Corridor-based functional performance measures correlate better with physical activity during daily life than treadmill measures in persons with peripheral arterial disease

Mary M. McDermott, MD,^a Philip A. Ades, MD,^b Alan Dyer, PhD,^a Jack M. Guralnik, MD, PhD,^c Melina Kibbe, MD,^a and Michael H. Criqui, MD, MPH,^d Chicago, Ill; Burlington, Vt; Bethesda, Md; and San Diego, Calif

Objective: To compare associations of physical activity during daily life with treadmill walking performance and corridor-based functional performance measures in persons with lower extremity peripheral arterial disease (PAD). *Study Design:* Cross-sectional.

Subjects: One hundred fifty-six men and women with PAD who completed baseline measurements and were randomized into the study to improve leg circulation (SILC) exercise clinical trial.

Main Outcome Measures: Participants completed a Gardner-Skinner treadmill protocol. Corridor-based functional performance measures were the 6-minute walk, walking velocity over four meters at usual and fastest pace, and the short physical performance battery (SPPB) (0-12 scale, 12 = best). Physical activity during daily life was measured continuously over 7 days with a Caltrac (Muscle Dynamics Fitness Network, Inc, Torrence, Calif) accelerometer.

Results: Adjusting for age, gender, and race, higher levels of physical activity during daily life were associated with greater distance achieved in the 6-minute walk (*P* trend = .001), faster fast-paced four-meter walking velocity (*P* trend < .001), faster usual-paced four-meter walking speed (*P* trend = .027) and a higher SPPB (*P* trend = .005). The association of physical activity level with maximum treadmill walking distance did not reach statistical significance (*P* trend = .083). There were no associations of physical activity with treadmill distance to onset of leg symptoms (*P* trend = .795). *Conclusion:* Functional performance measures are more strongly associated with physical activity levels during daily life than treadmill walking measures. (J Vasc Surg 2008;48:1231-7.)

Persons with lower extremity peripheral arterial disease (PAD) have greater functional impairment and faster rates of functional decline compared to persons without PAD.¹⁻³ Identifying new therapies that improve functional performance and prevent functional decline in patients with PAD has the potential to significantly benefit the large and growing number of men and women with PAD.

Treadmill walking performance is typically the primary outcome in clinical trials evaluating medical therapies for

Additional contributors: Luigi Ferrucci, MD, PhD,^c Donald Lloyd-Jones, MD,^a and William H. Pearce.^a

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improving walking impairment in patients with PAD. However, the degree to which treadmill testing reflects functional performance during daily life is unclear. Treadmill walking performance is measured in a highly controlled setting. Treadmill protocol specifies initial walking velocity and the rate of increase in walking speed and intensity. In contrast, participants set their own pace in corridor-based functional performance measures, such as the 6-minute walk test. Therefore, treadmill protocols may represent a relatively artificial measure of walking and may be a less optimal measure of daily or usual walking performance than corridor-based performance measures.

This study determined whether treadmill walking performance and corridor-based functional performance, respectively, were associated significantly with objectivelymeasured physical activity during daily life among persons with PAD. We hypothesized that corridor-based functional performance measures would be more strongly associated with physical activity during daily life than treadmill walking measures.

METHODS

Study overview. The study to improve leg circulation (SILC) is a randomized controlled clinical trial testing the ability of treadmill exercise and lower extremity resistance training, respectively, to improve walking performance in PAD participants with and without intermittent claudica-

From the Departments of Medicine and Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago,^a Department of Medicine, Vermont School of Medicine,^b Laboratory of Epidemiology, Demography and Biochemistry and Clinical Research Branch, National Institute on Aging, Bethesda,^c and Departments of Preventive Medicine and Family Medicine, University of California at San Diego.^d

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Competition of interest: none.

Correspondence: Mary M. McDermott, MD, 750 N. Lake Shore Drive, Tenth Floor, Chicago, IL 60611 (e-mail: mdm608@northwestern.edu). 0741-5214/\$34.00

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Table I. Exclusion criteria and number of potential participants meeting each criterion in the study in leg circulation

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Excl	usion	crites	ria

Dementia (n = 6)Above or below knee amputation (n = 1)Foot ulcers or critical limb ischemia (n = 6)Nursing home residence or extreme frailty (n = 8)Inability to walk on a treadmill (n = 5)Inability to speak English (n = 1)Unable or unwilling to come to the medical center three times weekly (n = 57)Failure to complete six run-in exercise sessions in a 3-week period (n = 23)Major surgery or a myocardial infarction during the previous 3 months (n = 2)Major surgery planned during the next year (n = 12)Current participation in other clinical trials (n = 0)Participant is already exercising at a level comparable to that offered by either exercise arm of the trial (n = 14)Unstable angina (n = 6)Abnormal baseline stress test without a follow-up normal stress imaging study (n = 32)Walking limitation due to a reason other than lower extremity ischemia (n = 24)Baseline SPPB = 12 (n = 123)Poorly controlled blood pressure (n = 9)

*Includes potential participants who failed to show for initial study appointments.

tion. Baseline data from SILC were used in the present analyses. The study design is cross-sectional.

The institutional review boards of Northwestern University, Catholic Health Partners Hospital, Evanston Northwestern Hospital, Rush Medical Center, University of Illinois-Chicago, the Jesse Brown Veterans Administration Medical Center in Chicago, and Mt. Sinai Hospital in Chicago approved the protocol. Participants gave written informed consent. The funding source for this study played no role in the design, conduct, reporting of the study, or decision to submit the manuscript.

Participant identification. Potential participants were recruited from among consecutive patients diagnosed with PAD in the non-invasive vascular laboratories and from relevant clinics (vascular surgery, cardiology, general medicine, geriatrics, and endocrinology) at Northwestern Memorial Hospital and other Chicago-area hospitals. Newspaper and radio advertisements, mailings to Chicago residents age 60 and older, fliers, and other community outreach methods were used to identify potentially eligible participants.

Inclusion and exclusion criteria. The inclusion criterion was an ankle brachial index (ABI) <0.95. Exclusion criteria and the number of potential participants meeting each criterion are in Table I.

Ankle brachial index measurement. A hand-held Doppler probe (Nicolet Vascular Pocket Dop II; Nicolet Biomedical Inc, Golden, Colo) was used to obtain systolic pressures in the right and left brachial, dorsalis pedis, and posterior tibial arteries.¹⁻⁴ Each pressure was measured twice: in the order listed and in reverse order. The ABI was calculated by dividing the mean of the dorsalis pedis and posterior tibial pressures in each leg by the mean of the four brachial pressures.⁴ Average brachial pressures in the arm with highest pressure were used when one brachial pressure was higher than the opposite brachial pressure in both measurement sets and the two brachial pressures differed by 10 mm Hg or more in at least one measurement set, since in such cases subclavian stenosis was possible.⁵ The lowest leg ABI was used in analyses.

Medical history. Medical history was obtained from patient-report (see Appendix, online only). Participants were asked whether a physician had ever told them that they had angina, heart failure, diabetes, myocardial infarction, disk disease, spinal stenosis, hip or knee arthritis, cancer, or pulmonary disease.

Functional performance measures

Six-minute walk. The 6-minute walk test is a measure of walking endurance that has excellent test re-test reliability in persons with PAD.⁶⁻⁸ Following a standardized protocol,⁶⁻⁸ participants walk up and down a 100-foot hallway for 6 minutes after instructions to cover as much distance as possible. The distance completed during the 6-minutes is recorded. The intra-class correlation coefficient for test re-test reliability of the 6-minute walk was 0.90 (P < .001) in our laboratory among 155 PAD participants who completed the tests approximately 1-2 weeks apart.

Repeated chair rises. Participants sit in a straightbacked chair with arms folded across their chest and stand up five times consecutively as quickly as possible. Time to complete five chair rises was measured.^{9,10}

Standing balance. Participants were asked to hold three increasingly difficult standing positions for 10 seconds each: standing with feet together side-by-side and parallel (side-by-side stand), standing with feet parallel with the toes of one foot adjacent to and touching the heel of the opposite foot (semi-tandem stand), and standing with one foot directly in front of and touching the other (tandem stand).^{9,10} Scores range from zero (unable to hold the side-by-side stand for 10 seconds) to four (able to hold the full tandem stand for 10 seconds).^{9,10}

Four-meter walking velocity. Walking velocity over four meters was measured with a four-meter walk performed at "usual" and "fastest" pace. For the "usual" paced walk, participants were instructed to walk at their usual pace, "as if going down the street to the store." Each walk was performed twice. The faster walk in each pair was used in analyses.^{9,10} The intra-class correlation coefficient for test re-test reliability were 0.83 (P < .0001) for the usual paced four-meter walk and 0.88 (P < .0001) for the fast paced four-meter walk in our laboratory among 155 PAD participants who completed the tests approximately 1-2 weeks apart.

Short physical performance battery. The short physical performance battery (SPPB) combines data from the usual paced four-meter walking velocity, time to rise from a seated position five times, and standing balance. Individuals receive a zero score for each task they are unable to complete. Scores of one to four are assigned for remaining tasks, based upon quartiles of performance for over 6,000 participants in the Established Populations for the Epidemiologic Study of the Elderly.^{9,10} Scores are summed to obtain the SPPB, ranging from 0 to $12.^{9,10}$ Test re-test reliability of the summary performance score was 0.72 (P < .001) in our laboratory among 144 PAD participants who completed the test approximately 1-2 weeks apart.

Treadmill walking performance

Maximal treadmill walking distance and distance to onset of ischemic leg symptoms were measured using the Gardner-Skinner protocol.¹¹⁻¹³ Treadmill testing was administered by an exercise physiologist blinded to study hypotheses. Participants able to walk at least 2.0 miles per hour (MPH) began exercising at 2.0 MPH. Grade began at zero and was increased by 2% every 2 minutes. Participants unable to walk at least 2.0 MPH began at 0.5 MPH (modified Gardner protocol). Speed was increased by 0.50 MPH every 2 minutes until the participant reached 2.0 MPH, after which speed was maintained at 2.0 MPH and grade was increased by 2% every 2 minutes until the participant was unable to continue. Previous study shows that the test re-test intraclass reliability coefficient is 0.93 for maximum walking distance and 0.89 for distance to onset of leg symptoms.¹¹

Physical activity levels measured objectively over 7 days

Physical activity levels were measured objectively over 7 days using a vertical accelerometer (Caltrac, Muscle Dynamics Fitness Network, Inc, Torrence, Calif).¹⁴⁻¹⁶ The Caltrac accelerometers are designed to calculate the number of kilocalories (Kcal) expended by combining data from measured physical activity (vertical movement) with data on each participant's age, weight, height, and gender. Kilocalories expended are dependent on intrinsic characteristics of the individual, such as age, gender, and body mass index (BMI). We aimed to compare actual physical activity levels, rather than Kcals expended. Therefore, for each participant we programmed identical values for age, weight, height, and gender, allowing us to compare physical activity levels between participants irrespective of individual variation in age, weight, height, and gender.¹⁴⁻¹⁶ Thus, the accelerometers measured "activity units" rather than calories expended.¹⁴⁻¹⁶ After wearing activity monitors continuously for 7 days, participants reported the number of activity units and steps displayed on the accelerometer by telephone and mailed their activity monitors back to investigators. Simultaneously with the Caltrac accelerometers, participants wore Digiwalker (Yamax Inc, Tokyo, Japan) step counters continuously for 7 days.^{17,18} However, the Caltrac monitors were selected a priori as the primary physical activity outcome measure because the Caltrac monitors have been well validated as measures of physical activity in persons with PAD.¹⁴⁻¹⁶

Other measures

Height and weight were measured at the study visit. The BMI was calculated as weight/(square of height in meters). Smoking history was obtained by administration of a standardized questionnaire. Leg symptoms were measured with the San Diego claudication questionnaire.¹⁹

Statistical analyses

Functional performance measures (6-minute walk, four-meter walking velocity at usual and fastest pace) and treadmill outcomes (maximal treadmill walking distance and treadmill distance to onset of leg symptoms) were divided into quartiles. Established categories for the SPPB were used to define SPPB performance.¹⁰

To determine associations of functional performance measures and treadmill walking performance with daily physical activity, mean functional performance for each quartile/category of physical activity were compared using analyses of variance, adjusting for age, gender, and race. Analyses were repeated with additional adjustment for comorbidities, BMI, ABI, leg symptoms, smoking, and treadmill protocol type (Gardner vs modified Gardner). We also assessed associations of quartiles/categories of functional performance measures with treadmill walking performance (dependent variable), adjusting for age, gender, and race.

RESULTS

Of 485 persons who attended a baseline visit, 329 met one or more exclusion criteria (Table II), leaving 156 participants. Baseline characteristics of the 156 eligible, randomized participants are shown in Table II. Comparisons of Caltrac physical activity and Digiwalker step measures showed that the lowest quartile of Caltrac physical activity (<374 activity units) was comparable to <6,957steps walked over 7 days while the highest quartile of Caltrac physical activity (>849 activity units) was comparable to >24,655 steps walked over 7 days.

Table II shows patient characteristics across quartiles of physical activity. Higher physical activity was associated with younger age (P = .023), a lower prevalence of diabetes mellitus (P = .006), and a lower BMI (P = .004).

Fig 1 shows associations of physical activity levels with corridor-based functional performance measures, adjusting for age, gender, and race. Higher levels of physical activity were associated with greater 6-minute walk distance (P trend = .001), faster normal-paced four-meter walking velocity (P trend = .027), faster rapid-paced four-meter walking velocity (*P* trend < .001), and a higher SPPB score (P trend = .005), adjusting for age, gender, and race. The association of physical activity level with maximum treadmill walking distance was nearly statistically significant (Fig 2). Physical activity level was not associated with treadmill distance to onset of leg symptoms, adjusting for age, gender, and race (Fig 2). After additional adjustment for comorbidities, BMI, ABI, leg symptoms, and smoking, only rapid-paced four-meter walking velocity remained associated significantly with physical activity levels (first physical

	Quartiles of Physical Activity Level					
	Entire Cohort	Caltrac I st quartile (≤ 374)	Caltrac 2 nd quartile (> 374 < 609)	Caltrac 3 rd quartile (≥ 609 ~ < 849)	Caltrac 4 th quartile (≥ 849)	P-value
Age (years)	70.6 ± 10.3	72.8 ± 9.9	73.8 ± 9.3	70.5 ± 11.3	67.0 ± 9.4	.023
Male	48%	46%	54%	41%	47%	.711
African American race	40%	43%	38%	32%	39%	.818
Ankle brachial index	0.61 ± 0.17	0.60 ± 0.18	0.58 ± 0.15	0.64 ± 0.16	0.64 ± 0.20	.409
Education level						
Less than high school	10%	16%	11%	3%	11%	.259
High school/college degree	71%	68%	70%	73%	72%	.958
Professional/graduate degree	19%	16%	19%	24%	17%	.803
Body mass index (kg/m^2)	30.2 ± 6.8	31.9 ± 7.1	31.3 ± 6.7	26.9 ± 4.8	30.0 ± 6.5	.004
Diabetes mellitus	44%	49	65%	30%	31%	.006
Current smoker	24%	32%	22%	22%	19%	.554
Angina	12%	11%	19%	11%	9%	.613
Myocardial infarction	22%	19%	23%	27%	22%	.873
Heart failure	14%	8%	16%	17%	14%	.720
Pulmonary disease	13%	14%	14%	11%	11%	.959
Statin use	63%	62%	68%	73%	50%	.209
Anti-platelet therapy	65%	60%	70%	68%	69%	.748
Beta-blocker	46%	49%	54%	49%	36%	.469
ACE inhibitor	41%	41%	41%	49%	36%	.744

Table II. Associations of quartiles of Caltrac-measured physical activity levels with participant characteristics

Participant characteristics are shown across quartiles of physical activity, measured objectively over 7 days by a Caltrac vertical accelerometer. Means and standard deviations are shown.



Fig 1. Associations of functional performance measures with physical activity during daily life in persons with peripheral arterial disease (n = 156).*

* Functional performance across quartiles of physical activity are shown. Data adjust for age, gender, and race. Physical activity was measured continuously for seven days using a Caltrac vertical accelerometer.

activity quartile -1.00 meters/second, second physical activity quartile -1.03 meters/second, third physical activity quartile -1.18 meters/second, fourth quartile -1.15 meters/second, (*P* trend = .006).

In additional descriptive analyses, we compared corridor-based walking performance measures with max-

imum treadmill walking distance and treadmill distance to onset of leg symptoms, adjusting for age, gender, and race (Table III). Greater 6-minute walk distance (P trend < .001) and faster rapid-paced four-meter walking velocity (P trend = .005) were associated with greater maximal treadmill walking distance, adjusting for



Fig 2. Associations of treadmill walking measures with physical activity during daily life in persons with peripheral arterial disease (n = 156).*

* Functional performance across quartiles of physical activity are shown. Data adjust for age, gender, and race. Physical activity was measured continuously for seven days using a Caltrac vertical accelerometer.

Table III. Associations of corridor-based walking performance with treadmill walking performance among 156 men and women with peripheral arterial disease*

	Quartiles of 6-minute walk performance				
	Quartile 1 ≤268 meters	Quartile 2 >268 - <326 meters	Quartile 3 326 - 375 meters	Quartile 4 >375 meters	P trend
Maximum treadmill walking distance (meters)	277 (33)	293 (31)	399 (32)	516 (33)	<.001
symptoms (meters)	120 (21)	119 (20)	152 (20)	214 (20)	.003
	Quartiles of four-meter walking velocity (normal pace)				
	Quartile 1 ≤0.727 M/Sec	Quartile 2 >0.727 - <0.811 M/Sec	Quartile 3 0.811 - 0.915 M/Sec	Quartile 4 >0.915 M/Sec	
Maximum treadmill walking distance (meters)	335 (36)	317 (34)	406 (34)	424 (35)	.087
symptoms (meters)	135 (23)	117 (20)	174 (20)	179 (21)	.097
	Quartiles of four-meter walking velocity (rapid pace)				
	Quartile 1 (<0.94 M/sec)	Quartile 2 (0.94 - <1.08 M/sec)	Quartile 3 (1.08 - 1.23 M/sec)	Quartile 4 (>1.23 M/sec)	
Maximum treadmill walking distance Distance to onset of treadmill symptoms	304 (37) 112 (23)	339 (34) 136 (21)	407 (34) 171 (20)	436 (37) 182 (22)	.005 .072
	Short physical performance battery categories $(0-12 \text{ scale}, 12 = \text{best})$				
	Category 1 (0-4)	Category 2 (5-8)	Category 3 (9-11)		
Maximum treadmill walking distance Distance to onset of treadmill symptoms	317 (68) 181 (46)	367 (35) 143 (20)	372 (22) 146 (12)		.622 .583

*Data shown are maximal treadmill walking distance and treadmill distance to onset of ischemic leg symptoms across quartiles of functional performance measures. Means and standard errors are shown. Data are adjusted for age, gender, and race.

age, race, and gender. Walking velocity at usual pace and the SPPB were not significantly associated with maximum treadmill walking distance (Table III). Only 6-minute walk distance was associated significantly with treadmill distance to onset of leg symptoms (P trend = .003) (Table III).

DISCUSSION

Among 156 persons with PAD, our results show that better performance on each of four measures of corridorbased functional performance: 6-minute walk distance, walking velocity at usual speed, walking velocity at fastest speed, and the SPPB were associated significantly with higher physical activity levels during daily life. Maximum treadmill walking distance and treadmill distance to onset of leg symptoms were not associated significantly with physical activity levels during daily life, although associations of maximum treadmill walking distance with physical activity showed a trend toward statistical significance. These findings indicate that performance on corridor-based functional measures are more closely linked to physical activity levels during daily life than treadmill walking performance.

Treadmill walking performance is traditionally used to measure changes in walking performance following therapeutic interventions among persons with PAD. Treadmill testing has potential advantages that include monitoring of study participants in a tightly controlled setting and use of a standardized protocol that specifies initial treadmill speed and grade and rates of increase in treadmill speed and grade at precisely determined intervals, allowing direct comparisons between participants. However, treadmill testing creates a more "artificial" environment compared to corridorbased functional measures, in which walking speed is determined by the patient. Consistent with these differences, previous study in persons without PAD shows that treadmill walking is associated with greater anxiety and requires greater balance than corridor-based walking measures.²⁰⁻²² For example, a previous study of 12 healthy elderly volunteers (aged 71-80 years) and 12 healthy young volunteers (aged 21-37) compared physiologic responses during treadmill walking vs the 6-minute walk.²⁰ The elderly group, but not the young group, had consistently higher heart rates and slower step rates during treadmill testing as compared to corridor walking.²⁰ In a separate study of 11 patients with chronic obstructive pulmonary disease (COPD), the distance covered during the 6-minute walk test was significantly greater than distance covered during 6 minutes of treadmill walking (530 meters vs 481 meters, P < .01).²¹ Together these findings suggest that treadmill testing may be less applicable to usual walking ability in the community than corridor-based functional performance measures.

Of the four corridor-based functional performance measures studied, only the SPPB did not correlate significantly with treadmill walking performance. In contrast to the 6-minute walk, and the four-meter walking velocities, the SPPB encompasses more direct measures of balance and leg strength. These components of functioning appear to be distinct from the outcomes of maximum treadmill walking distance and treadmill distance to onset of leg symptoms. Nonetheless, the baseline SPPB score predicts the rate of mobility loss among persons with PAD.²³ A baseline SPPB score predicts mobility loss and mortality among persons without PAD.9,10 Cross-sectional data reported here show that better SPPB scores are associated with higher physical activity levels. Together, these data suggest that the SPPB outcome is distinct from treadmill walking measures, but is nonetheless a well validated measure of lower extremity performance in PAD persons.

This study has limitations. First, data are cross-sectional. This study could not determine whether treadmill walking performance is more sensitive to the effects of interventions than walking performance measures. One prior randomized controlled clinical trial demonstrated greater increases in maximum treadmill walking performance than in 6-minute walk performance after a 6-month supervised exercise intervention.²⁴ Second, the exclusion criteria for this study may limit the generalizability of the findings. Third, participants with PAD included persons with and without intermittent claudication symptoms. In contrast, most clinical trials in persons with PAD are restricted to those with classical symptoms of intermittent claudication.

In conclusion, findings reported here suggest that corridor-based functional performance measures better reflect usual physical activity levels during daily life than treadmill walking performance. Our findings suggest that corridor-based functional performance measures are an important complement to treadmill walking performance and may better reflect certain aspects of usual walking during daily life than treadmill walking performance. Future studies of performance in persons with PAD should include measures of corridor-based functional performance, rather than only treadmill-based performance.

AUTHOR CONTRIBUTIONS

- Conception and design: MMM, PA, AD, LF, JG, WP, DL-J, MK, MC
- Analysis and interpretation: MMd, PA, AD, LF, JG, WP, DL-J, MK, MC
- Data collection: MMd
- Writing the article: MMd, PA, AD, LF, JG, WP, DL-J, MK, MC
- Critical revision of the article: MMd, PA, AD, LF, JG, WP, DL-J, MK, MC
- Final approval of the article: MMd, PA, AD, LF, JG, WP, DL-J, MK, MC
- Statistical analysis: MMd, AD
- Obtained funding: MMd
- Overall responsibility: MMd

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Additional material for this article may be found online at www.jvascsurg.org. **Appendix (online only).** Questionnaire items used to obtain medical history among participants in the study to improve leg circulation.

- Do you now or have you ever smoked cigarettes? la. If "Yes":
 - Years ago quit?
 - How many years have/did you smoke?
 - How many packs per day (past or current)?
- 2. Has a doctor ever told you that you had diabetes?
- 3. Has a doctor ever told you that you had angina or chest pain due to heart disease?
- 4. Has a doctor ever told you that you had a heart attack or myocardial infarction?

- 5. Has a doctor ever told you that you had heart failure or congestive heart failure?
- 6. Has a doctor ever told you that you have lung disease such as emphysema or chronic bronchitis?
- Has a doctor told you that you had cancer? If yes, determine type of cancer – list all types and
- year.8. Has a doctor ever told you that you had arthritis in your knees?
- 9. Has a doctor ever told you that you had arthritis in your hips?
- 10. Has a doctor ever told you that you had spinal stenosis?
- 11. Has a doctor ever told you that you had a degenerated, slipped, or herniated disc or sciatica?