the subjects were performed during this study using 2 elastic stocking conductors. First, the below-knee leg circumference before wearing the stockings was measured in the standing position after the subject remained still for 5 minutes. The sites measured were the ankle, sural region, and middle thigh. Then, the subject wore the stockings and remained still for 5 minutes before the second measurement of the below-knee leg circumference and the stocking's compressive pressure was performed. The compressive pressure was measured by PicoPress (Microlab Elettronica, Ponte San Nicolò, Italy) at the ankle and the lateral side of the sural region. Then, the subject assumed the supine position and remained still for 5 minutes while wearing the stockings, before the below-knee leg circumference and compressive pressure were measured. Finally, the stockings were removed, and the subject remained still for 5 minutes before the last measurement of the below-knee leg circumference was made. When the elastic stocking conductor measured the circumference during this study, the conductor referred to the relevant textbooks [3]. Care was taken to avoid placing the tape measure obliquely and biting of the skin by excessively pulled stockings so that each staff could conduct the measurements appropriately.

The device for ultrasonic assessment was TUS-A300 (a product of TOSHIBA Co., Ltd.) combined with a 7.5-MHz linear probe [4]. During ultrasonography, the subject remained sitting, with the knee joint bent at an angle of 60 degrees. During this process, care was taken to avoid compression of the popliteal vein. The leg measured (right or left leg) was selected at random. The measurement of vascular diameter (VD) and peak blood flow velocity (PV) was conducted by a cardiovascular technologist using the ultrasound pulse Doppler method immediately before and 20 and 40 minutes after wearing the stockings. Along the median longitudinal plane,

the popliteal vein was detected, and the Doppler angle from the popliteal vein was kept within 50 degrees. Under this setting and after stabilization of pulse waves by the pulse Doppler method, VD (the diameter crossing rectangularly with the vascular wall) and PV were measured over 10 consecutive sessions (Figure 3). The mean of 10 measurements was adopted as the value of each parameter.

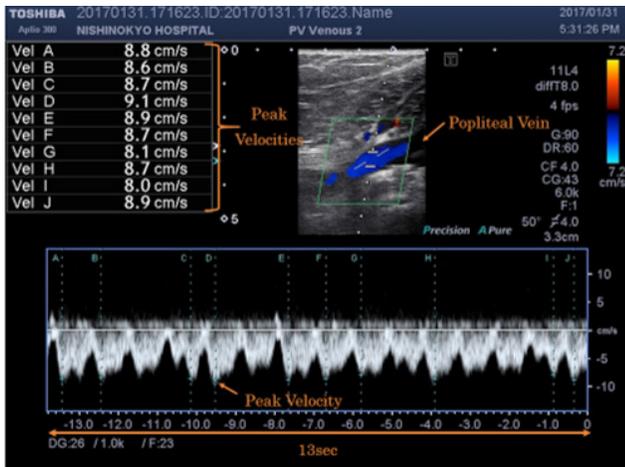


Figure 3: Measurement of peak velocity by pulsed Doppler ultrasonography.

The user’s impression of the use of this product was evaluated using a questionnaire that compared the stockings in this study to the existing elastic stockings “Dr. Walk” (a general medical device marketed by Hasetora Linen Service Co., Ltd.). After a 15-minute walk wearing the stockings, 6 parameters related to the impression of the stockings (fitness, leg mobility), sensation of compression (ease in use, biting, dislocation, and ventilation (likelihood for becoming stuffy), were rated on a 10-point scale.

The data on below-knee leg circumference before/after wearing of stockings were analyzed statistically by Wilcoxon signed-rank test. In addition, Friedman’s test was conducted on the changes in VD and PV at 20 and 40 minutes after wearing the stockings from the pre-wearing data. If a significant difference was found, the mean was compared by post-hoc comparison: Bonferroni method. $P < 0.05$ was regarded statistically significant.

Results

The mean circumference of the sural region decreased from 35.4 cm (before wearing) to 35.0 cm (after wearing) in the standing position and from 34.7 cm to 34.4 cm in the supine position, although it cannot be ruled out that these changes were within the range of error (Figures 4 and 5). The test results of below-knee leg circumference before/after wearing of stockings were showed $P = 0.343$ in the standing position and $P = 0.05$ in the supine position, and there was no significant difference in the circumference diameter of the leg. The mean compressive pressure in the standing position was higher at the ankle (23.9 mmHg) than at the sural region (19.3 mmHg). The mean compressive pressure in the supine position was also higher at the ankle (20.4 mmHg) than at the sural region (16.3 mmHg) (Figures 6 and 7).

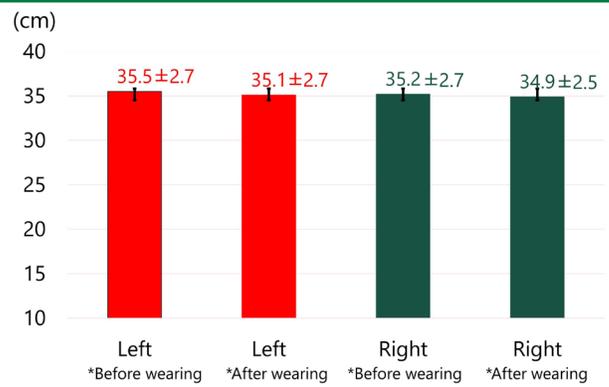


Figure 4: Calf circumference in the standing position (average).

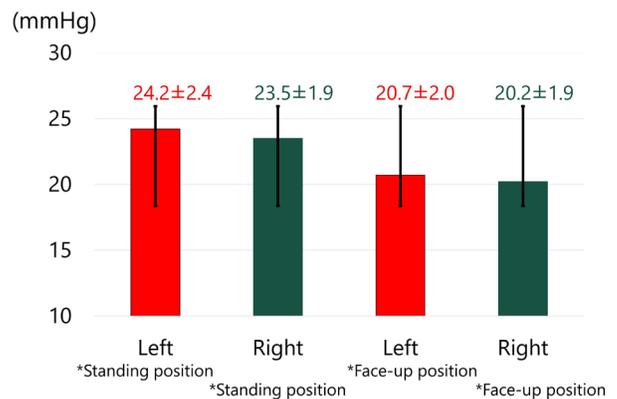


Figure 5: Calf circumference in the face up position (average).

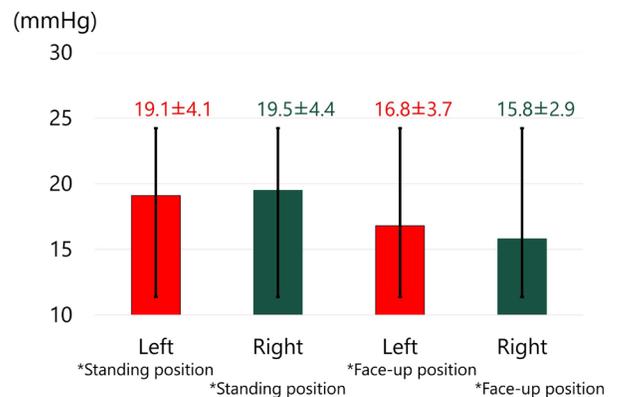


Figure 6: Compression level in the ankle (average).

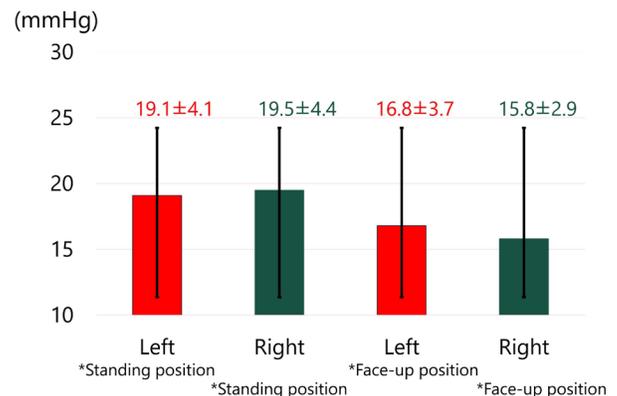


Figure 7: Compression level in the calf (average).

The mean VD of the popliteal vein decreased significantly from 8.65 mm (before wearing) to 8.48 mm (20 minutes after wearing the stockings) and 8.39 mm (40 minutes after wearing the stockings). The mean PV of the popliteal vein increased significantly from 4.65 cm/s (before wearing) to 5.62 cm/s (20 minutes) and 5.51 cm/s (40 minutes) ($P < 0.008$, Table 2). Furthermore, a post hoc comparison was conducted and significant increases were confirmed before and after 20 minutes ($P < 0.05$) and before and after 40 minutes ($P < 0.05$). However, because the number of cases was small and the power of the normality test was low, it was considered to be a conservative result.

Measurement Item	Time(minutes)			P-value*
	0	20	40	
Peak velocity (cm/sec)	3.9(2.5 - 8.7)	4.8(3.0 - 9.6)	4.8(3.0 - 10.4)	0.008
Vein diameter (mm)	8.6(7.1 - 10.9)	8.48(6.8 - 11.0)	8.3(6.5 - 11.0)	<0.001
	Pair			
	0 vs 20min	0 vs 40min	20min vs 40min	
Peak velocity (P-value**)	<0.05	<0.05	1.000	
Vein diameter (P-value**)	<0.05	<0.05	0.063	

*Friedman's test(Two-tailed)
**Wilcoxon signed-rank test(Two-tailed)

Table 2: Measured results for the peak velocity (PV) and the vessel diameter (VD) of the popliteal vein.

The results of the questionnaire survey were analyzed by comparison of the mean score of each parameter. The total score of the parameters related to the impression of use was 14.9 (male 16.2/female 13.5; full total score = 20) for the below-knee compression stockings prepared for this study and 15.6 (female 16.5/male 14.7; full total score = 20) for the existing elastic stockings being medically used. The total score of the parameters related to the sensation of compression was 22.0 (male 24.3/female 19.7; full total score = 30) for the test stockings and 22.3 (male 22.8/female 21.7; full total score = 30) for the existing elastic stockings. The score of the parameter related to ventilation was 6.8 (male 8.0/female 5.5; full score = 10) for the test stockings and 7.6 (male 8.1/female 7.0; full score = 10) for the existing elastic stockings. The mean total of all parameters was 43.7 (male 48.6/female 38.8; full total score = 60) for the test stockings and 45.5 (male 47.5/female 43.5; full total score = 60) for the existing elastic stockings. Thus, the test stockings prepared on a trial basis were comparable to the existing elastic stockings for medical use on the whole, although the test stockings were slightly inferior to the existing elastic stockings with respect to the likelihood of becoming stuffy and the sensation of fitness (Figure 8).

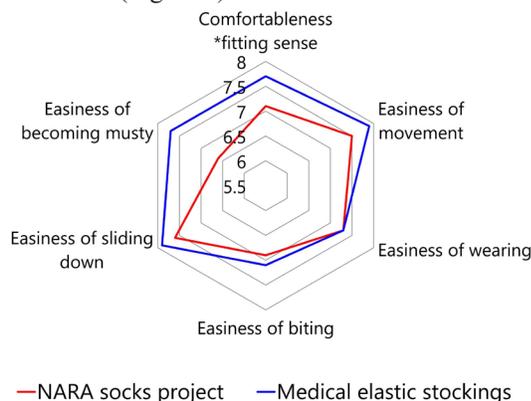


Figure 8: Survey results of the participants' feelings while wearing the compression stockings.

Discussion

Leg-compressing stockings currently available include the elastic stockings approved as medical devices and the below-knee compression stockings commercially distributed without approval as medical devices. The effect of elastic stockings in preventing venous thromboembolism (VTE) has been demonstrated in many clinical studies [5-7]. A compressive pressure of approximately 20 mmHg has been particularly recommended for preventing VTE [8]. Therefore, we hypothesized that the use of the below-knee compression stockings that were we prepared on a trial basis might be useful in preventing VTE by reducing the below-knee leg circumference and increasing the popliteal vein PV. According to previous reports, the incidence of VTE did not differ between the high socks type product and the stocking type product [9-11]. Therefore, the present study used the high socks type product.

Use of the below-knee compression stockings tended to decrease the circumference of the sural region both in the standing and supine positions, accompanied by elevation of popliteal vein PV and a tendency for VD reduction in the quiet sitting position. These results suggest that this type of stocking is useful in alleviating congestion of deep-seated veins of the lower extremities. The compressive pressure of this type of stocking needs to be calculated by correlating data from human bodies and dummies. Generally, the correlation of human body hardness to dummy hardness is closer in the ankle region. In the sural region, however, the data are likely to be affected by the shape of curvature of the human body [12].

In the present study, the mean compressive pressure in the entire study population was 24.1 mmHg at the ankle and 12.6 mmHg in the sural region. However, the mean compressive pressure in 3 subjects weighing ≥ 70 kg was 17.1 mmHg at the ankle and 11.6 mmHg in the sural region, and it was much higher among the 4 subjects weighing ≤ 45 kg (26.3 mmHg at the ankle and 13.4 mmHg in the sural region). Thus, we considered that the compressive pressure varied depending on the physique of individual subjects. Regarding the correlation between dummy data and human body data, the compressive pressure was 24.4 mmHg at the dummy ankle, 20.4 mmHg at the human ankle, 12.3 mmHg in the dummy sural region, and 16.3 mmHg in the human sural region, thus indicating that the compressive pressure was higher at the ankle than at the sural region, similar to the above-mentioned results. The compressive pressure of the test stockings is lower than that of the elastic stockings for medical use, but it is known that the compressive pressure of approximately 20 mmHg at the ankle is useful in preventing thrombosis [13,14]. Regarding the popliteal vein PV while using the stockings, previous reports demonstrated that the results varied depending on the type (pressure or length) of the stockings used, the body position (supine, standing) and so on [4,7,15].

In the present study, measurements were taken in the sitting

position, with reference to previously reported similar studies [4,15]. The PV increased from 4.65 ± 1.9 cm/s (95% confidence interval [CI] = 2-5 cm/s) before wearing the stockings to 5.62 ± 2.1 cm/s (95% CI = 3-6/s) after wearing the stockings, thus endorsing the effectiveness of the test stockings. The results of this study suggest that compression of the legs with this type of stockings can improve leg blood circulation. Hence, it seems advisable to wear these below-knee compression stockings during situations likely to cause retention of leg blood flow (e.g., while standing for long durations and air travel), even by healthy individuals.

As far as elastic stockings for medical use are concerned, high-quality products are available, and there are many alternatives to the material, size, compressive pressure, and other characteristics. Therefore, individual patients can select a product tailored to their desired features. This is an advantage of elastic stockings for medical use. The shortcomings of elastic stockings for medical use include requirement of physician's examination before purchase and high price. These shortcomings seem to serve as an obstacle against the increased use of compression therapy. However, the commercially distributed below-knee compression stockings are disadvantaged with respect to relatively insufficient compressive pressure, lack of sufficient pressure gradient, difficulty in fitting (owing to lack of matching the ankle position,) and discomfort during use. These features require further improvement. The below-knee compression stockings tested in this study do not require the user to visit a medical facility before purchase and could be provided at a low price while retaining the quality of the elastic stockings for medical use. We expect that this type of stocking will contribute to increasing the use of compression therapy and reviving the local industry in Nara Prefecture.

This study had several limitations. First, although a previous report indicated the need to evaluate the efficacy of compression therapy during physical activity of living subjects,¹⁶ the present study was confined to evaluation at rest, thus lacking analysis of sufficient parameters. Second, this type of stockings does not allow minute size adjustment tailored to the patient's body size, unlike the elastic stockings for medical use, and is therefore not suitable for treating lymphedema that requires high compressive pressure. The use of these stockings has to be limited to certain specific purposes such as prevention of thrombosis. Despite these limitations, the results of this study suggest that the use of the below-knee compression stockings can stimulate venous blood circulation of the leg and may be useful in preventing VTE.

Conclusion

The test stockings appear to be useful in stimulating venous blood circulation of the leg if their use is limited to some specific purposes, such as prevention of thrombosis, although strict compression therapy is not possible with this type of stockings, unlike the elastic stockings approved for medical use. On the basis of these results, we plan to devise concrete campaigns and actions that focus on reviving the local industry in Nara Prefecture and increasing the use of compression therapy across the country.

Everyone will wear a hat and sunglasses naturally when a strong sun is shining. I believe that in the future everyone will wear compression stockings naturally during their flights and when a natural disaster strikes. Our ultimate goal is to reduce human suffering from thrombosis and then we hope that this project will lead to revive the local industry.

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