Rapid foot and calf compression increases walking distance in patients with intermittent claudication: Results of a randomized study

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Objective: **The aim of our pilot study was to determine the usefulness of rapid, high-pressure, intermittent pneumatic calf and foot compression (IPCFC) in patients with stable intermittent claudication, with reference to the end points of improvement in initial claudication distance (ICD) (distance at which patient feels pain or discomfort in the legs), and improvement in absolute claudication distance (ACD) (distance at which patient stops walking because the pain or discomfort becomes severe).**

Methods: **Thirty male patients presenting with stable, intermittent claudication (ACD between 50 and 150 meters on treadmill testing at 3.8 km/h, 10° gradient) were recruited into this pilot study from a single center. Fifteen patients were randomized to treatment with IPCFC (applied for 1 hour twice daily in the sitting position) and were also advised to have daily exercise, and 15 patients served as controls, who were advised exercise alone. All patients received aspirin and had resting and postexercise ankle/brachial index (ABI) measured at enrollment along with ICD and ACD on treadmill testing (3.8 km/h, 10° gradient). The mean age, baseline ICD, and ACD of the treatment and control groups were 70.4 ± 7 years and 70.7 ± 9 years, 55.8 ± 15 meters and 68.4 ± 17 meters, and 86.7 ± 19 meters and 103.9 ± 27 meters, respectively. Both groups were equally matched for risk factors, including smoking, type II diabetes mellitus, and hypercholesterolemia. IPCFC was applied. The study protocol included follow-up visits at 1, 2, 3, 4, 6, and 12 months with the ABI, ICD and ACD being measured at every visit.**

Results: **The percent change from baseline for ICD and ACD for each patient visit and the mean ± standard deviation (SD), standard error (SE), and median were calculated for the control and treatment groups. The percent change from baseline measurements (mean ± SD) for ICD and ACD in the control group at 4, 6, and 12 months were 2.2 ± 18 and 2.3 ± 18, 2.9 ± 17 and 5.2 ± 20, and 3.6 ± 18 and 5.8 ± 20, respectively. In contrast, the changes in ICD and ACD at 4, 6, and 12 months in the treatment group were 137.1 ± 128 ($P < .01$) and 84.3 ± 82 ($P < .01$), 140.6 ± 127 ($P < .01$) and 96.4 ± 106 ($P = .01$), and 150.8 ± 124 ($P < 0.01$) and 101.2 ± 104 ($P < 0.01$), respectively. Although the ABI showed a slight increase in the treatment group, these differences were not statistically significant.**

Conclusions: **The results of this pilot study show that IPCFC improves walking distance in patients with stable intermittent claudication. A significant increase in ICD and ACD was seen at 4 and 6 months of treatment, respectively, and the improvement was sustained at 1 year. The combination of IPCFC with other treatment such as risk-factor modification and daily exercise may prove useful in patients with peripheral arterial occlusive disease. It may be a useful first line of therapy in patients with disabling claudication who are unfit for major reconstructive surgery. Improved walking on long-term follow-up and experience from different centers may establish a role for this treatment modality in the future. (J Vasc Surg 2005;41:794-801.)**

Claudication is a disease predominantly affecting older patients,[1-3] with a higher incidence in men.[4-6] Although the natural history of claudication is benign, the progression of symptoms may necessitate intervention, either by endovascular techniques or by conventional bypass grafting.

Intermittent pneumatic compression using low pressure (typically 50 mm Hg) is a widely accepted modality for deep vein thrombosis prophylaxis.[7,8] Although early reports showed the efficacy of pneumatic compression in increasing tissue perfusion in patients with peripheral arterial occlusive disease (PAOD),[9] it is only recently that there has been a resurgence of interest in this modality.[10-14] Popliteal artery blood flow has been shown to be increased by rapid, high-pressure calf compression[11] and by combined, rapid calf and foot compression using high compression pressures[13] >100 mm Hg applied rapidly (300 millisecond rise time). When intermittent compression was applied to both the calf and foot, popliteal artery blood flow increased nearly threefold compared with foot compression alone.[13] A more recent study with intermittent pneumatic foot compression (IPFC) alone has shown a marked improvement in walking distance in patients with stable intermittent claudication.[14]

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The aim of our study was to determine the role of rapid, high-pressure IPFC in patients with stable claudication. We describe the early clinical results of the use of IPCFC in patients with stable claudication with reference to the end points of improvement in the initial claudication distance (ICD) (distance at which the patient initially feels pain or discomfort in the legs), and improvement in the absolute claudication distance (ACD) (distance at which the patient stops walking because the pain or discomfort becomes severe).

METHODS

Patients with symptoms suggestive of PAOD who presented to the vascular clinic at a single center were evaluated for enrollment in this pilot study, which was approved by and conducted in accordance with the local institutional review board. Informed consent was obtained from all patients before the study began. All patients had PAOD diagnosed 6 to 12 months earlier and had stable claudication. The criteria for inclusion in the study were a resting ABI <0.90, except in those with ABI >0.90 secondary to distal incompressible vessels; a fall in the ABI by >0.1 in the affected limb on treadmill exercising (3.8 km/h at a 10° gradient for 1 minute); and an ACD between 50 and 150 meters on treadmill exercise (3.8 km/h at a 10° gradient).

The ACD was measured during two screening visits 1 week apart, and patients whose ACD differed by <10 meters were eligible to join the study.

The exclusion criteria for the study included ischemic or venous stasis ulcers; a history suggestive of rest pain; myocardial infarction ≤ 6 months, cardiac arrhythmia, exercise-limiting congestive cardiac failure, or angina; patients being treated with rheologic agents, namely pentoxifylline or cilostazol; the use of investigational drugs ≤ 6 months; or a history of a lower extremity revascularization procedure.

A detailed history was obtained from all patients, followed by clinical examination with assessment of pulses (femoral/popliteal/dorsalis pedis and posterior tibial). A resting and postexercise ABI (3.8 km/h at 10° gradient for 1 minute) was performed in all patients. The ABI was calculated by dividing the highest systolic pressure in the pedal artery by the highest brachial artery pressure, and the postexercise ABI was performed as per a previously described protocol.[15] All patients were studied in two screening visits where they exercised on a treadmill (3.8 km/h at 10° gradient) for the measurement of the ICD and ACD. The ICD was the distance that the patient could walk before complaining of pain or discomfort in the affected limb; the ACD was the distance that the patient could walk before the severity of pain or discomfort caused the test to be terminated. All patients were rested for 20 minutes before the commencement of exercise for the measurement of ICD and ACD. A stopwatch was used to measure the time taken in seconds to reach the ICD (t1) and ACD (t2). Given that the speed of the treadmill was 3.8 km/h, the following calculations were used for determining the ICD and ACD:

Treadmill speed = 3.8 km/h or 3800 meters over 3600 seconds;

ICD (m) = $3800 \times t1/3600 = 38\ t1/36 = 1.06\ t1$;

ACD (m) = $1.06\ t2$

A difference of >10 meters in the ACD in the two screening visits excluded patients from the study. Alternate patients who fulfilled the criteria for enrollment in the study were randomized into either treatment with the ArtAssist IPCFC device (ACI Medical, Inc., San Marcos, Calif) or assigned to the control group.

Patients who were randomized to the treatment group were encouraged to use the IPFCC device for an hour twice daily, in the sitting position. This device had two pressure cuffs, one of which was wrapped around the foot and extended to the ankle, and another around the calf. Compression was first applied to the foot and spread proximally to the calf with air pulses delivered separately to the two cuffs from a control unit. The pressure in each cuff was rapidly inflated to the relatively high pressure of 120 mm Hg, with an approximate 300-millisecond rise time and a 1-second delay between inflation of the foot and calf cuff. The cuffs held the pressure for 3 seconds each before deflating, foot first followed by the calf. The settings in the unit provided for three cycles of compression per minute. The compression pressure of 120 mm Hg and sequential inflation with a 1-second delay, with the patient in the sitting position, were adopted based on results from a previous study.[16] Additionally, all patients randomized to treatment were also encouraged to exercise daily. Patients randomized to the control group were encouraged to exercise.

During the follow-up period, patients were studied at 1, 2, 3, 4, 6, and 12 months. The resting ABI, ICD, and ACD were measured in all patients during these visits. Importantly, in patients who failed to attend for follow-up, telephone follow-up was obtained in terms of overall well being, device usage in the treatment group, adherence to daily exercise in the control group, and any changes in the walking distance.

Statistical analysis. The percent changes from baseline for ICD and ACD were calculated for each patient at each study visit and the mean ± standard deviation (SD), standard error (SE), and median were calculated for the control and treatment groups. The groups were compared using a Wilcoxon rank sum test at a 5% significance level. No adjustments were made for multiple testing.

The goal of data analysis was to assess differences in outcomes between the two treatment groups over the entire study period. Loss of information from subjects who failed to attend one or more follow-up visits was minimized by applying the "last observation carried forward" (LOCF) method to missing data. This technique, sometimes used in randomized clinical trials,[17] uses measurements recorded from the last observed period before a missed visit to replace missing data in subsequent follow-ups. LOCF assumes that outcomes remain constant since the last observed value. Because the experimental treatment in this study was expected to induce a change in the ICD and

Table I. Baseline characteristics by study group at enrollment in study

Variable	*Control Group* % (n)*	*Treatment Group* % (n)*	*P*†
Age	70.7 ± 9.0	70.4 ± 7.2	.8843
Type II diabetes mellitus	46.7 (7)	46.7 (7)	1.0000
Hypertension	66.7 (10)	60.0 (9)	1.0000
Hypercholesterolemia	53.3 (8)	53.3 (8)	1.0000
Current smoker	26.7 (4)	40.0 (6)	.6985
ICD (m)	68.4 ± 17.3	55.8 ± 14.9	.0588
ACD (m)	103.9 ± 27.5	86.7 ± 18.9	.0887
ABI-RT	0.63 ± 0.20	0.70 ± 0.13	.3395
ABI-LT	0.64 ± 0.15	0.58 ± 0.11	.2798

ICD (m), Initial claudication distance in meters; *ACD (m), a*bsolute claudication distance in meters; *ABI,* ankle/brachial index; *RT,* right; *LT,* left.
*Data are mean ± standard deviation
†The Mann-Whitney *U* test *P* value was applied for continuous variables and Pearson's χ^2 test *P* value with Yates' correction was applied for categorical variables. There were no statistically significant differences between the two groups at baseline. Only two marginally significant differences ($P < .1$) for ICD and ACD were seen and the differences were in favor for the control group.

ACD and perhaps have a carry-over effect even after cessation of the treatment, and no substantial change was expected in the control group, this technique for handling missing values might have been conservative.[18]

Additional statistical testing was performed using Kaplan-Meier estimation and log-rank tests to determine if there were differences between the treatment and control groups with respect to the ICD and ACD. JMP software, version 5.1 (SAS Institute Inc., Cary, NC, 2003), was used for statistical analysis.

RESULTS

A select group of 34 patients were screened and 30 were recruited into the study (15 to the treatment group with the ArtAssist IPFCC device, and 15 served as controls). Reasons for exclusion included the ACD >150 meters in two patients, inability to attend for follow-up in one, and severe hip pain with inability to exercise in another. All subjects were men. The mean age of the control and treatment groups was 70.7 ± 9 and 70.4 ± 7 years. The clinical examination showed that the arterial disease was infrainguinal in all patients. The risk factors (diabetes, hypertension, hypercholesterolemia needing treatment and smoking), ICD, and ACD for patients recruited into the control or treatment groups are summarized in Table I. Complete follow-up for all patients was available at 2 months; after this, the number of patients attending for follow-up in the treatment and control groups at 3, 4, 6, and 12 months were 12 and 12, 11 and 9, 10 and 6, and 6 and 5, respectively.

As already mentioned, telephone follow-up was obtained from all patients who failed to attend follow-up. During the course of telephone follow-up, patients in the treatment group reported that the improvement in walking distance was sustained, whereas those in the control group reported no change since the last visit. The percent change from baseline measurements for the ICD and ACD in the treatment and control groups for each study visit is summarized in Table II, and in Figs 1 and 2.

A rapid improvement in ICD that was seen between 2 and 4 months was sustained at 6 months and 1 year (Fig 1). For the ACD, the improvement was rapid until 6 months, with a slight increase at 1 year (Fig 2). Using Kaplan-Meier estimation and the log-rank tests at a 5% significance level, we found significant differences for ICD at all times in the treatment and control groups except at 1 and 12 months, although $P = .06$ at 12 months was close to being significant (Figs 3, *A;* 4, *A;* and 5, *A*). Significant differences in ACD between the treatment and control groups occurred only at 2 months, with $P = .07$, .24, and .56 at 4, 6, and 12 months, respectively (Figs 3, *B;* 4, *B;* and 5, *B*).

The analysis using LOCF to replace the missing values showed significant differences at all times (1, 2, 3, 4, 6, and 12 months) for both ICD and ACD. We believe that the differences are, at least in part, likely due to the reduced sample size during follow-up visits and also to "overachievers" in the treatment group dropping out of the study early and not attending for follow-up, as the analysis of ICD and ACD in patients dropping out of the study showed interesting trends. Four of the five patients in the treatment group who dropped out of the study at 6 months showed a significant improvement in walking distance, with an average increase in ICD and ACD of 117% and 60% compared with baseline; only one patient in this group showed a decrease in ICD (−4%) and ACD (−1%).

At the end of 1 year, four patients in the treatment group who had attended follow-up at 6 months dropped out of the study. Analysis of the walking distance in these patients at 6 months showed that they were overachievers who had performed better than others in their group, with a percent increase of 298% in ICD and 229% in ACD. The analysis of walking distances in patients from the control group who dropped out of the study showed either no improvement or a slight decrease from baseline for the ICD and ACD.

With the Wilcoxon rank sum test (Mann-Whitney *U* test), 33 subjects per treatment group are needed to yield 80% power to detect a true probability of 0.70 that an ACD or ICD in the treatment group will be higher than an ACD or ICD in the control group. In our study, the number of people in the control and treatment groups was 6 and 10 at 6 months, and 5 and 6 at 12 months. The probability was 60% that an ACD from the treatment group was greater than an ACD from the control group and 87% for the ICD.

DISCUSSION

The role of intermittent compression in the prophylaxis of deep vein thrombosis is well established.[7,8] Early clinical reports showed the beneficial effects of compression therapy in the treatment of patients with PAOD[9]; however, the lack of physiologic quantification of im-

Table II. Percent change from baseline measurements in initial claudication distance and absolute claudication distance in the control and treatment groups

Variable in meters	*Control group % Change from baseline*			*Treatment group % Change from baseline*			
	Mean ± SD	*SE*	*Median (range)*	*Mean ± SD*	*SE*	*Median (range)*	*P**
ICD (1-mon)	3.2 ± 13.4	3.5	4.6 (−29.5, 27.0)	53.3 ± 80.8	20.9	26.0 (−12.1, 286.5)	.0121
ACD (1-mon)	3.8 ± 5.9	1.5	3.8 (−9.0, 16.4)	29.6 ± 34.4	8.9	21.3 (−11.5, 104.2)	.0327
ICD (2-mon)	−1.6 ± 11.2	2.9	−2.3 (−22.5, 22.6)	98.3 ± 93.7	24.2	93.3 (−3.9, 300.0)	.0002
ACD (2-mon)	3.3 ± 8.9	2.3	5.3 (−16.5, 19.6)	72.2 ± 71.7	18.5	49.3 (−1.2, 280.0)	<.0001
ICD (3-mon)	1.5 ± 20.9	5.4	2.9 (−30.5,59.7)	122.2 ± 112.6	29.1	86.9 (−3.9, 351.2)	<.0001
ACD (3-mon)	4.6 ± 20.4	5.3	5.4 (−44.4, 42.6)	79.2 ± 82.6	21.3	52.0 (−1.2, 275.0)	.0001
ICD (4-mon)	2.2 ± 18.0	4.6	4.3 (−30.5, 33.33)	137.1 ± 128.0	33.1	86.9 (−3.9, 392.3)	<.0001
ACD (4-mo)	2.3 ± 18.5	4.8	5.4 (−44.4, 39.4)	84.3 ± 81.7	21.1	56.2 (−1.2, 275.0)	<.0001
ICD (6-mon)	2.9 ± 17.5	4.5	4.3 (−30.5, 33.33)	140.6 ± 127.0	32.8	88.0 (−3.9, 392.3)	<.0001
ACD (6-mon)	5.2 ± 20.2	5.2	7.2 (−44.4, 46.0)	96.4 ± 105.7	27.3	66.8 (−1.2, 384.0)	<.0001
ICD (12-mon)	3.6 ± 18.3	4.7	5.8 (−30.5, 33.3)	150.8 ± 123.7	31.9	106.0 (−3.9, 392.3)	<.0001
ACD (12-mon)	5.8 ± 20.4	5.2	7.2 (−44.4, 40.5)	101.2 ± 103.7	26.8	72.8 (−1.2, 384.0)	<.0001

ICD, Initial claudication distance in meters; *ACD*, absolute claudication distance in meters; *SD*, standard deviation; *SE*, standard error of mean.
* Wilcoxon rank sum test *P* value

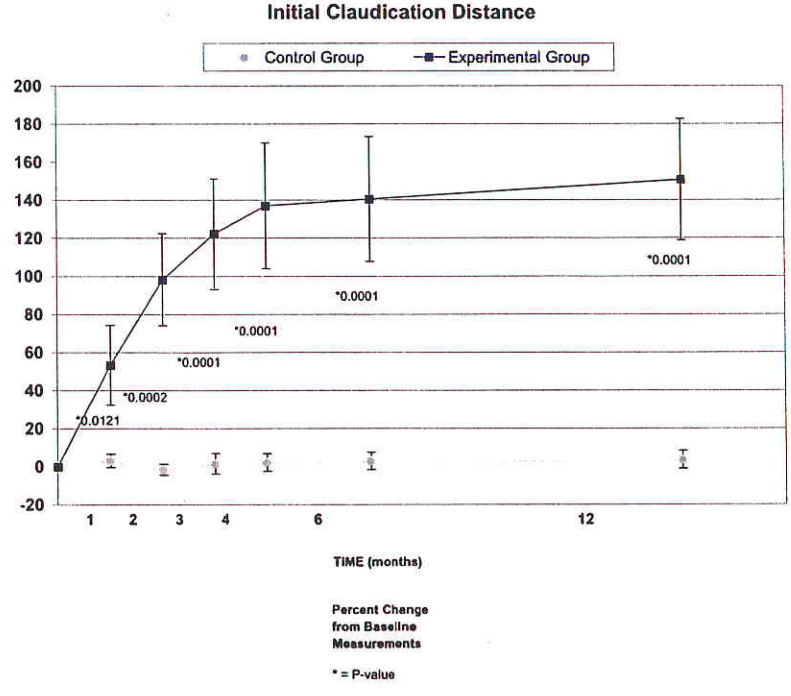

Fig 1. Percent changes in the initial claudication distance in the treatment and control group (mean ± standard error of the mean) (**P* value).

provement, either in terms of increased blood flow or tissue perfusion, delayed further investigation of this treatment modality. It was not until 1978 that Gaskell and Parrot,[19] with the use of radioactive Xe133 scanning, demonstrated that mechanical compression increased flow in the limbs of patients with arteriopathy in the sitting position.

Recent improvements in noninvasive color flow duplex imaging have enabled quantification of popliteal artery blood flow and studies have demonstrated increased flow

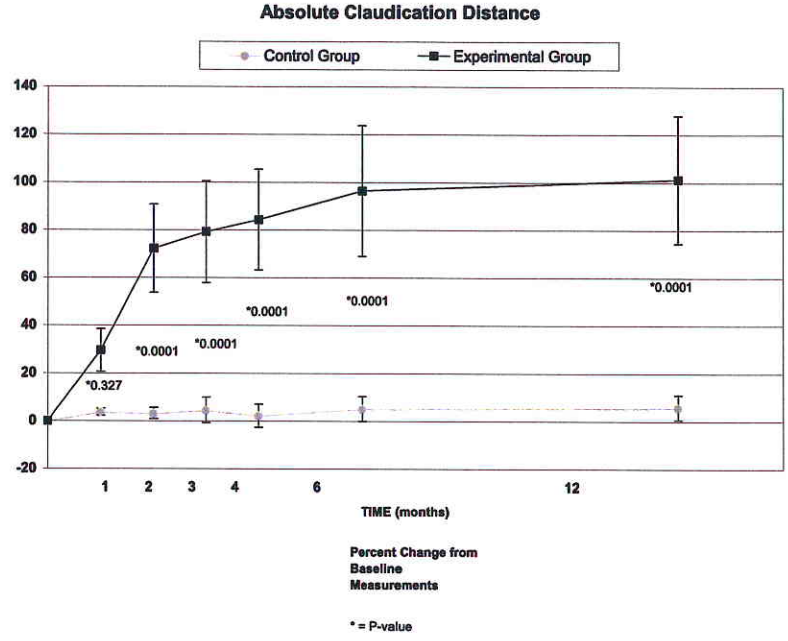

Fig 2. Percent changes in the absolute claudication distance in the treatment and control groups (mean± standard error of mean) (**P* value).

after the use of rapid, high-pressure compression therapy.[11,13] Additionally, the beneficial effects of compression therapy in improving tissue perfusion to the foot have also been demonstrated with the use of laser Doppler scanning.[12,13,20]

Numerous mechanisms have been postulated for the increase in blood flow after this form of intermittent pneumatic compression therapy. In the sitting position, hydrostatic pressure causes an increase in arterial and venous pressures, and after rapid pneumatic compression, venous pressure is decreased to almost zero, with little or no decrease in arterial pressure. The percent increase in arteriovenous pressure gradient results in a similar increase in flow according to the equation: Flow = ΔPressure/Resistance.

Because the compression phase is significantly shorter than the relaxation phase, the increased flow is sustained while the veins slowly refill. Recent work has shown that the use of a compression pressure of 120 mm Hg with a 1-second delay between foot and calf compression leads to optimal lowering of venous pressures.[16]

The venoarteriolar reflex (VAR) exists as a protective mechanism that causes vasoconstriction and prevents swelling that might otherwise occur after an increase in the venous pressure due to postural changes involving the limb.[21] The VAR causes contraction of precapillary sphincters, resulting in an increase in peripheral vascular resistance with a concomitant decrease in arterial blood flow.[22] The use of pneumatic compression decreases venous pressure, which momentarily abolishes the VAR.[23]

Vasodilatation at the microcirculatory level decreases peripheral resistance, and flow therefore increases, based on the previous flow equation. The increased flow in turn aids in the development of collaterals with improved limb perfusion. Other postulated mechanisms for the increase in blood flow include the production of endothelial-derived vasodilating factors such as nitrous oxide and prostacyclin as a result of increased shear stress.[24,25]

Although intermittent pneumatic compression therapy has been shown to increase popliteal artery blood flow in patients with angiographically proven superficial femoral artery stenosis,[13] a more recent study has documented increased tissue perfusion after use in patients with distal infrapopliteal disease.[20] In our study, PAOD was documented by clinical examination and the resting and postexercise ABI. The ICD and ACD for patients recruited into the study in the control and treatment group in meters were 68.4 ± 17 and 55.8 ± 14.9, and 103.9 ± 27 and 86.7 ± 18.9, respectively. The differences in ICD and ACD were marginally significant and in favor of the control group.

The ICD and ACD remained unchanged in the control group (exercise only), whereas IPCFC and daily exercise resulted in significant increases in the treatment group. The ICD increases in the treatment group were rapid until 4 months, and the increases thereafter, although minimal, were sustained at 6 months and 1 year (Fig 1). The ACD, on the other hand, showed significant increases at each study visit until 6 months, but only a minimal increase thereafter at 1 year (Fig 2). Although, patients in the treatment group used the device for up to a year, extended use >6 months produced only a marginal increase in walking. The effects of withdrawal therapy are not addressed in our pilot study.

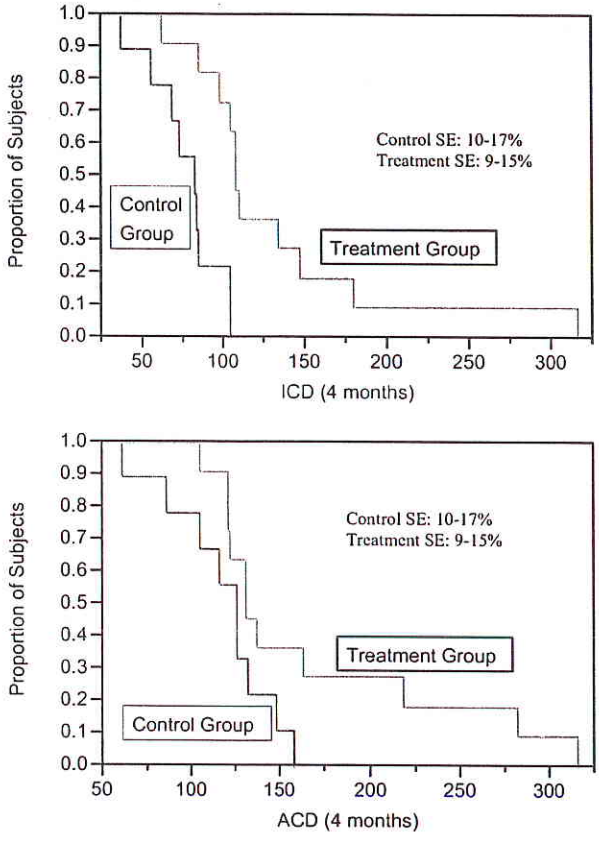

Fig 3. A. Proportion of subjects walking at least the specified initial claudication distance *(ICD)*in meters at the 4-month follow-up visit. Control vs treatment group, $P < .01$. **B.** Proportion of subjects walking at least the specified absolute claudication distance *(ACD)* in meters at the 4-month follow-up visit. Control vs treatment group, $P = .07$.

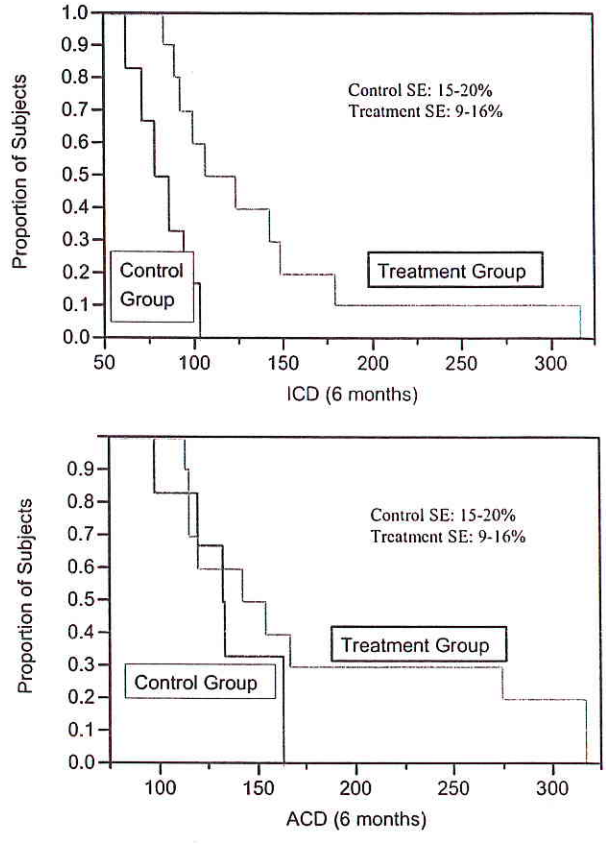

Fig 4. A. Proportion of subjects walking at least the specified initial claudication distance *(ICD)* in meters at the 6-month follow-up visit. Control vs treatment group, $P < .01$. **B.** Proportion of subjects walking at least the specified absolute claudication distance *(ACD)* in meters at the 6-month follow-up visit. Control vs treatment group, $P = .24$.

A limitation of this study was that significant data were lost for patients who failed to attend for follow-up. However, an analysis of walking distance data in patients in the treatment group who dropped out showed that they were significant overachievers, with a percent increase of 298% in ICD and 229% in ACD compared with baseline. It is therefore logical to assume that with these increases in walking distances, these patients did not feel the need to attend further follow-up. The analysis of walking distance in patients in the control group who dropped out showed either no improvement or a slight deterioration from baseline ICD and ACD.

A recent study has demonstrated significant improvement in ICD and ACD by using intermittent pneumatic foot compression (IPFC) alone.[14] This study involved the same treadmill protocol as ours and required patients to use the IPFC device for 4 hours daily over 4.5 months and with follow-up available to 1 year. This study has shown comparable improvement in walking distances with ours, but the increases in ICD and ACD in our study were obtained with half the daily "dose" of compression therapy. This finding may, in fact, demonstrate the combined value of foot and calf compression. Furthermore, this would also be in keeping with the finding that combined foot and calf compression increases popliteal artery blood flow three times more than foot compression alone.[13]

An interesting finding in the study that used IPFC [14] was that the maximum increase in ACD was seen in the first 3 months after treatment, with little improvement thereafter. Also, a significant increase in the ABI was seen at the end of 3 and 5 months after treatment with IPFC. In our study with IPCFC, the ABI showed an increase in the treatment group, although this did not reach statistical significance compared with baseline.

The traditional treatment of claudication includes a modification of risk factors (eg, smoking cessation) and daily exercise. Although unsupervised exercise alone produces insignificant improvement in walking distance,[26] supervised exercise programs have been shown to be effective, with significant improvement in walking.[27] However, these programs may not be readily available at most medical centers and are also expensive to run. The use of a portable

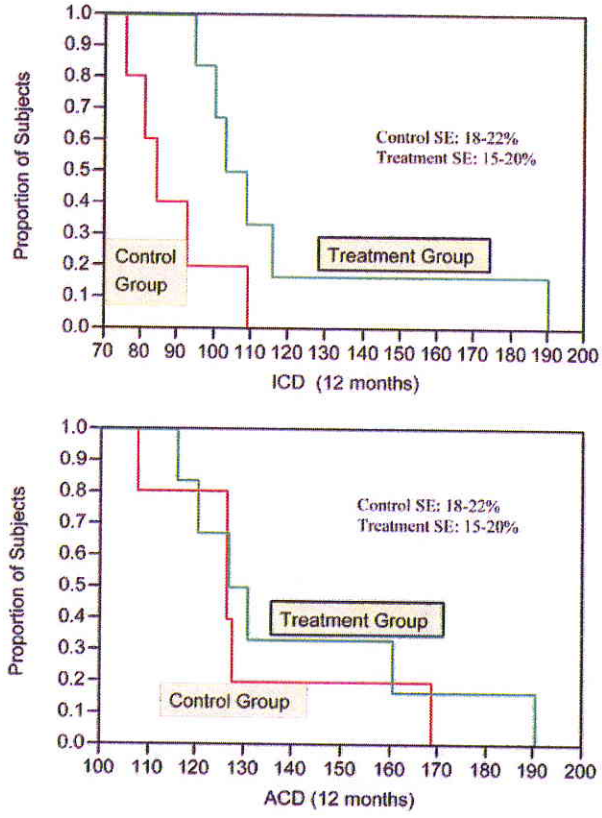

Fig 5. A. Proportion of subjects walking at least the specified initial claudication distance *(ICD)* in meters at the 12-month follow-up visit. Control vs treatment group, $P = .06$. **B.** Proportion of subjects walking at least the specified absolute claudication distance *(ACD)* in meters at the 12-month follow-up visit. Control vs treatment group, $P = .56$.

pneumatic compression device, on the other hand, allows these patients to receive treatment at home.

A built-in timer in these devices that is hidden from the patient allowed us to determine the extent of patient compliance and usage. This study did not require patients to maintain an activity log or complete a physical activity questionnaire, leading to the argument that the improvement in walking distance in the treatment group might represent a placebo effect, with the benefit resulting from a significant expectation of improvement. Importantly, it is interesting to note that the increases in walking distance in our study and with the use of IPFC[14] appear to be comparable to those obtained with pharmacologic modalities[28] and with no side effects reported.

The early results of IPCFC treatment in patients with claudication in our pilot study have been encouraging, and the long-term results are still awaited. If the improvements in walking distances are sustained, the combination of intermittent pneumatic calf and foot compression with other treatment such as modification of risk factors and daily exercise may prove to be useful in patients with PAOD. It may also prove useful as the first line of therapy in the treatment of patients with risk factors and disabling claudication who may otherwise be unfit for major reconstructive surgery and whose quality of life is severely impaired.[29,30] Experiences from different centers and larger studies may establish a role for this treatment modality in the future.

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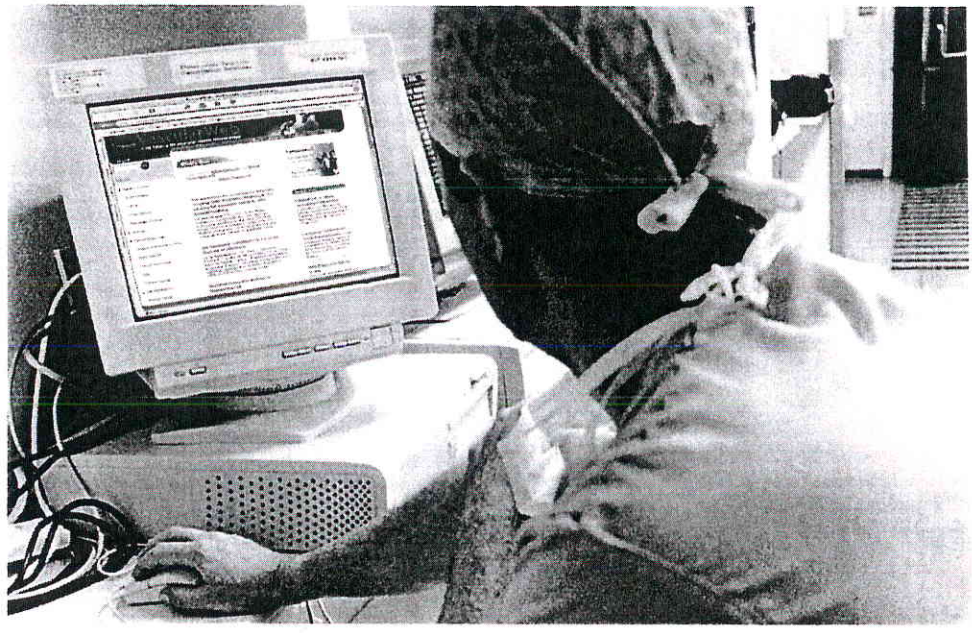

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