



## In-shoe plantar pressure measurements for patients with knee osteoarthritis: Reliability and effects of lateral heel wedges

Kristyn M. Leitch<sup>a,d</sup>, Trevor B. Birmingham<sup>a,b,d,\*</sup>, Ian C. Jones<sup>a</sup>, J. Robert Giffin<sup>a,c</sup>, Thomas R. Jenkyn<sup>a,d,e</sup>

<sup>a</sup> Wolf Orthopaedic Biomechanics Laboratory, University of Western Ontario, London, Ontario, Canada

<sup>b</sup> School of Physical Therapy, University of Western Ontario, London, Ontario, Canada

<sup>c</sup> Department of Surgery, University of Western Ontario, London, Ontario, Canada

<sup>d</sup> Department of Biomedical Engineering, University of Western Ontario, London, Ontario, Canada

<sup>e</sup> Department of Mechanical and Materials Engineering, University of Western Ontario, London, Ontario, Canada

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### ABSTRACT

Although plantar pressure measurement systems are being used increasingly during gait analyses to investigate foot orthotics, there is limited information describing test–retest reliability of such measurements. Objectives of this study were to (1) examine the test–retest reliability of lateral heel pressure (LHP) and centre of pressure (COP) during walking with and without lateral heel wedges, and (2) evaluate the effects of 4° and 8° lateral heel wedges on the magnitude of LHP, the pathway of the COP and the peak external knee adduction moment (KAM) in subjects with and without knee osteoarthritis (OA). Twenty-six subjects, 12 patients with knee OA and 14 healthy subjects, were evaluated during three lateral heel wedge conditions (control, 4° and 8°) with standardized footwear. Three-dimensional analyses of gait with optical motion capture, floor-mounted force plate and in-shoe plantar pressure were completed on two occasions. Intraclass correlation coefficients (ICC<sub>2,1</sub>) for LHP were excellent (0.79–0.83) while ICCs for COP in the medial–lateral and anterior–posterior directions were more variable (0.66–0.86). Reliability was slightly diminished when using heel wedges. Standard errors of measurement suggested considerable day-to-day variability in an individual's measures. Lateral heel wedges significantly ( $p < 0.001$ ) increased LHP, shifted COP anteriorly and laterally, and decreased the KAM. No significant differences were observed between subjects with and without OA. Although the day-to-day variability appears too large to confidently evaluate changes in individual patients, and decreases in reliability with increases in wedge size indicate caution, these results suggest in-shoe measurement of LHP and COP are appropriate for use in studies evaluating biomechanical effects of foot orthoses for knee OA.

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### 1. Introduction

Plantar pressure measurement systems are being used increasingly during gait analyses when investigating foot biomechanics [1–3]. When combined with optical motion capture, plantar pressure measurements can be particularly informative for investigating the effects of various types of foot orthoses [1,3]. Plantar pressure measurement during walking is a relatively recent addition to gait analysis, and although initial reports suggest in-shoe plantar pressure measurements have acceptable

repeatability, further reliability testing when used with foot orthoses is required [4–12].

An important application of in-shoe plantar pressure measurements is the study of lateral heel wedges for patients with knee osteoarthritis (OA). Approximately 17% of individuals 45 years of age or older have symptomatic knee OA and there is a pressing need to identify interventions that limit its progression given its substantial burden on individuals and society [13–15]. Lateral heel wedges are a potential conservative intervention for the gait-related effects of medial compartment knee OA [16,17]. They are proposed to decrease excessive loading of the medial compartment of the knee by altering the location of the centre of pressure (COP) under the foot during stance [18]. However, results of studies evaluating the effectiveness of lateral heel wedges are inconsistent, as are recommendations for their clinical use [16,17,19,20]. Kakihana et al. [18] and Maly et al. [21] calculated the COP pathway based on force plate data and reported that a lateral shift

\* Corresponding author at: School of Physical Therapy, Elborn College, University of Western Ontario, London, Ontario, Canada, N6G 1H1.

Tel.: +1 519 661 2111x84349; fax: +1 519 661 3866.

E-mail address: [tbirmingham@uwo.ca](mailto:tbirmingham@uwo.ca) (T.B. Birmingham).

in the COP with respect to the foot occurred while subjects wore a foot orthosis, suggesting an increase in pressure on the lateral aspect of the foot. Van Gheluwe et al. [3] used an in-shoe pressure system with seven different wedging conditions. They found that lateral wedging increased peak pressure of the lateral rearfoot and a lateral shift in the COP. In a running study using an in-shoe plantar pressure measurement system, Nigg et al. [2] also suggested that a lateral, full length, wedge produced a lateral shift of the COP. Alternately, Erhart et al. [1] used a floor mat pressure measurement system and reported an increase in medial pressure while wearing a similar orthosis.

While differences in testing conditions, such as footwear and walking versus running, may partly explain varying results regarding the effects of heel wedges, it is presently unclear to what extent measurement variability may contribute to the inconsistency in findings. Although reports of the validity, within-session repeatability and feasibility of plantar pressure measurements exist [4,7,10,22–26], data describing test–retest reliability of in-shoe plantar pressure measurements during walking are limited [6,9,11]. We are also unaware of any studies evaluating the test–retest reliability of heel pressure measurements in patients with knee OA, or during the use of lateral heel wedges. Similarly, the minimal detectable change in an individual's measures has not been determined, limiting their potential clinical use. Therefore, objectives of this study were: (1) to examine the test–retest reliability of plantar pressure measurements of LHP and COP during walking trials completed with and without lateral heel wedges, and (2) to evaluate the effects of 4° and 8° lateral heel wedges on the magnitude of LHP, the pathway of the COP and the peak external knee adduction moment (KAM) in subjects with and without medial compartment knee OA.

## 2. Methods

### 2.1. Subjects

Twenty-six subjects underwent testing on two separate occasions at least 24 h apart but within the same week. Twelve subjects were patients who had a clinical diagnosis of OA confined primarily to the medial compartment of the tibiofemoral joint. Fourteen subjects were healthy adults with no symptoms affecting the lower extremities. Subject characteristics are summarized in Table 1. Consistent with knee OA, mass and BMI were substantially higher in patients than controls. All subjects provided informed consent before participating. This study was approved by the institution's Research Ethics Board for Health Sciences Research Involving Human Subjects.

### 2.2. Gait analysis procedure

During each test session, subjects underwent three-dimensional gait analysis with an 8 camera optical motion capture system (EvaRT, Motion Analysis

**Table 1**

Subject characteristics (showing the means, standard deviations (SD) and ranges of values [min–max]), the ratio of males to females, and the range of OA severity in the sample.

	Controls (n = 14)	Patients (n = 12)	Overall (n = 26)
Age, years	44 (8) [33–61]	48 (9) [38–70]	46 (9) [33–70]
Height, m	1.68 (0.09) [1.58–1.83]	1.72 (0.11) [1.52–1.90]	1.70 (0.1) [1.52–1.90]
Mass, kg	70.40 (13.29) [48.83–98.54]	90.55 (16.80) [67.20–121.06]	79.70 (17.92) [48.83–121.06]
BMI, kg/m <sup>2</sup>	24.89 (3.55) [17.36–29.56]	30.45 (4.22) [25.18–37.55]	27.46 (4.74) [17.36–37.55]
Males	4	5	9
Females	10	7	17
Kellgren and Lawrence grade, # of patients			
1		2	
2		2	
3		3	
4		5	

BMI, body mass index.

Corporation, Santa Rosa, CA, USA) with integrated force plate (OR-6, Advanced Mechanical Technologies Inc., Watertown, MA, USA) and an in-shoe plantar pressure measurement system (Pedar-X<sup>®</sup> insoles, Version 11.3.8 Software, Novel Electronics Inc., St. Paul, MN, USA). The camera and foot pressure systems were synced together through a pulse signal that was sent from the pressure to camera systems. The in-shoe pressure system obtained specific plantar pressure measures of LHP magnitude and path of the COP. Each insole had 99 capacitive cells distributed across the insole. The dynamic range of each cell was 40–600 kPa [27]. The in-shoe pressure system was calibrated according to manufacturer instructions and data were collected at 60 Hz. It was previously shown that sampling rates between 50 and 100 Hz were adequate for walking [28]. Therefore we chose a sampling rate of 60 Hz to coincide with kinematic data collection.

Passive reflective markers were placed on the subjects in a modified Helen Hayes configuration [29]. Four extra markers were placed bilaterally over the medial malleoli of the ankles and the medial knees during an initial static standing trial to establish joint centres and the subject's mass. The extra four markers were then removed prior to gait testing. Kinematic data were collected at 60 Hz. Kinetic data were collected with the force plate at 1200 Hz. Subjects were instructed to walk 8 m across the laboratory at a self-selected normal speed. The force plate was embedded flush with the floor midway along the 8 m walkway. Walking trials were repeated until a minimum of five force plate foot strikes were recorded for each limb.

Lateral wedges were made from ethylene-vinyl acetate (EVA) foam (Nickleplast extra firm, 55 shore A durometer). Three heel wedge conditions were tested in random order: (1) no wedge, (2) 4° wedge, and (3) 8° wedge. The wedges were placed underneath the insole on the lateral side of the shoe (Fig. 1). Only the self-reported dominant leg (defined as the subject's kicking leg), was tested in healthy individuals and the leg being treated for OA was tested in the patient group.

The lateral heel wedges were placed in standardized footwear, which was used due to the suggestion that the Pedar-X system is influenced by shoe sole type [30]. A neutral shoe was used to avoid any influence of the shoe itself on participant foot kinematics. The New Balance 882 (New Balance Athletic Shoes Inc., Boston, MA, USA) was chosen for its generous toe box and ability to accommodate the heel wedge along with the pedar insole and was provided to all subjects during gait testing.

### 2.3. Data analysis

Kinematic and kinetic data from the optical system and force plate were processed using commercially available software (Orthotrak, Motion Analysis Corporation, Santa Rosa, CA, USA). The external adduction moment about the knee was calculated throughout the stance phase of gait using the inverse dynamics method. The first peak in the adduction moment during stance was identified from each foot strike and was averaged across the five trials per participant. Adduction moments were normalized to body weight and height and reported as a percentage (i.e., %BW × ht).

To analyze the plantar pressure data, an in-house program was written that used the sync signal to relate heel strikes between the two systems. The heel was defined as approximately the rear 30% of the foot and divided into two quadrants. The lateral heel quadrant was used to quantify LHP experienced at the instant of the first peak in KAM (Fig. 1). The overall magnitude of the LHP and the path of the COP were calculated using commercially available software (Novel Electronics Inc., St. Paul, MN, USA) and custom-written software (Visual Basics Microsoft Canada, Mississauga, ON, Canada). The sum of the cell pressures in the lateral heel quadrant was recorded at the time of the first peak KAM for each trial. Also at this instant, the *x*-coordinate (medial–lateral direction) and the *y*-coordinate (posterior–anterior direction) of the COP were recorded. These three measures were then each averaged across the five trials for each participant.

### 2.4. Statistical analyses

To evaluate test–retest reliability, the LHP and COP data were pooled from all subjects. The differences between days 1 and 2 were plotted against the mean of days 1 and 2 to graphically evaluate reliability [31]. Intraclass correlation coefficients (ICC type 2, 1) and standard errors of measurement (SEM) were also calculated [32,33]. ICCs were interpreted as follows: >0.75 excellent reliability; 0.4–0.75 fair-to-good reliability; <0.4 poor reliability [34]. The ICC is considered a relative measure of reliability (i.e., it is the ratio of the variability between subjects to the total variability). Therefore, it provides an indication of how well a measure is capable of differentiating among the subjects on whom the measurements were taken [35]. Unlike the ICC, the SEM expresses the reliability of an individual's score. The SEM allows one to interpret an individual's measurements within a certain amount of measurement error.

To evaluate the effect of the wedges and the differences between subjects with and without knee OA, the mean of days 1 and 2 for each dependent variable was averaged for each subject. We then used a repeated measures analysis of covariance (ANCOVA) with one within-subject factor (no wedge, 4° wedge, 8° wedge) and one between-group factor (OA, Healthy). Age and body mass were included as covariates to adjust for differences in these characteristics between the two groups. Scheffe post hoc analyses were planned following any significant main effects or interactions. Statistical analyses were performed using commercial statistics

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