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ORIGINAL CONTRIBUTION

Nonprescription, padded, lightweight support socks in treatment of mild to moderate lower extremity venous insufficiency

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Currently, strength greater than 20 mm Hg of compression is considered necessary for support hose used to treat symptomatic venous insufficiency in lower extremities. This strength is frequently uncomfortable, which reduces compliance and therefore clinical effectiveness. Whether more comfortable, nonprescription, light-compression support hose is effective in the treatment of mild to moderate venous insufficiency was investigated in 36 men with subjective complaints and objective signs (per Doppler ultrasound) of lower extremity venous insufficiency. All participants wore padded, light-compression (6 mm Hg), crew-height socks for 1 month. Then, participants were assigned to one of two groups on the basis of initial Doppler results. The half with the worst results wore stronger-compression (12 mm Hg) over-the-calf support socks, on the assumption that patients with worse venous insufficiency would require more support; those with the better Doppler results continued to wear the light-compression socks. Participants were retested at monthly intervals for 3 months.

In each group, data indicated that the venous insufficiency for all patients improved objectively and subjectively. Many of the objective venous values improved with either statistical or highly statistical significance—specifically deep venous valve function, superficial venous valve functions, and venous capacity—without statistically altering arterial function. Improvement occurred in the first month of the trial and continued throughout the study. The use of light-compression support socks is effective and should be considered as a first line of therapy in treatment of mild to moderate venous insufficiency.

(Key words: Venous insufficiency, compression socks, support hose, Doppler ultrasound, thrombophlebitis)

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Venous insufficiency is frequently seen and treated in the general practitioner's office. Its prevalence is increasing as the population ages, becomes obese, is more sedentary, smokes, and has poor dietary habits. Besides causing much physical discomfort and cosmetic disfigurement, one complication of venous insufficiency, deep venous thrombosis (DVT), can result in as many as 600,000 hospitalizations per year.[1] Increasing availability of objective noninvasive diagnostic methods has made for easier diagnostic confirmation and objective measurement of the severity of venous insufficiency. Early treatment of venous insufficiency can improve the quality of life for millions of working or aging Americans (or both) and also save money in terms of reduced sick leave and decreased number of hospitalizations.

Symptoms of venous insufficiency include edema of the feet, ankles, and legs; paresthesias; claudication; leg cramps; hot or cold feeling feet or toes; aching in the feet or legs; and varicose veins. Varicose veins alone are preva-

Table 1
Complications of Varicose Veins

- Stasis dermatitis
- Subcutaneous edema
- Cutaneous thickening
- Pigmentary changes
- Eczema
- Ulceration
- Spontaneous thrombosis/phlebitis

Table 2
Risk Factors for the Development of Venous Insufficiency

- Obesity
- Pregnancy
- Occupations that require standing
- Smoking
- Diabetes mellitus
- Heart disease
- Age older than 65 years

lent in 20% to 40% of the United States population, indicating the magnitude of this problem. Large varicosities are often associated with stasis dermatitis, subcutaneous edema, cutaneous thickening, pigmentary changes (including petechia, eczema, and ulceration), and spontaneous thrombosis or phlebitis[2] (*Table 1*). The diagnosis of venous insufficiency can be made through history (See *Table 2* for risk factors) and physical examination, including good vascular examination. Confirmation is through noninvasive Doppler ultrasound, which generally takes about 30 to 45 minutes to complete, including the patient's vascular history.

Currently, strength greater than 20 mm Hg compression is considered necessary for support hose in treatment of symptomatic venous insufficiency in the lower extremities. This strength is frequently uncomfortable, which reduces compliance and therefore clinical effectiveness. We investigated whether more comfortable, nonprescription, light-compression support hose could be effective in the treatment of mild to moderate venous insufficiency and

Table 3
Summary Statistics for Study Parameters (Mean Values)

Parameter	Type of socks	n	Baseline	Time, mo 1	2	3
■ Subjective score	Crew	18	6.8	1.2	0.3	0.3
	Over-the-calf	18	5.9	2.3	0.5	0.3
	All	36	6.3	1.9	0.4	0.3
■ Ankle-brachial indices	Crew	36	1.15	1.14	1.12	1.15
	Over-the-calf	36	1.09	1.13	1.12	1.14
	All	72	1.12	1.14	1.12	1.14
■ Superficial venous fill time (sec)	Crew	36	23	25	27	28
	Over-the-calf	36	23	27	28	30
	All	72	23	26	28	29
■ Deep venous fill time (sec)	Crew	36	23	25	27	29
	Over-the-calf	36	21	25	28	31
	All	72	22	25	27	30
■ Venous outflow (%)	Crew	36	57	64	67	65
	Over-the-calf	36	58	58	62	66
	All	72	57	61	65	65
■ Venous capacitance	Crew	36	3.8	3.8	4.3	4.6
	Over-the-calf	36	3.6	3.8	4.0	4.7
	All	72	3.7	3.8	4.1	4.7

Table 4
Study Versus Baseline Values: Levels of Significance*

Parameter	Type of socks	n	Time, mo 1	2	3
■ Subjective score	Crew	18	**<.001**	<.001	<.001
	Over-the-calf	18	<.001	<.001	<.001
	All	36	<.001	<.001	<.001
■ Ankle-brachial indices	Crew	36	.687	.172	.796
	Over-the-calf	36	.176	.321	.091
	All	72	.430	.946	.220
■ Superficial venous fill time	Crew	36	.246	.018	.003
	Over-the-calf	36	.032	.022	<.001
	All	72	.017	<.001	<.001
■ Deep venous fill time	Crew	36	.207	.038	<.001
	Over-the-calf	36	.050	<.001	<.001
	All	72	.021	<.001	<.001
■ Venous outflow	Crew	36	.143	.010	.060
	Over-the-calf	36	.878	.469	.155
	All	72	.342	.023	.024
■ Venous capacitance	Crew	36	.911	.121	.010
	Over-the-calf	36	.298	.059	<.001
	All	72	.615	.017	<.001

*P <.05 is statistically significant. P <.001 is highly significant.

improve clinical results through improved compliance.

Materials and methods

A modified single-crossover study of 36 men with objective and subjective signs of mild to moderate venous insufficiency (established by Doppler ultrasound) was performed to evaluate the effectiveness of treatment with padded, light-support (6 mm Hg), crew-height socks (crew socks) and padded, stronger-compression (12 mm Hg), over-the-calf support socks (over-the-calf socks). Both types of socks had the same medium-density padding at the sole of the foot and support at the bottom of the arch of the foot, but only the crew socks also had support at the top of the arch of the foot. Because of limitations of HATRA testing, these compression pressures were unavailable. (HATRA is the name of the machine used to test compression of hosiery in millimeters of mercury using standard foot and leg measurements for each size of hosiery.)

ThorLo socks (Thronberg Hosiery, Statesville, NC) were selected because of general commercial availability, comfort, low-compression support, and unique design, including moderate-density padding for the sole of the foot. Because of the nature of the socks, performance of a single-blind study was impossible, but each patient was used as his own control. All testing was done by the same technician and with the same Doppler unit (Medsonics PVL [Imex 7000P], Imex Co, Golden, Colo).

All participants had at least one objective finding of mild to moderate venous insufficiency, as demonstrated by Doppler ultrasound, and had at least one subjective symptom of venous insufficiency. Participants were instructed to wear the socks given for that particular month exclusively during that month and to return three more times at 1-month intervals. Arterial insufficiency could be no worse than mild, as defined by the ankle-brachial index (ABI). An ABI of 0.95 or greater is considered normal, and indices of 0.94 to 0.70 are considered to represent mild arterial insufficiency.[1] (Various references use different values for normal, for example, 0.95, but moderate venous insufficiency is either less than or equal to 0.7 or 0.6. The more strict definition was used). Throughout the study, arterial status was monitored with the understanding that if any participant's ABI dropped to 0.7 or less, they would be excluded from the study. No effort was made to further restrict the study population, so that the results would be more rep-

Table 5
Advice for Patients Needing To Reduce Risk of Venous Insufficiency

- ☐ Support hose should be worn.
- ☐ Changes in skin color, temperature, and texture should be watched for, and any changes should be reported to a physician.
- ☐ The patient should stop smoking.
- ☐ Weight loss should be advised if patient's weight is more than 20% over ideal.
- ☐ Moderate exercise such as walking should be encouraged.
- ☐ Legs should be elevated as patient watches television or reads.
- ☐ Legs should be elevated when patient goes to bed, if there are no cardiac or pulmonary complications.
- ☐ Regular checkups should be encouraged.

resentative of the real world in which general practitioners function.

All patients who were chosen to be participants in the study were given eight pairs of padded crew socks to wear exclusively for the next month. Wives were invited to attend testing sessions and were also given a free pair of socks to improve the participants' compliance. Because women wear both socks and nylons, they were excluded to ensure that any changes measured would reflect the effect of the socks only and not also that of nylons or support hosiery. After the 1 month, patients were assigned to one of two groups based on initial objective measurements of venous status, by the rationale that patients with more severe venous insufficiency would need stronger support. The group in the 50th percentile of least negative objective venous changes continued to wear the padded crew socks. Those who were in the worst 50th percentile according to objective venous status were switched to the padded over-the-calf socks.

Each patient was reexamined with Doppler ultrasound at monthly intervals for 3 months. Monthly data were then compared for each of the following groups: the initial data, before use of the socks; data after use of the crew socks for 1 month; data from the group wearing the over-the-calf socks and the group wearing the crew socks; and then all participants as a whole. Statistical methods used to evaluate the data included independent group t test and one-way analysis of variance with $P<.05$.

Objective vascular values measured with Doppler ultrasound

- ***Superficial venous valve function, and deep venous valve function by photoplethysmography (PPG)***—Valve function is measured as time in seconds to fill the vein after emptying. A PPG probe is positioned approximately 3 inches above the ankle. The patient then flexes and extends the ankle five times to empty out the posterior tibial vein. The time for the vein to refill is measured from the low point after flexion-extension to the high point on the tracing.
- ***Venous capacitance and venous outflow by strain gauge***—Venous capacitance and venous outflow are measured by elevating the knee and foot 14 inches, toning the deep veins by applying 55 mm Hg cuff pressure to the thigh for 1 minute, releasing pressure for 1 minute, and repeating this cycle twice for each leg, and then applying 55 mm Hg cuff pressure to the thigh for 2 minutes, releasing pressure, and obtaining a tracing. The height and shape of the tracing is recorded, and percentage of volume reduction is measured. Venous capacitance is a measure of the ability of the vein to distend and indirectly is a measure of its flexibility. Venous outflow is measured as percentage of venous capacity reduction 2 seconds after the thigh pressure is released. Deep venous thrombosis, previous vein damage, mass, or sclerosis of the vein wall will all affect the tracing and the venous outflow.
- ***Arterial ankle and brachial pressures with subsequent ABI***—The ABI is calculated by dividing the arterial pressure measured at the ankle by the arterial pressure measured at the brachial artery, both in millimeters of mercury. Values of 0.95 or more are normal.
- ***Posterior tibial arterial waveform and peak flow velocities***—Flow velocities are measured by Doppler ultrasound.

Subjective evaluation

The subjective evaluation was performed by calculating a subjective score based on the number and frequency of vascular complaints for each patient at each evaluation. Patients were interviewed at each evaluation and the number of complaints, weighted for frequency, were recorded. A rare complaint was counted once, an occasional complaint was counted twice, and a frequent complaint was counted three times. The subjective score was calculated as the sum of all weighted complaints.

Results

The 36 men with mild to moderate venous insufficiency ranged in age from 27 to 83 years old. The mean age was 60.3 years in the group wearing the crew socks (6 mm Hg) and 56.8 years in the group wearing the over-the-calf socks (12 mm Hg).

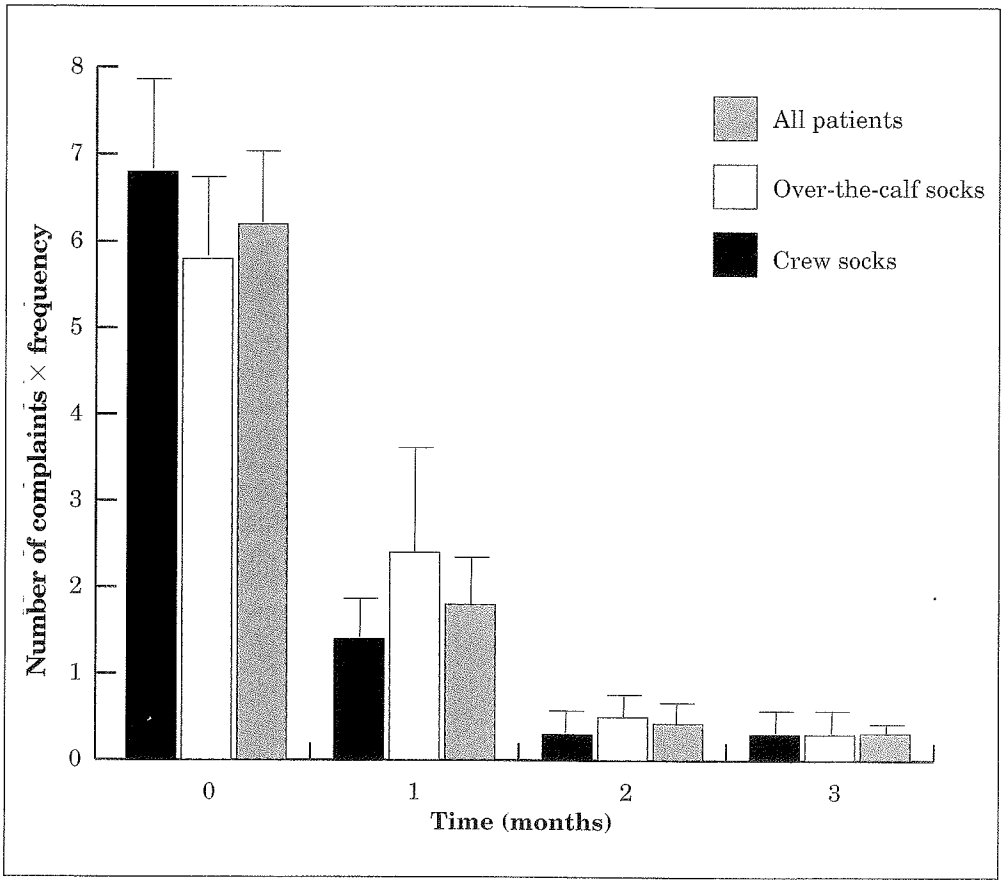

Figure 1. *Average subjective score per person, calculated by adding the number of complaints weighted by frequency. Error bars indicate standard errors of the mean.*

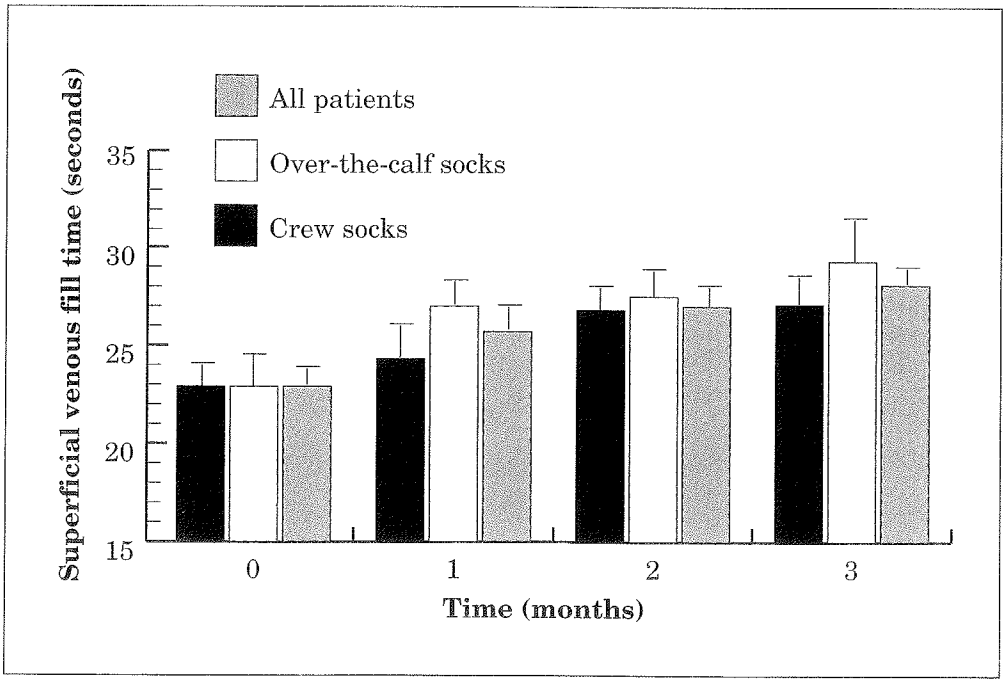

Figure 2. *Average per person superficial venous fill time in seconds as a measure of superficial venous valve function (normal, >23 seconds). Error bars indicate standard errors of the mean.*

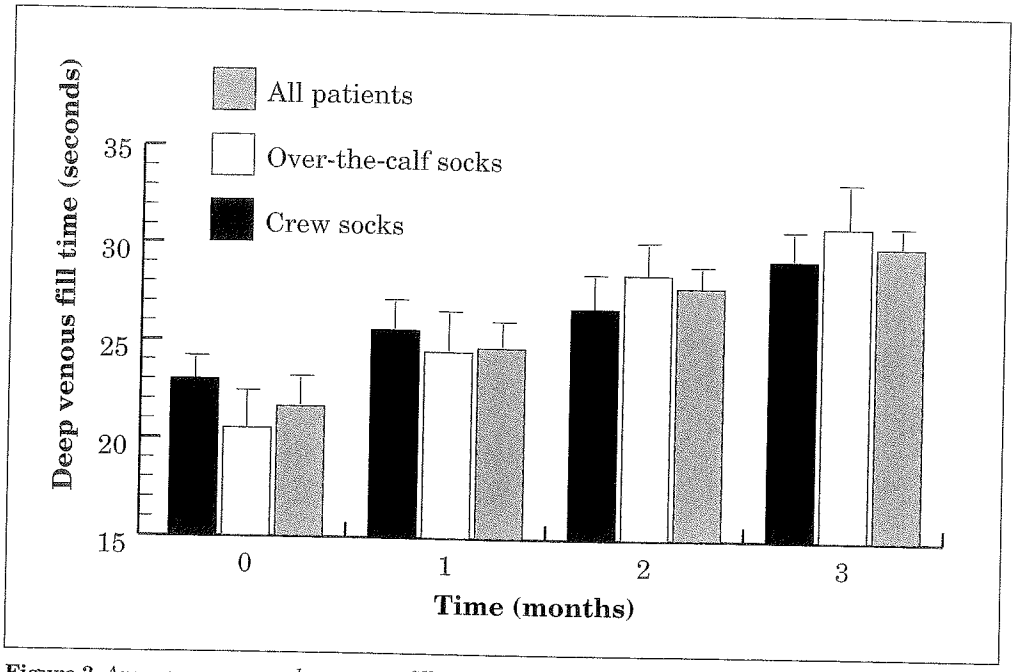

Figure 3. *Average per person deep venous filling time in seconds, as a measure of deep venous valve function (normal, >23 seconds). Error bars indicate standard errors of the mean.*

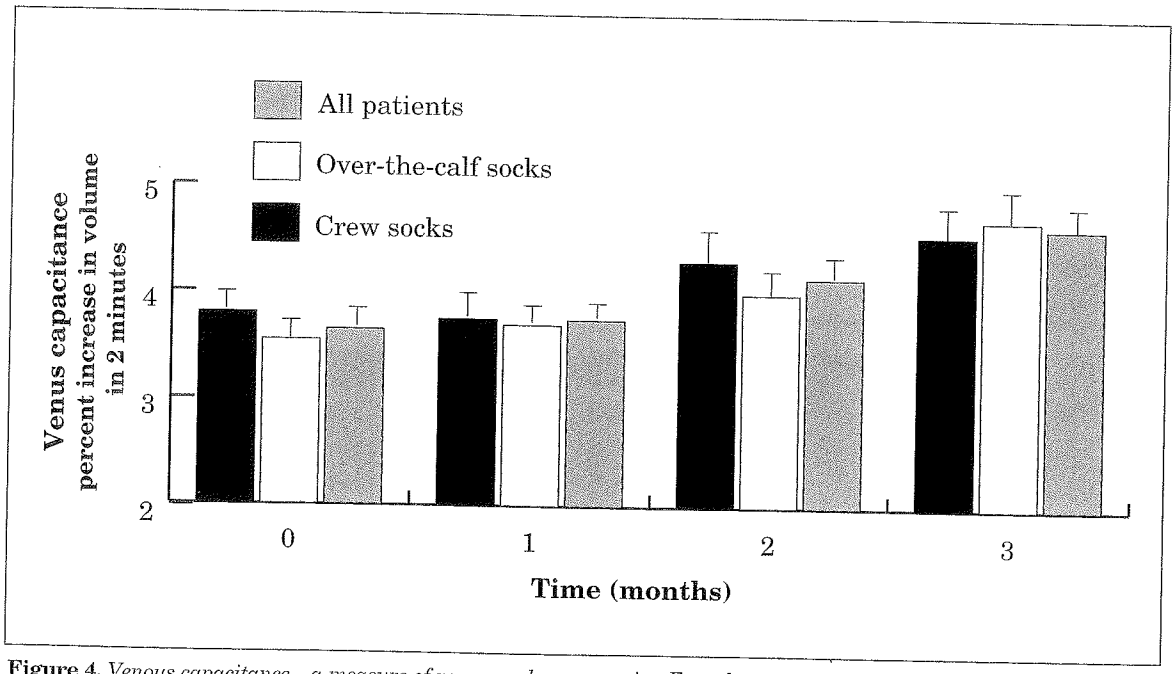

Figure 4. *Venous capacitance—a measure of venous volume capacity. Error bars indicate standard errors of the mean.*

In all patients, from the start of the study to the end of 3 months in crew socks or 1 month in crew socks and 2 months in over-the-calf socks, venous insufficiency was statistically significantly improved as measured by deep venous valve function ($P<.001$), and venous capacity ($P<.001$) (*Tables 3* and *4*).

From the start of the study to the end of 3 months, the number and severity of subjective complaints (as measured by the subjective score) was dramatically decreased.

Subjective scores decreased significantly ($P<.001$), from an average of 6 to an average of only 2, after the first month of the crew socks

being worn. The average subjective score continued to decrease in the second month of the trial and decreased from 2 to less than 1 per participant in the group that wore first the crew socks and then the over-the-calf socks. By the third month, the average subjective score per participant remained less than 1 ($P<.001$) (*Figure 1*).

Arterial function, as measured by ABI, was not statistically altered from the baseline throughout the entire study period, regardless of which strength of support socks the participant wore ($P=.534$). The average ABI ranged from 1.122 at the first examination to 1.145 at the last examination.

Venous valve function, as measured by PPG, was evaluated for deep and superficial veins. Superficial venous valve function was statistically significantly increased after 1 month in the all-patients group (the crew socks and the over-the-calf socks groups combined) and the group wearing the over-the-calf socks ($P=.032$), and after 2 months for the group wearing the crews socks ($P<.018$). The additional improvement was not statistically significant from the second month to the third month, but it was statistically significant from each trial to baseline (crew socks, $P=.003$; over-the-calf socks, $P<.001$; the all-patients group, $P<.001$) (*Table 4* and *Figure 2*). The veins evaluated are part of the calf muscle pump.

Deep venous valve function was statistically significantly improved after the first month in the all-patients group ($P<.001$) and the group crossed over to wearing the over-the-calf socks ($P<.001$), and by the end of the third month in the group wearing the crew socks exclusively for the 3 months ($P<.004$). The deep venous valve fill times increased from 21.9 seconds at baseline to 25.0 seconds (normal value) after 1 month, 27.0 seconds after 2 months, and 30.0 seconds after 3 months of either type of support socks being worn (*Figure 3*).

Initially, venous capacitance did not statistically change. However, after 3 months, venous capacitance was 33% increased in the all-patients group ($P<.001$), 34% increased in the group crossed over to the over-the-calf socks ($P<.001$), and 21% increased in the group wearing the crew socks exclusively during the study ($P=.17$) (*Figure 4*).

Venous outflow remained statistically unchanged throughout the study. The actual volume of blood that the vein was able to release did increase as the actual venous capacity was increased, but the percentage outflow was constant in the all-patients group ($P=.65$), in the group wearing the crew socks exclusively ($P=.102$), and in the group crossed over to wearing the over-the-calf socks ($P=.280$).

Discussion

The general progression of the improvement in the study was an initial decrease in subjective complaints with an increase in superficial venous valve function, followed by an increase in deep venous valve function and, finally, increase in venous capacitance of the deep leg vein. This progression is consistent with the mechanism of the calf muscle pump. In the normal state, superficial venous valves are functional and blood is shunted to the deep venous circulation and then returned to the heart. As superficial venous valves become slack and lose function, the blood is decreasingly shunted to the deep venous circulation, and return flow is increasingly shunted to the superficial venous circulation (*Figure 5*). Eventually, this system becomes overloaded and the superficial veins become engorged, enlarged, and tortuous, and their valves less functional (*Figure 6*). The calf muscle pump can be stimulated by a pressure of 10 mm Hg to 15 mm Hg at rest,[3] or pressure difference of 14 mm Hg in diastole and 20 mm Hg in systole.[4] The pressures provided by the crew socks and by the over-the-calf socks aided in supplying the necessary pressures for the calf muscle pump to function normally.

The pressures used in this study were considerably lower than those in our previous study of women using light- and firm-support hose (14 mm Hg and 16 mm Hg, respectively),[5] but they were great enough to result in many statistically significant positive changes in both objective venous values and subjective venous complaints, without significant negative alterations of arterial status. At the time of the first investigation into this area of treatment, it was generally considered that to be effective, support hose strength of compression had to be greater than 20 mm Hg and preferably in the range of 40 mm Hg to 50 mm Hg.[6]

As reflected by the decrease in the number and frequency of venous complaints, patients felt better. Not only did the participants improve dramatically both subjectively and objective-

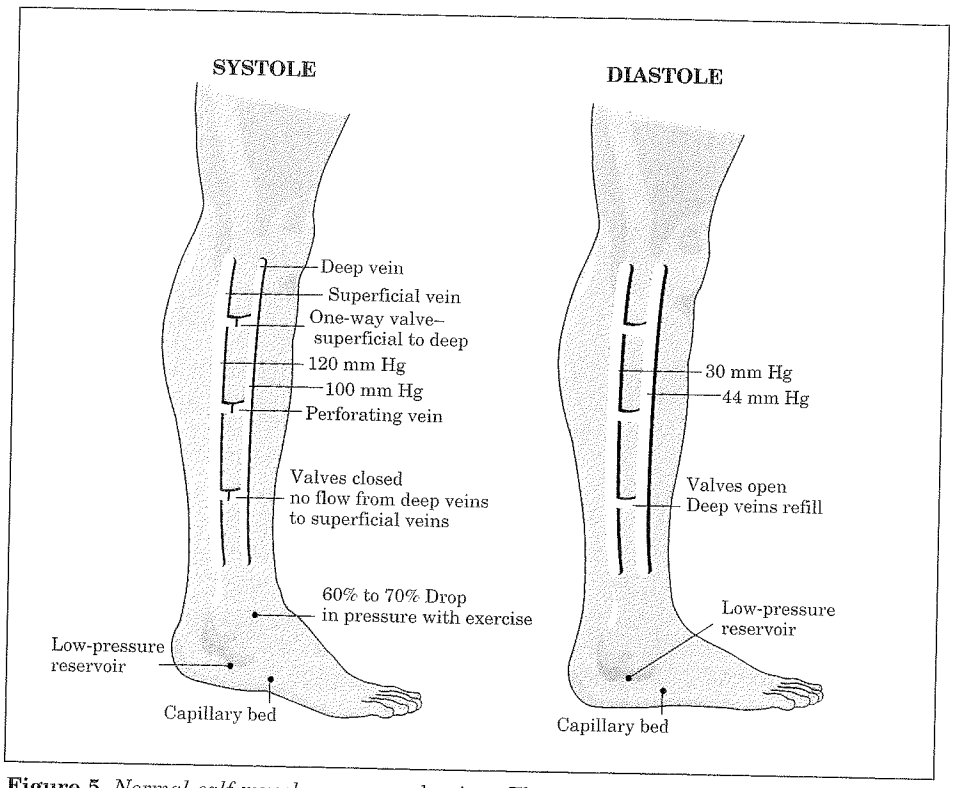

Figure 5. *Normal calf muscle pump mechanism. The calf muscle pump returns deep venous blood to the heart during systole. During diastole, the deep veins refill from the superficial veins via perforating veins with competent valves.*

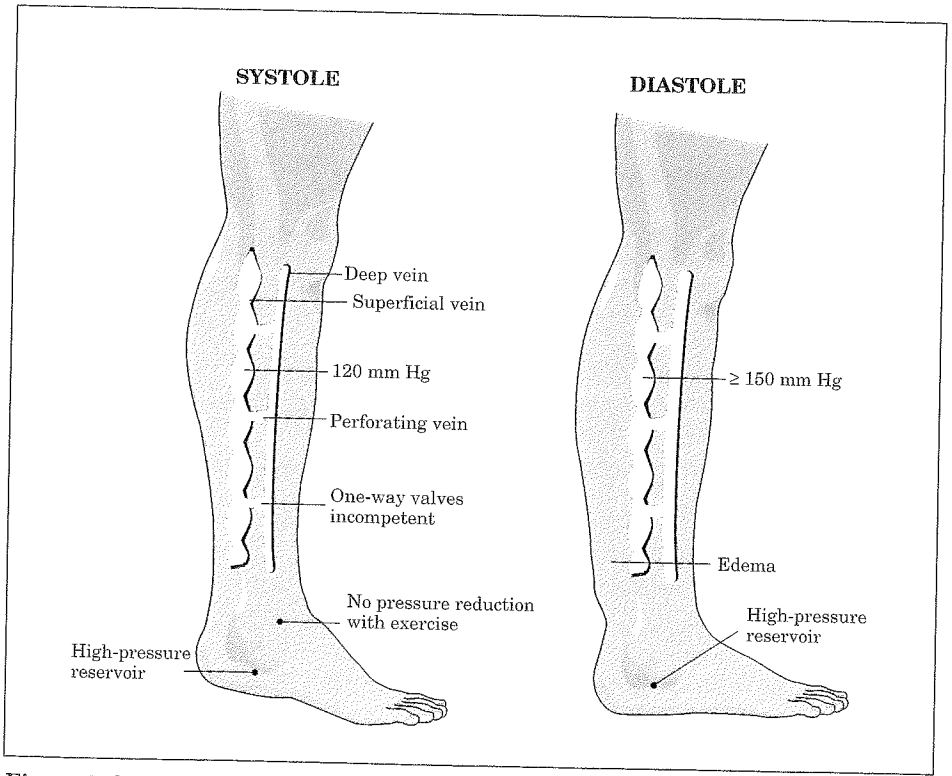

Figure 6. *Calf muscle pump mechanism in chronic venous insufficiency. The calf muscle breaks down. The pressures in the deep and superficial veins and foot reservoir are virtually the same; therefore, there is no efficient return flow to the heart.*

ly, but many also made other positive lifestyle changes: four smokers quit (and one wife also quit), many lost weight without specifically trying to, and many also exercised more. Recommendations that practitioners may make in helping patients are given in *Table 5*.

It should be noted that several patients underwent major surgery, including cholecystectomy, aortic aneurysm repair, and quadruple cardiac bypass, but all continued in the study. None of the participants had to be excluded.

Comment

The use of nonprescription, padded, lightweight support socks is a simple and effective mode of treatment and should be considered as a first line of therapy for mild to moderate venous insufficiency. Once the patient has subjective relief of complaints, other positive lifestyle changes can be promoted.

Two years after this clinical research was begun, 35 of the original 36 participants (one participant is deceased) were continuing to wear nonprescription, padded, lightweight support socks.

Acknowledgment

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