ABSTRACT

Objectives: It is challenging to accurately monitor the progress of intermittent claudication patients during or after treatment. Furthermore, diagnostic tools for intermittent claudication are not always adequate to determine whether other diseases are the primary cause of any walking complaints. This makes it difficult to determine the optimal treatment for the patient and impairs proper follow-up. The objective was to investigate the feasibility of measuring disease specific changes in the gait pattern of intermittent claudication patients by using a smartphone accelerometer.

Methods: This study is a clinical Proof-of-concept study. Included were 12 subjects. Seven of the subjects were healthy controls, the other five intermittent claudication patients. Raw accelerometer data was collected during a standardized walking test with an Iphone. Processed data was analyzed using the GaitPy package in Python, resulting in 20 different gait parameters per gait cycle. The data were divided, resulting in three groups: The control group, the patient group without symptoms and the patient group with active symptoms. Mann-Whitney U tests and Wilcoxon ranks test were used to examine the outcomes.

Results: Five of the 20 parameters are significantly different between patients before symptoms and patients with active symptoms. All parameters except cadence and stride duration differ between our control group and the patients while experiencing symptoms. Nine of 20 parameters where significantly different between the control group and the patient group without symptoms.

Conclusions: This study demonstrated the potential clinical applicability of measuring changes in intermittent claudication gait characteristics with a smartphone.
1 INTRODUCTION

The diagnosis intermittent claudication (IC) is a challenging one, because the hallmark symptom, pain while walking, is also caused by several other pathologies [2, 3, 13]. Current diagnostic tools are often not specific enough to determine which pathology is the main cause of the symptoms and consequently which treatment regimen will benefit the individual patient most. Furthermore, it is challenging for the physician and patient to monitor daily disease development.

The Dutch Health institute performed an in-depth investigation of peripheral arterial occlusive disease (PAOD) care, in particular IC [25]. The focus of this investigation was to determine ways to improve both care for, and health of, IC patients, and indicates that there is a clear need to make the outcomes of care more transparent. Gait analysis allows to better characterize IC patients and it shows promising results to assess severity of PAD [5]. Hence gait analysis could be used to assess walking ability of patients for both diagnostic and therapeutic purposes. This information can be useful to identify measures for clinical decision making and value based healthcare.

Telemedicine is the use of telecommunication technology for the delivery of medical care or services from a distance [21]. Telemedicine can reduce the need for hospital visits, decreases the workload for health care professionals and leads to more empowerment of patients in their care process resulting in higher patient satisfaction and reduction in health care costs [8]. Studies investigating the use of telemedicine in PAOD are limited [14]. However, gait parameters can be measured remotely with modern apps and smartphones, and these parameters differ between healthy subjects and IC patients. The decreased blood flow to the muscles alters the gait of people with IC [12]. The speed declines, stride length shortens, cadence decreases and the stance phase becomes longer, and thus the swing phase shorter.

Gait parameters in IC patients are commonly measured with motion tracking systems based on camera images [4]. An easy-to-use, low-cost, accessible alternative approach is an accelerometer. It can translate movement into acceleration data [15]. Nowadays almost everybody has a smartphone with an accelerometer. With the help of a smartphone and a suitable app (native, secure and connected to the Electronic Health Record), the walking data of patients can be (tele)monitored in an accessible, inexpensive, natural and reliable manner [17]. This could improve the diagnosing and following-up IC-patients in daily life. The aim of this study was to investigate the feasibility of measuring the specific gait pattern of IC-patients by using a smartphone accelerometer. A subgoal of this study was to verify whether differences in gait pattern between healthy people and IC patients can be measured using a smartphone. Comparing the gait pattern of symptomatic IC-patients with the gait pattern of these patients before symptoms occur and with healthy volunteers, could be a first step of diagnosing IC based on disease specific gait parameter values.

2 MATERIALS AND METHODS

This study was approved by the local Medical Ethical Committee (NW2019-51).

SUBJECTS

A total of five subjects diagnosed with IC and referred to the outpatient clinic of the department of Vascular Surgery, Jeroen Bosch Hospital, ’s Hertogenbosch, The Netherlands, were included in this study. IC was diagnosed by experienced vascular surgeons using a treadmill test (see Table 1). Patients exhibited the typical symptoms of IC without any other pathology. A group of seven healthy volunteers functioned as control. For both groups, variables that might play a role in their walking patterns were assessed in a questionnaire (see Appendix A).

MATERIALS

The unmodified smartphone (iPhone 5S; iOS 12.4.6) [1] used in this study, includes an accelerometer (LIS331DL, manufactured by STMicroelectronics N.V., Amsterdam, the Netherlands). The sampling frequency of the accelerometer was set to 100 Hz. The app used to retrieve the raw accelerometer data (X-Y-Z axis acceleration in g of the smartphone) and
the subject input, is the ‘JBZetje’ app (Brightfish B.V., Hoofddorp, the Netherlands). This app is already used to manage remote supervised walking therapy. JBZetje uses Apple’s ResearchKit tasks to get device motion data (Apple).

**TEST PROCEDURES**

The group of patients performed a walking test true to their daily environment: they walked outside on a flat course, wearing their usual shoes, at their preferred pace. Tri-axial acceleration was measured while the subjects walked with the smartphone horizontally in their right hand in front of them, at approximately bellybutton height. The subjects reported, by touching a button on the smartphone, when they experienced pain. Subjects walked until they could no longer continue due to the pain. This way, data of the gait pattern with active symptoms was acquired. The group of controls performed a similar walking test, except for the fact that they did not experience pain. They walked a total distance of approximately 100 meters. All patients completed a disease-specific questionnaire about the walking test (see Appendix A). This questionnaire is also part of the JBZetje app. All subjects, except one, performed the walking test twice. In between these tests was a break until they were ready to start over.

**DATA PROCESSING**

Anonymous data were processed using Python (version 3.7.6). The user acceleration (acceleration corrected for gravity) and the attitude (the phone’s orientation relative to the starting position) were retrieved from the data recorded by the app [6]. The attitude data was converted to a rotation matrix. This rotation matrix was used to correct for user rotations of the smartphone. The rotation matrix was multiplied with the user acceleration to obtain the global user acceleration.

**DATA ANALYSIS**

Only the global acceleration in the vertical direction in g was used for analysis. Twenty gait parameters were determined using the GaitPy package in Python (version 3.6.0) [7]. The unit of these parameters is milliseconds, except for the cadence (steps/min), the length parameters (m) and the gait speed (m/s). Nine of the parameters are asymmetries. Asymmetries are the differences between a step and the successive step. In Figure 1 stance phase, swing phase, single limb support and double support are illustrated. The swing fase of one leg is the same as the single limb support fase of the other leg, thus only the single limb support fase was used.

| PATIENT NUMBER | AGE | RIGHT LEG | LEFT LEG | WALKING DISTANCE |
|----------------|-----|-----------|----------|------------------|
| 1              | 49  | 0.52 MF (after effort 0.31 MF) | 0.49 MF (after effort 0.41 MF) | 250 meters |
| 2              | 64  | 0.57 MF (after effort 0.21 MF) | 0.60 MF (after effort 0.29 MF) | 245 meters |
| 3              | 68  | 1.07 BF (after effort 1.05 BF) | 0.80 BF (after effort 0.73 BF) | 330 meters |
| 4              | 65  | 0.93 BF (after effort 0.63 BF) | 1.05 BF (after effort 0.72 BF) | 250 meters |
| 5              | 68  | 0.48 MF (after effort 0.27 MF) | 0.43 MF (after effort 0.20 MF) | 180 meters |

![Figure 1](image)  

Features of the gait cycle [16].
Double support can be subdivided in initial double support, at the beginning of one gait cycle, and terminal double support, at the end of the same gait cycle.

Outcome parameters with a negative time value were excluded.

The data were divided into three groups: a control group, the group of patients before they experienced symptoms and the same group of patients with active symptoms. The first ten detected steps of the group before symptoms and the last ten steps of the group with active symptoms were analyzed. That way, it was assured that the symptoms would be present in the “active symptoms” group and not present in the “before symptoms” group.

**STATISTICAL ANALYSIS**

The determined gait parameters were averaged per subject within the different groups. Descriptive statistics were computed, resulting in a mean and standard deviation per parameter per group (see Appendix B). Subsequently, the significance of the parameter differences between control and patient groups was examined using Mann-Whitney U tests in IBM SPSS statistics (version 26). Mann-Whitney U tests between the control group, patients with active symptoms and patients before symptoms were also performed to test differences between ratios of parameters relative to stride duration time. The differences in gait parameter values of a patient before and after the presentation of symptoms were tested using a Wilcoxon signed-rank test. A p-value of 0.05 or smaller was considered statistically significant for all tests.

**3 RESULTS**

**SUBJECT CHARACTERISTICS**

The subject characteristics are shown in Table 2. The results of the questionnaire after the walking test are shown in appendix C. Symptoms were present in all five IC patients after a walked distance of 200 to 500 meters. Four patients experienced pain in both legs, of which two experienced more pain in the right leg. One patient experienced only pain in the left leg. Four patients experienced pain in the calf and one patient experienced pain in the buttock. When standing still the pain disappeared within five minutes in all five IC patients.

| VARIABLE | CONTROL GROUP (N = 7) | PATIENT GROUP (N = 5) | P-VALUE |
|----------|------------------------|-----------------------|---------|
| Age      | 33.86 ± 14.89          | 62.8 ± 7.08           | 0.003   |
| Weight (kg) | 67.6 ± 4.32         | 77.2 ± 8.52           | 0.46    |
| Length (cm)  | 175.43 ± 5.31          | 171 ± 7.72            | 0.217   |
| Female    | 4                      | 3                     | –       |
| Male      | 3                      | 2                     | –       |

**DISTRIBUTION OF THE DATA**

Figure 2 displays the number of steps at a certain speed for every group. There is more variability within each of the patient groups than within the control group. The patient group with and without active symptoms are similar to each other in variability. Boxplots of all retrieved gait parameters are visible in Figure 3. The boxplots suggest a difference in all parameters between the patients before symptoms and the patients with active symptoms except for stride length and step length. According to the boxplots all parameters differ between our control group and the patient group with active symptoms. The boxplots also show a difference in all parameters between the control group and the patients before symptoms. The mean and standard deviation of all retrieved parameters for each group are in appendix B.

**GAIT ANALYSIS**

In Table 3 the results of the gait analysis are shown. We observed that five of the 20 gait parameters are significantly different between patients before the symptoms started and in the period the symptoms were evident. Also a significant difference in 18 of the 20 analyzed parameters between the healthy volunteer group and the patients with active symptoms was
demonstrated. Between the control group and the patients before symptoms, nine of the 20 parameters were significantly different. All asymmetry parameters except stride length asymmetry showed a significant difference, as well as the gait speed.

**RATIOS RELATIVE TO STRIDE DURATION TIME**

No significant differences are observed between groups in ratios relative to stride duration time in step duration, (initial/terminal) double support, single limb support and stance.

**4 DISCUSSION**

This study shows that the smartphone accelerometer is able to detect changes in gait pattern in IC-patients. It also verifies the possibility to measure differences in gait pattern between IC-patients and healthy subjects.
IC is not the only disease characterized by an uneven gait pattern [23]. Comparison to other patient groups with similar symptoms would be useful for a possible diagnosis based on asymmetries. On the other hand, asymmetries can still be used for determining objective improvement within groups of IC-patients, e.g. during (remote) supervised walking therapy or in a telemonitoring setting. Additionally, by showing patients feedback based on their gait pattern and physical behavior, they will gain objective insight into their daily activity and severity of the symptoms. Smartphone feedback can also stimulate patients to move more [10]. Furthermore, gait pattern measurements with a smartphone accelerometer in combination with an algorithm that detects IC-specific anomalies in walking patterns could be used to predict and follow-up on whether supervised walking therapy and/or (endovascular) surgery will improve the clinical and patient-experienced outcome for each patient. The same algorithm could then be used to deploy telemedicine and remote monitoring for IC-patients.

Subjects held the smartphone in their right hand during the walking test. In this way, the patients could easily report their pain. Gait parameters obtained by measuring trunk acceleration with a smartphone over the L3 spinous process were previously proven to be reliable [17]. It has also been found that smartphone measurements are more consistent when positioned on the foot than when positioned in the crotch [22]. On the other hand, as long as every subject keeps the phone in the same position (e.g. horizontally, at bellybutton (L5) height), the data collected should not be affected by it [11]. Therefore, in this study, sensor positioning is expected not to influence the findings, but this has to be taken into account in future applications and research. It is desired that the position of the smartphone during measurements does not affect the results of the analysis.

### Table 3 Comparison of gait pattern characteristics between groups.

|                      | CONTROL VS ACTIVE SYMPTOMS (a) | CONTROL VS BEFORE SYMPTOMS (a) | BEFORE SYMPTOMS VS ACTIVE SYMPTOMS (b) |
|----------------------|--------------------------------|--------------------------------|----------------------------------------|
|                      | Z     | ASYMP. SIG. (2-TAILED) | Z     | ASYMP. SIG. (2-TAILED) | Z     | ASYMP. SIG. (2-TAILED) |
| Stride duration      | -1.898 | 0.058 | -1.811 | 0.070 | -1.483 | 0.138 |
| Stride duration asymmetry | -2.252 | 0.024* | -2.697 | 0.007* | -2.023 | 0.043* |
| Step duration        | -2.075 | 0.038* | -1.458 | 0.145 | -1.214 | 0.225 |
| Step duration asymmetry | -3.225 | 0.001* | -2.340 | 0.019* | -2.032 | 0.042* |
| Cadence              | -1.634 | 0.102 | -1.369 | 0.171 | -0.944 | 0.345 |
| Initial double support asymmetry | -2.080 | 0.037* | -1.460 | 0.144 | -1.616 | 0.144 |
| Terminal double support asymmetry | -2.784 | 0.005* | -2.167 | 0.030* | -1.753 | 0.080 |
| Double support       | -2.075 | 0.038* | -1.458 | 0.145 | -1.625 | 0.104 |
| Double support asymmetry | -2.787 | 0.005* | -3.585 | 0.000* | -1.355 | 0.176 |
| Single limb support  | -1.987 | 0.047* | -1.810 | 0.070 | -0.135 | 0.893 |
| Single limb support asymmetry | -2.605 | 0.009* | -2.518 | 0.012* | -0.674 | 0.500 |
| Stance               | -1.987 | 0.047* | -1.545 | 0.122 | -1.490 | 0.136 |
| Stance asymmetry     | -2.870 | 0.004* | -2.428 | 0.015* | -2.023 | 0.043* |
| Step length          | -2.252 | 0.024* | -1.457 | 0.145 | -0.405 | 0.686 |
| Step length asymmetry | -3.223 | 0.001* | -2.435 | 0.015* | -1.753 | 0.080 |
| Stride length        | -2.253 | 0.024* | -1.546 | 0.122 | -0.405 | 0.686 |
| Stride length asymmetry | -2.252 | 0.024* | -1.865 | 0.062 | -2.023 | 0.043* |
| Gait speed           | -3.400 | 0.001* | -2.165 | 0.030* | -1.753 | 0.080 |

* = significant p < 0.05.
Based on the previous research, the stride length, stride duration, cadence, stance duration, swing duration, double limb support and gait speed are seen as the most important gait parameters [9]. The GaitPy package was used because it is able to output these parameters. GaitPy was initially written for extraction of gait features from accelerometer data generated by an accelerometer fixed at the L5 spinous process level [7]. Thus, GaitPy is not optimized for measurements obtained from a handheld smartphone. By instructing the subjects to hold the smartphone level at bellybutton height, the data will be generated from approximately the same height as L5. The data were additionally corrected for rotations made by the subject to the smartphone before the data was put into GaitPy. In this way it is possible to compensate for the fact that there are more rotations when handheld than when a smartphone is fixed to the lower back.

GaitPy calculates the sensor height based on the body length of the patient. Not every person has the same body proportions [20], which may result in an inaccurate determined sensor height and thus skew the gait parameter values. Therefore, using sensor height as input instead of the body length would be an improvement.

The subgoal was to verify whether differences in gait pattern between healthy people and IC-patients can be measured using a smartphone. The parameters show that patients with symptoms walk slower and have both feet on the ground for a longer period of time. Patients with active symptoms have a shorter step and stride length. This, in combination with no significant difference in cadence, could be the cause for the also slower gait speed. All asymmetry parameters differed significantly between patients with active symptoms and the healthy volunteers. Patients walk more inconsistent, meaning the right leg step differs from the left leg step. Every successive gait cycle of an IC-patient can differ from the one before. Although the cadence is not statistically different as was expected from other publications [12], it does show a trend (Figure 3). The data suggest that one of the patients had a higher cadence than the rest of the patient group; this might result in a higher mean and thus no significant difference.

This proof of concept study has some limitations. The number of subjects in the study is small. It is, therefore, of great importance that this study is repeated with a larger study population in order to create objective standards to classify disease specific gait patterns in IC-patients. Furthermore, there is a significant difference in age between the control group and the patient group. It is shown that the gait of a person changes with age [18, 19]. However, a noticeable difference in gait speed, stride length and step length between age groups in the control group was not found. All other significant parameters, such as the double support and the asymmetry parameters, are not age-influenced. Further investigation of gait parameters collected from a healthy volunteers with the same age characteristics as the IC-group would be able to verify this [16].

Since gait parameters may be interdependent, it is of great importance that future research investigates if and how dependency of gait parameters plays a role in IC-patients. In this study, only the vertical acceleration component (z) is used. The x and y acceleration values are not examined. However, x and y values can provide additional information about the amount of sideways drift [24]. They can also show which leg is on the ground. This can be useful to determine which leg is the cause for the asymmetries. It is desirable to not only be able to distinguish between IC-patients and healthy people, but also between IC-patients and other patients with an impaired walking distance and/or pattern and between IC-patients in different stages of the PAOD. To achieve this, research needs to be done with all subjects experiencing different causes for their walking difficulties.

5 CONCLUSION

Our proof of principle demonstrated the viability of measuring the changes in IC gait characteristics before and while experiencing symptoms with a standard smartphone. Five of the 20 gait parameters were significantly different between IC-patients before symptoms and IC-patients with active symptoms. These results suggest that walking data of patients can be (tele)monitored which is an improvement in following-up on IC-patients. Nine of the 20 parameters were significantly different between the control group and the patient group.
without symptoms. Between the control group and the patient group with active symptoms 18 of the 20 parameters were significantly different. These results are promising for the development of diagnostics for IC using a smartphone accelerometer.

ADDITIONAL FILES

The additional files for this article can be found as follows:

Appendix A. Questionnaire. DOI: https://doi.org/10.29024/jsim.117.s1
Appendix B. Mean and standard deviation table. DOI: https://doi.org/10.29024/jsim.117.s2
Appendix C. Questionnaire results. DOI: https://doi.org/10.29024/jsim.117.s3

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR AFFILIATIONS

Mark Greveling  
orcid.org/0000-0003-3811-6511  
University of Twente, NL
Maaike de Bondt  
orcid.org/0000-0003-0839-3112  
University of Twente, NL
Feike Weijzen  
orcid.org/0000-0003-3443-0140  
University of Twente, NL
Robert Geelkerken  
orcid.org/0000-0003-4640-8725  
University of Twente, NL
Mark Vlutters  
University of Twente, NL
Fabio Catarinella  
orcid.org/0000-0003-0761-4956  
Brightfish B.V., NL
Janwillem Hinnen  
orcid.org/0000-0001-5896-7984  
Jeroen Bosch Ziekenhuis, NL

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