

12-2-2015

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Keywords:

Biomechanics, Intermittent claudication, Falls, Rehabilitation, Variability

ABSTRACT

Individuals with peripheral arterial disease (PAD) report difficulty walking and experience 73% more falls than their healthy counterparts, but no studies have investigated functional mechanisms contributing to increased falls. Minimum toe clearance (MTC) is the minimum vertical distance between the toe of the swinging leg and the walking surface when the leg is swinging, and decreased values are associated with an increased risk for falls. This study is the first such analysis in patients with PAD. Eighteen individuals with PAD and eighteen healthy controls walked on a treadmill before and after the onset of claudication pain. Mean MTC and the standard deviation of MTC values across the trial were calculated. Mean MTC was not different between groups in the pain-free ($P = 0.244$) or pain conditions ($P = 0.565$). MTC variability was increased for patients with PAD in pain-free ($P = 0.048$) and pain conditions ($P = 0.019$). No significant differences existed between conditions for MTC mean ($P = 0.134$) or MTC variability ($P = 0.123$). Increased MTC variability is present before and after the onset of claudication pain, and may be a useful assessment for treatment and rehabilitation efficacy in these patients.

Introduction

The most common symptom of peripheral arterial disease (PAD) is intermittent claudication [1], which is characterized by a cramping type of muscle pain in the lower extremities brought on by physical activity and relieved with rest. As 12–20% of all individuals 60 years of age and older [2] are afflicted with PAD, and falls are a primary

source of injury and death among the elderly, falls are an additional concern in this patient population. Not surprisingly, reports estimate that individuals with PAD experience 73% more falls than their healthy counterparts along with a greater prevalence of ambulatory stumbling and overall unsteadiness [3]. However, there has been little investigation into what is contributing to this increased rate of falling in patients with PAD.

There are many possible mechanisms related to physical function to explain the stumbling and unsteadiness in patients with PAD. Many of these mechanisms have come as the result of recent studies

using advanced biomechanics analyses that have revealed differences in kinematic and kinetic measures between patients with PAD and healthy controls [4–10]. During the stance phase of walking, patients exhibit a completely different joint power profile when compared to healthy controls. This includes reduced power absorption at the knee in early stance and reduced power generation at the ankle during late stance [6,10]. Patients with PAD also have decreased step length, cadence, and walking speed [4,11], which can contribute to unsteadiness [12]. Another characteristic of gait in PAD patients is a decreased fluctuation of the vertical ground reaction force during stance phase, which has been interpreted to reflect a lower center of mass during stance [9]. The toe clearance of the swing leg has been shown to be sensitive to small angular changes in sagittal plane of the ankle, knee, and hip of the swing leg, the ankle and knee of the stance leg, as well as in the frontal plane of the stance leg at the hip joint [13]. Having a lowered center of mass is typically the result of altering one or more of these joints [14] and could lead to changes in the toe clearance profile. This in turn could cause problems with the swing leg coming in contact with the ground or another object. Changes have also been noted in the stride-to-stride differences during walking, termed gait variability, of patients with PAD. Gait variability differences found include increased standard deviations of ankle and hip ranges of motion, and increased coefficient of variation of ranges of motion at the ankle, knee, and hip [7]. These abnormalities are present prior to the onset of intermittent claudication pain and worsen in the presence of intermittent claudication [4]. This likely contributes to an increased risk for falls.

Another analysis associated with increased fall risk that should be investigated in patients with PAD is minimum toe clearance (MTC). MTC is the minimum vertical distance between the toe of the swing leg and the walking surface during mid-swing in the gait cycle when the foot is at its greatest velocity [13]. MTC is considered a critical gait event when assessing fall risk, because the majority of falls happen from contact between the swing leg and the ground or another object [15,16]. Based on these findings, a decreased MTC is considered to be associated with an increased risk of tripping, which can lead to falls [15]. It is therefore possible that patients with PAD have reduced toe clearance that could be leading to the increased incidence of falls. This decreased toe clearance could be present prior to the onset of claudication pain, after the onset of such pain, or possibly during both conditions. Determining the MTC during

the gait cycle of patients with PAD could lead to new insights into what is causing the increased incidence of falling in this population.

When movement involves multiple repetitions of the same task differences occur between repetitions and these differences are termed variability. Variability can be quantified as the dispersion around the mean value. Standard deviation of the movement is a common way to measure the amount of variability present. When an individual is walking it only takes a single step with low toe clearance to cause a trip. If the average MTC were similar then having an increased variability in MTC would suggest that the toe is swinging closer to the ground during some steps. Thus, understanding the MTC variability associated with walking could lead to a better understanding of the mechanisms responsible for the increased incidence of falling in PAD.

There is a substantial amount of research published in the independent areas of PAD and MTC, but to date no one has investigated the possibility of reduced MTC and/or increased MTC variability present during gait with PAD despite the above mentioned gait abnormalities and increased prevalence of falls in patients with PAD. Therefore, the purpose of this study was to investigate the difference in MTC between healthy individuals and patients with PAD both in pain-free and pain conditions. The increased number of falls observed in these patients led to the following hypotheses: (1) PAD patients would exhibit a reduced MTC due to lower limb impairment, (2) PAD patients would have increased MTC variability, and (3) PAD patients would have reduced MTC means and increased MTC standard deviations following onset of symptomatic claudication pain.

Materials and methods

Participants

Eighteen PAD patients (age: mean 60.4 (SD 8.9) years; height: mean 174.7 (SD 4.7) cm; mass: mean 82.3 (SD 17.8) kg) and eighteen healthy controls (age: mean 63.8 (SD 1.7) years; height: mean 173.6 (SD 7.6) cm; mass: mean 81.5 (SD 20.6) kg) participated in this study (Table 1). The Institutional Review Boards from the respective medical centers approved all study procedures and all subjects provided informed consent prior to enrolling in the study. Patients with PAD were clinically diagnosed and recruited from the vascular surgery departments at the Omaha Veterans' Affairs Medical Center and the University of Nebraska Medical Center. Control subjects were recruited from the community and were screened to determine the absence of PAD.

Two board-certified vascular surgeons evaluated patients and controls. Patients provided a detailed history, a physical examination, and were directly observed by the vascular surgeons to ensure walking impairment was secondary to claudication pain. Exclusion criteria included those who experienced pain when walking that was not due to claudication (e.g. arthritis, low back pain, peripheral neuropathy), as well as any ambulation limiting cardiac, neuromuscular, pulmonary, or musculoskeletal disease.

Controls were screened for ambulatory dysfunction and PAD. They were screened for ambulatory dysfunction in a similar manner as the patients with PAD, and were also required to have an ankle-brachial index ≥ 1.0 .

Table 1

Demographics of PAD and control participants, values are reported as Mean (SD). ABI = Ankle Brachial Index, this is the ratio of systolic blood pressures taken in the ankle and arm, an ABI < 0.9 indicates peripheral arterial disease and was used as inclusion criteria.

	PAD patients (n = 18)	Controls (n = 18)	P value
Age (years)	60.4 (8.9)	64.8 (11.6)	.207
Body mass (kg)	82.3 (17.8)	80.7 (20.3)	.805
Body height (cm)	174.7 (4.7)	173.2 (7.6)	.504
ABI-L	0.71 (0.18)	> 0.90	
ABI-R	0.60 (0.22)	> 0.90	



Fig. 1. Illustration of the calculation of minimum toe clearance. A virtual marker was created using Cortex (Motion Analysis Corporation, Santa Rosa, CA) software. A position was calculated by projecting a line from the heel marker through the toe marker for the length of the shoe. From this point another line was projected toward the plantar surface of the shoe the distance to the floor where the toe marker was created.

Procedures

All subjects walked on a treadmill at their self-selected pace while kinematic data was recorded (60 Hz; 12-camera Motion Analysis Corp., Santa Ana, CA) using a modified Helen Hayes marker set that has been used with the same population in previous research [5]. Patients with PAD performed one treadmill walking trial in a pain-free condition. The trial lasted until the onset of claudication pain, or for 3 mins in patients who did not reach the onset of claudication pain. After the pain-free condition was

completed, subjects walked on the treadmill set at a 10% incline until the onset of moderate claudication pain, a two on the ACSM claudication pain scale [17]. The treadmill was then immediately lowered while the subject continued to walk until the pain forced them to stop, or for a maximum of 3 mins. Data for the pain condition started from the point that the treadmill was flat. Control subjects similarly walked at a self-selected pace for 3 mins while the same kinematic data was collected.

A virtual marker was created within the motion capture software (Cortex, Motion Analysis Corp., Santa Rosa, CA) using the physical markers located on the heel, fifth metatarsal and second metatarsal-phalangeal joint (Fig. 1); this prevented potential interference from a physical marker at the distal tip of the hallux. After creating the virtual toe marker, the MTC was calculated for every step using custom scripts created in Matlab (Mathworks Inc, Natick, MA). Due to the limited walking distances capable by individuals with PAD, our analysis was confined to the first 40 strides for every subject, which included left and right strides. The mean MTC and MTC variability (i.e. standard deviation) was then calculated for these 40 strides.

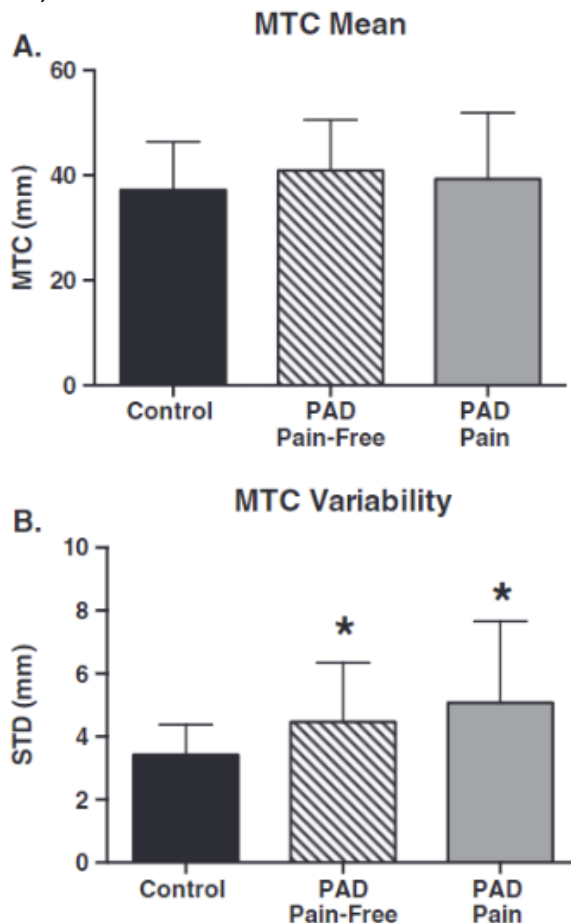


Fig. 2. (A) Group means for minimum toe clearance values. No significant differences were found when comparing any of the groups. (B) The standard deviations showed a significant difference when comparing the control to the PAD pain-free condition ($P = 0.048$) and when comparing the control to the PAD pain condition ($P = 0.019$). No significant difference was found when comparing the pain free and pain conditions between the patients with PAD ($P = 0.134$). * significant difference compared to control.

Statistical analysis

Statistical significance was tested with independent t-tests for controls versus PAD pain-free and controls versus PAD pain conditions. A dependent t-test was utilized to compare the PAD pain-free and pain conditions. All statistics were calculated using SPSS version 20.0 software (SPSS Inc, Chicago, IL). Mean MTC and MTC variability were both analyzed with significance set at $P < 0.05$.

Results

Demographics are presented in Table 1. There were no differences in age, mass, or height. Patients with PAD had slower self-selected treadmill speeds (1.4 ± 0.4 versus 2.4 ± 0.5 mph; $P < 0.001$, $d = 2.21$). Mean MTC for the healthy controls was 37.2 mm, while the PAD pain-free had a mean of 40.9 mm and the PAD pain had a mean of 39.3 mm (Fig. 2A). These values were not significantly different when comparing healthy controls to PAD in either a pain-free or pain condition ($P = 0.244$, $d = 0.39$ and $P = 0.565$, $d = 0.19$ respectively; Fig. 2A), there was also no difference when comparing PAD pain-free versus pain conditions ($P = 0.134$, $d = 0.14$; Fig. 2A).

When comparing MTC variability the healthy controls had an average standard deviation of 3.4 mm, while the PAD pain-free had a mean of 4.5 mm and the PAD pain had a mean of 5.1 mm (Fig. 2B). This demonstrated a significant increase in MTC variability when comparing healthy controls and PAD patients in pain-free and pain conditions ($P = 0.048$, $d = 0.72$ and $P = 0.019$, $d = 0.86$ respectively, Fig. 2B). However there was no difference between MTC variability of the PAD pain-free and pain conditions ($P = 0.123$, $d = 0.26$; Fig. 2B).

Discussion

The purpose of our study was to determine whether patients with PAD exhibited differences in MTC compared with healthy controls, which could be a factor contributing to the known increased fall risk in this population. Our first hypothesis was that patients with PAD would exhibit a reduced MTC. This hypothesis was not supported as no significant differences were found between patients with PAD and healthy controls in either the pain-free or the pain condition. Patients with PAD did, however, have greater MTC variability in both pain-free and pain conditions compared to their healthy counterparts [7]. Finally, it was thought that the further deterioration of gait that occurs with the onset of claudication pain would similarly yield further worsening of MTC and MTC variability. While the MTC variability displayed this sort of trend (Fig. 2B), there was no statistically significant difference in either MTC or MTC variability when comparing performance in a pain-free to the pain condition.

Fig. 3 highlights a representative comparison of the individual strides for a control subject and a patient with PAD in the pain-free condition. The patient with PAD exhibits a decreasing trend in MTC as the trial progresses. This demonstrates that even though the mean of 40 strides is not different there are several strides where the foot is coming

closer to the ground as compared with the control subject. This figure also highlights the increased amount of variability present in the MTC of patients with PAD.

Our findings, specifically that the patients with PAD experience similar toe clearance values as healthy controls while experiencing a greater amount of variability, have also been seen in aging individuals [18,19]. This information is meaningful because it shows that increased prevalence of falling may not be a result of decreased MTC alone. Rather, increased MTC variability may indicate a greater risk for tripping and falling since it only takes one stride with a low MTC to come in contact with the ground or other object, and lead to a fall. When assessing the MTC of patients with PAD it may be more important to investigate the variability instead of only looking at the mean MTC.

The mean MTC values seen in patients with PAD could also reflect a compensation for the typical ambulatory limitations. Previous research has shown that MTC will increase with slower walking speeds and shorter step length [20], both of these gait alterations are seen in PAD [4,11]. These limitations in gait may lead the patient with PAD to consciously alter gait as a protective mechanism. It is also possible that decreased proprioceptive information could cause incorrect estimates of MTC by the neuromuscular system. A reduction in proprioceptive information will result in several changes to gait parameters [21]; it is possible that patients with PAD will lift their feet more in an effort to avoid trips. Patients in this study were screened for peripheral neuropathy so the effect of reduced proprioception in this sample would likely be small, but it could affect the population as a whole.

If the cognitive attention is being directed toward maintaining normal gait, that itself could increase patients' risk of falling, and could explain some of the increased MTC variability. Previous research has demonstrated that cognitive tasks can reduce the stride-to-stride variability in younger and older adults [22] as well as reduce postural sway [23]. Cognitive tasks that require an internal focus of attention, such as directing attention to the control of gait, have been shown to disturb gait more than cognitive tasks that require an external focus of attention [24]. This does not mean that adding external cognitive tasks to a gait task would result in a safer gait, but that the current subjects may have had an internal focus on their gait, which may have caused gait disturbances.

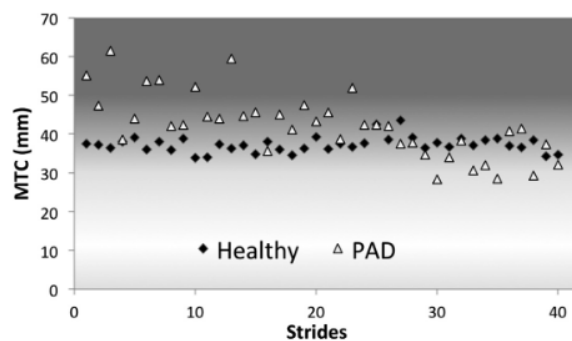


Fig. 3. Example of minimum toe clearance (MTC) during swing phase for a typical healthy control and patient with PAD in the pain-free condition. Although the mean MTC is greater for the patients with PAD there are several strides where the MTC is lower, which results in no significant differences in mean MTC, but a significant difference in MTC variability. This patient shows a decreasing trend in MTC across the forty strides.

Another gait characteristic of patients with PAD is they have significantly greater variability in joint angles at the hip, knee, and ankle [7,25]. This could directly affect the height of toe clearance since the toe is the end point of the limb. Thus, variability in joint angles will also directly contribute to the amount of toe clearance during the swing phase. Myers et al. also showed differences in the temporal structure of variability in addition to the changes in the amount of variability [7]. In order to better investigate these findings it would be beneficial to separate PAD patients who have a history of falls from those who do not. This would give a clearer picture about MTC and its link to fall risk in patients with PAD. An interesting note in this research is that there were no significant differences seen in the MTC means or MTC variability when comparing the pain-free and pain conditions. This research supports previous findings that PAD patients experience ambulatory limitations from the first step they take, even prior to the onset of claudication pain [6,8,9].

Walking velocity and step length can contribute to changes in MTC [20]. However, the purpose of this study was to investigate if there were differences between the groups and not to determine the exact mechanisms that may be responsible for these differences. Because of this, all participants walked at their self-selected pace to mimic what they would experience during normal, everyday walking. This resulted in the patients with PAD walking at a slower velocity compared to the healthy controls. Future investigations should be conducted to determine what mechanisms might be responsible for the increased MTC variability seen in PAD patients.

This study did have limitations to consider. The mean MTC values reported for the healthy controls are greater than those typically seen in the literature [18,19]. This could be due to the virtual representation of the toe; specifically the toe was calculated as the floor height from the superior second metatarsal-phalangeal joint projected toward the end of the foot. This did not take into account the curvature of the athletic shoes, which the subjects were wearing. The same procedure was applied to all of the subjects, so comparisons between groups represent real differences. Although this method has been used before more robust methods have been developed since, utilization of this method was due to a limited marker set that did not allow utilization of the newer techniques. The analysis was also limited to the first 40 strides due to the ambulatory limitations of the patients with PAD.

Conclusions

In conclusion these research findings suggest that comparing the mean MTC may not be adequate at assessing an increased risk of falling due to tripping in patients with PAD. Exploring the mechanisms driving increased variability of MTC may provide greater insights and a clearer picture of the gait limitations that are leading to an increased incidence of falling in this population. The authors indicate no conflict of interest in this research.

Acknowledgments

We would like to thank Dr. Kendra Schmid for statistical advice. This work was supported by Award Number 1I01RX000604 from the Rehabilitation Research and Development Service of the VA Office of Research and Development (to JMJ), NIH 5R01AG034995 to (IIP), VA Cooperative Studies Project #498 (NCT 000 945 75; to IP), the Nebraska Research Initiative (to SAM), and the National Institute of General Medical Sciences of the National Institutes of Health under Award Number P20GM109090 (to SAM). The content of this paper is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the VA Office of Research and Development. Furthermore, this material is the result of work supported with resources and facilities at the VA Nebraska-Western Iowa Health Care System.

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