International Journal of
INTELLIGENT SYSTEMS AND APPLICATIONS IN ENGINEERING
ISSN:2147-6799 www.ijisae.org Original Research Paper

Validity and Reliability of DT-Walk for Assessment and Biofeedback of Asymmetries in Limb Loading and Plantar Pressure in Knee Osteoarthritis

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Submitted: 19/01/2023 **Accepted:** 26/03/2023

Abstract: Background: Biomechanical alterations are the primary changes that result in development, progression, or increased risk of injury/disease. The use of wearable has gained significant importancein clinical research for early diagnosis and prediction of injury/disease, thereby providing rehabilitation based on the information received from such devices. **Objective:** This study aims to develop a wearable device for real-time assessment and feedback of limb load asymmetry (LLA) and dynamic plantar pressure asymmetry (PPA). **Method:** A focus group discussion was conducted with an experienced group of physiotherapists to identify the needs of the clinicians for the assessment and rehabilitation of patients with gait and balance disorders in knee osteoarthritis. The prototype device (DT-walk) was fabricated in a pair of insole-based devices, using two inertial measurement unit (IMU) sensors, ten force-sensitive resistors(FSR), and a pair of insoles-shaped custom-made pressure-sensitive matrix made of 16×8 using velostat and copper tape. A set of five FSRs are used in each insole that lies underneath the custom pressure sensitive matrix. Each controller unit incorporates one microcontroller, wireless communication module, storage, and power unit. The data was sent to a mobile computing device forreal-time analysis and visualization. **Results:** DT-walk showed excellent intra-rater and inter-rater reliability and good to excellent validityagainst the WinTrack platform for static LLA and dynamic PPA in KOA. The reliability had ICC>0.9, SEM=0.002-0.00668, MDC= 0.00556-0.01852 and CV=5.43-13.15%. Validity had ICC>0.9, SEM=0.00234-0.98608, MDC= 0.00648-2.73327 and CV=2.31-82.68%. **Conclusion:** The DT-walk, a wearable device, was equally effective in assessing asymmetries in limbloading and plantar pressure compared to the platform-based device. Future studies should evaluate the validity of this device in healthy and diseased conditions.

Keywords: *wearable, limb load, plantar pressure, knee osteoarthritis, asymmetry.*

1. Introduction

Standing and walking are two important primary functional positions for performing activities of daily living, but they are complex tasks for humans. Walking requires a high amount of balance, stability, and a well-synchronized oscillatory movement of different joints of the body. [1], [2] The body's stability, balance, and motions are facilitated by the oscillatory movement of the joints [3] and the synchronized activity of neuronal and musculoskeletal system with the environment. [4] A good static and dynamic posture, that is, standing and walking, respectively, reduces the burden on the foot,ankle, knee, and hip and enhances one's appearance. Various medical conditions can affect the walkingpattern; for example, any change in the lower limb and trunk musculoskeletal structures can result inabnormal limb load distribution.

Biomechanical gait alteration may occur due to the injury or changes in joint structure resulting in altered weight-bearing patterns to avoid pain, further contributing to the development and progression of osteoarthritis [5]. Occupation-related physical activities involving frequent sitting andstanding, prolonged standing or walking, and vigorous physical activity predispose the individual to develop KOA at an early age[6]. Occupations requiring prolonged standing or walking up and down stairs put the knee joint under continuous compression, which causes early degeneration of joint cartilage. [7] Weightlifting puts additional load on the knee joints, further compressing the meniscus and potentially damaging the ACL and MCL. [8], [9] The asymmetrical limb loading can further leadto altered kinetic and kinematic of the lower limb, which further enhances joint degeneration [7]. Along with limb load asymmetry, increased tibiofemoral rotation and peak knee abduction moment are two important factors for hip and knee osteoarthritis. [10] [7]

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Gait can be assessed objectively and accurately by expensive, commercially available gait lab systems or subjectively by clinical observation due to the unavailability of gait analysis labs in most clinical practices. The gait analysis systems typically require a multi-camera motion capture system, a pressure or force sensing platform, and motion analysis software and are expensive and time- consuming to set up and use. [11] Additionally, the area of movement is limited, meaning that only alimited number of gait cycles can be assessed. [12] Therefore, cost-effective, wearable sensor-based alternatives are being developed to resolve these limitations and have gained popularity in the past decade. Sensors, like gyroscopes, magnetometers, accelerometers, pressure sensors, and inclinometers, are used to measure gait parameters. [13] Although wearable devices have become available, they still lack assessment capabilities due to limited sensor configurations. Therefore, this study aims to develop a low-cost wearable device for assessing limb load asymmetry (LLA) and plantar pressure asymmetry (PPA).

2. Materials and Methods

A series of focus group discussion sessions were conducted with the clinical experts to understand their needs and expectations for a new wearable device for KOA. Based on recommendations regarding the structure, contents, and design of the prototype of the DT-walk, the device was developed in consultation with technical experts. DT-walk consists of force-sensitive resistors (FSR), an insole-shaped pressure-sensitive matrix, and a data acquisition and processing unit. This research has been reviewed and approved by the Institutional Ethical Committee of the Lovely Professional University, Phagwara, Punjab (LPU/IEC/2019/03/18).

1.1 Fabrication of the force-sensitive resistor unit

The FSR unit consists of five FSRs embedded on a thin layer of the ethylene-vinyl acetate sheet, allowing us to detect physical pressure, squeezing, and weight. The FSRs are made up of 2 layers of conductive material separated by a spacer that changes its resistive value (in ohms Ω) depending on how much it is pressed. Each FSR unit comprises five square-shaped FSRs of 1.5" ×1.5". The square-shaped FSR was placed on a key plantar pressure area that receives maximum pressure (Figure 1), assisting in precisely identifying the gait phase and pressure on each of them.

1.2 Fabrication of the insole shaped pressure sensitive matrix

Each custom-made pressure-sensitive insole consists of a top and bottom insulation layer, copper strips in the horizontal and vertical orientation, and a layer of velostat sheet (Figure 2). Copper tape and velostat sheets used in this device are commercially available. The pressure-sensitive matrix is formed by pasting copper strips on the top and bottom insulating layers in vertical and horizontal directions. A velostat sheet is placed between the two layers of copper strip. The copper strips were attached to the microcontroller via a 16-channel multiplexer, giving the output when the current waspassed through the circuit and pressure was applied to it (Figure 3). Each cross-sectional area formedby the velostat and copper layers acts as a pressure-sensing unit, resulting in the development of a lightweight, flexible, high-resolution insole that can be worn and carried easily.

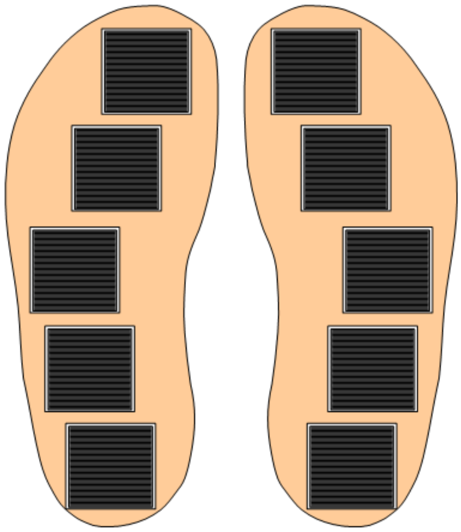


Fig. 1. Left and right force-sensitive resistor unit

1.3 Data Acquisition and processing system

The inputs from the custom-made pressure-sensitive matrix were acquired using a 16-channel multiplexer/demultiplexer pair. The top and bottom layers of the copper strip represent the columns and rows of the insole-shaped pressure-sensitive matrix. Analog and digital signals were managed bythe microcontroller (Arduino Mega 2560) that allows connecting sequentially to voltage through each column via M_{top} and output through each row via M_{bottom}. The top layer with vertical copper strips was attached to the voltage supply via a 16-channel multiplexer, M_{top}. Furthermore, the bottom layerwith horizontal copper strips was attached to the ground through resistance via a 16-channel multiplexer, M_{bottom}. The inputs from all the FSRs in each insole were collected directly by the same microcontroller. The voltage was passed through one of the two pins of FSR, and the output was recorded on the other pin by applying resistance over the ground. The data collected from the FSR and the pressure-sensitive matrix were sent to the DT-walk application installed on a computer via a private wireless network. (Figure 2 & 3)

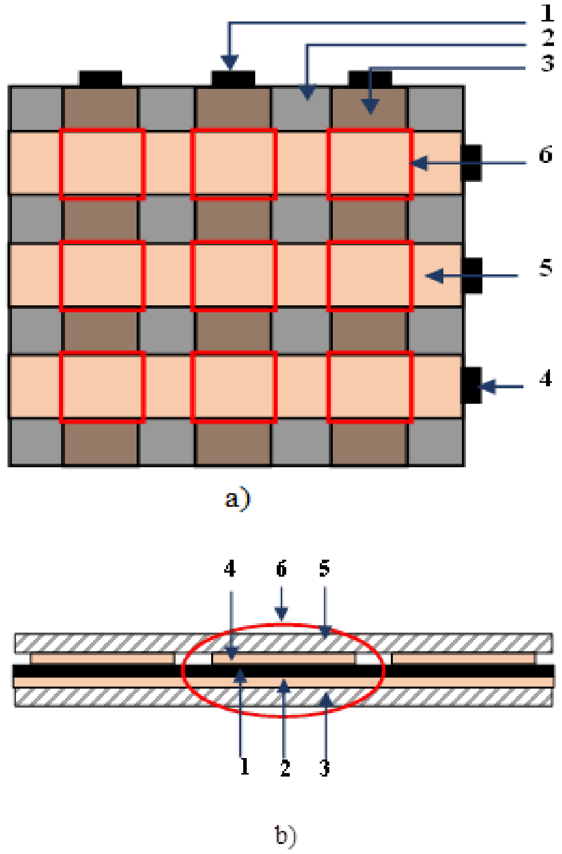


Fig. 2. Schematic diagram of a custom-made pressure sensitive matrix. (a) superior view and (b) cross-sectional view of a 3x3 matrix with its components- 1) column strip connector, 2) velostat, 3) copper column strip, 4) row strip connector, 5) copper row strip, and 6) pressure sensing area.

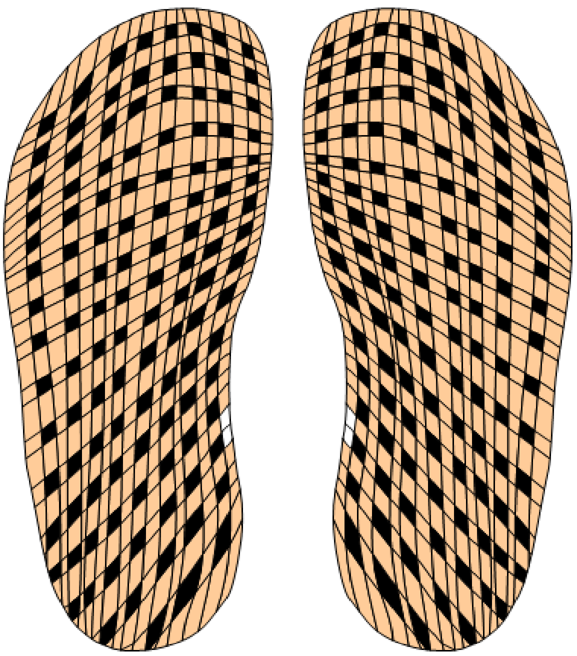


Fig. 3. Custom made pressure sensitive matrix made developed using copper and velostat.

1.4 Fabrication of prototype of DT-walk

The prototype device of DT-walk consists of two components- the insole component and data acquisition and processing systems. The insole unit consists of two separate pressure detection systems; the first one uses five FSRs to identify pressure on the plantar pressure areas of the foot. Theother component of the insole was a custom-made pressure sensitive matrix developed using copper strips and a pressure sensitive conductive material layer. Custom-made pressure-sensitive matrix wasdesigned in the shape of a shoe insole in which velostat is placed between two layers of copper strip,out of which one layer of copper is placed in the horizontal direction (16 rows) and the other in the vertical direction (8 columns). Each intersection point of the copper strips with velostat between them forms a pressure-sensing unit. In this insole, there are 128 pressure-sensing units for each foot. The FSR unit and the custom-made pressure-sensitive matrix are then enclosed in a single casingsuperimposed over each other, where the FSR component lies at the bottom, and the matrix lies on the top surface. The connecting wires of both components were taken out from the lateral side where there is less interference with walking. The connecting wires are attached to the data acquisition and processing unit, which can be strapped around the ankle. The data acquisition and processing unit communicate with the DT-Walk application installed on a computer through a private wireless communication network. The DT-Walk application lets the user see and record the subject's data in real-time. The LLA was calculated as follows:

$$LLA = \frac{\sqrt{(LL_{left} - LL_{right})^2}}{(LL_{left} + LL_{right})} \times 100$$

where $LLleft$ refers to limb loading on the left leg, and $LLright$ refers to limb loading on the right leg. Furthermore, the PPA was calculated as follows:

$$PPA = \frac{\sqrt{(PP_{left} - PP_{right})^2}}{(PP_{left} + PP_{right})} \times 100$$

Where $PPleft$ refers to the maximum plantar pressure exerted on the left leg, and $PPright$ refers to the maximum plantar pressure exerted on the right leg during a single gait cycle.

Finally, the customized pressure sensitive matrix was inserted into a leather pouch made in the shapeof the sole of a shoe. The insole unit was then pasted on custom-made footwear with housing in the shape of the insole unit. The wires connecting the top and bottom layer of the pressure sensitive matrix copper strip and the FSR unit were taken out from the lateral side of the leather pouch and connected to the microcontroller and power unit attached to the leg of the subject via straps. The DT-walk application communicated with the DT-walk devices to receive data on the computing device. (Figure 4 & 5)

Fig. 4: Working prototype of DT-walk.

Fig. 5: Pre-validation testing for private network communication between DT-walk device and DT-walk application.

1.5 Procedure

Samples were selected based on the inclusion and exclusion criteria. Patients fulfilling the inclusion criteria were asked to participate and consent to participate in the study. Then the study procedure was explained to the patient after receiving the signed consent form. Then the general assessment was performed, followed by preparation for assessment of LLA and PPA using WinTrack System (Medicapteurs Technology, France) and DT-walk for reliability and validity.

The reliability of DT-walk was tested to establish its ability to reproduce a consistent and similar result using the test and retest method for both intra-rater and inter-rater reliability. Patients were asked to stand while wearing DT-walk. Sample data were collected for each participant for at least two repetitions. For intra-rater reliability, the researcher applied DT-walk on the patient and connected it with the DT-walk application. The patient was asked to stand in their normal standing posture. The static limb loading data was recorded 30 seconds after the patient had confirmed their standing position to avoid any artifacts. The same procedure was followed for the second reading after a rest for about 15-20. The first reading for PPA was recorded after completing 15-20 minutes of static limb loading assessment. For PPA, the patient was asked to stand on the floor and wait for the therapist's instruction. The patient walked on the floor between the start and end points on the therapist's command while the therapist recorded the data. Similarly, the data was collected for nine samples, and the data collected from the first and second assessments were analyzed for the reliability of the DT-walk.

For inter-rater reliability, two physiotherapists with a minimum of 3 years of clinical experienceperformed the assessment test using DT-walk on the same patient at an interval of 15-20 minutes for three repetitions. The application process for applying DT-walk was explained to both physiotherapists. Both physiotherapists assessed, as explained earlier, and recorded the data for LLAand PPA. The mean of three readings recorded by the two therapists was used to analyze the inter- rater reliability of the DT-walk.

Fig. 6: Application of DT-walk device on patient’s leg while standing and walking on WinTrack platform for validity of DT-walk in standing position.

For validity, the patient was prepared for the assessment using WinTrack as per WinTrack User Manual. The researcher applied DT-walk on the patient and connected it with the DT-walk application. The patient was asked to stand on the WinTrack platform with DT-Walk applied to theirleg. The physiotherapist then instructs the patient to stand in their normal standing posture. The static limb loading data was recorded 30 seconds after the patient confirmed their standing position to avoid any artifacts using both WinTrack System and DT-Walk simultaneously for LLA. The first reading for PPA was recorded after completing 15-20 minutes of static limb loading assessment. For PPA, the patient was asked to stand close to the start point marked on the floor and wait for the therapist's instruction. The patient walked over to the WinTrack platform at the therapist's command while the therapist recorded the data. This procedure was repeated three times for all nine subjects. (Figure 6)

1.6 Statistical Analysis

All the data were analyzed on SPSS version 25.0. Demographic data like age, gender, weight, height,BMI, physical activity, lifestyle, injury history, and limb involvement were analyzed descriptively. Data related to outcome measures were analyzed statistically to evaluate the validity and reliability ofDT-walk in assessing LLA and PPA among patients with bilateral KOA.

Reliability of DT-walk

The coefficients of variation (CV%), standard error of measurements (SEM), minimal detectable changes (MDC), and intra-class correlation coefficient (ICC) calculations were performed to establishthe reliability of DT-walk [14], [15]. The computation of a coefficient of the agreement provides a quantitative index of the reliability of the testing system [16]. SEM is inversely proportional to the reliability of a test; that is, the larger the SEM, the lower the reliability of the test and the less precision there is in the measures taken, and scores obtained [17]. The MDC measures the minimum amount of difference in an individual's score that ensures the change is not a result of measurement error, with 95% confidence [15]. For ICC, the following descriptors were used: "Poor" < 0.40, "Fair" 0.40 - 0.59,"Good" 0.60 - 0.74, and "Excellent" 0.75 - 1.00 [18]. The SEM was calculated using the mean of the standard deviations (SD_{mean}) of data obtained at the two paired sessions and the ICC with the followingformula:

$$SEM = SD_{mean} \times \sqrt{1 - ICC}$$

and MDC values were calculated using the following formula:

$$MDC = 1.96 \times SEM \times \sqrt{2}$$

Validity of DT-walk

The Bland-Altman plot, CV%, SEM, and MDC calculation was employed with 95% confidence to test the validity of DT-walk [15]. A Bland–Altman graph was employed to analyze the agreement between data sets acquired by two systems. The y-axis represents the difference between the two values, while the x-axis represents the average of these values [19]. The computation of a coefficient of the agreement provided a quantitative index of the reliability of the testing system [16].

3. Results

ICCs and 95% confidence intervals in patients with knee osteoarthritis, as well as the results of the statistical analysis of the comparison of the two sets of assessment for validity and reliability of DT-walk for assessment of LLA and PPA, are shown in Tables 1 and 2.

Table 1. Test-retest reliability and validity of DT-walk for limb load asymmetry in bilateral kneeosteoarthritis for limb load asymmetry.

	Mean (SD)	ICC	95% Confidence Interval		SEM	MDC	CV %
			Upper limit	Lower limit			
Intra-rater							
Reading 1	17.93 (13.00)	0.99963	0.99992	0.99850	0.00668	0.01852	5.43
Reading 2	17.81 (13.04)						
Inter-rater							
Rater 1	17.88 (12.98)	0.99990	0.99998	0.99954	0.00200	0.00556	13.15
Rater 2	17.90 (12.97)						
Validity							
WinTrack	17.78 (12.84)	0.99986	0.99997	0.99939	0.00234	0.00648	2.31
DT-walk	17.88 (12.98)						

SD: standard deviation; ICC: Intraclass coefficient; SEM: standard error of mean; MDC: Minimum detectable change; CV: Coefficient of variance.

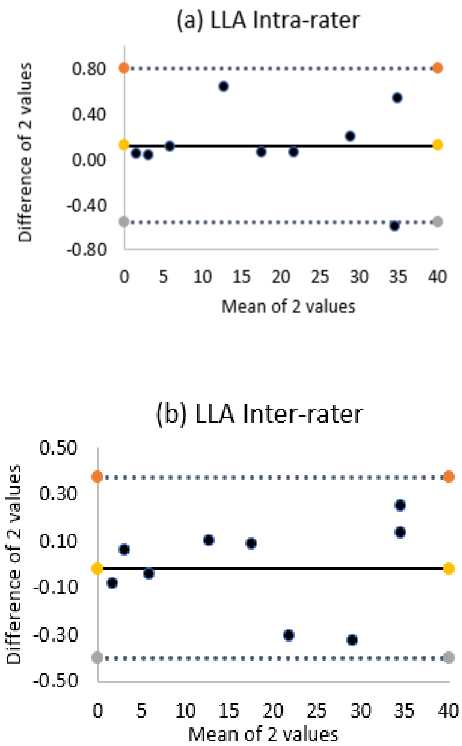
Table 2. Test-retest reliability and validity of DT-walk for dynamic plantar pressure asymmetry in bilateral knee osteoarthritis for limb load asymmetry.

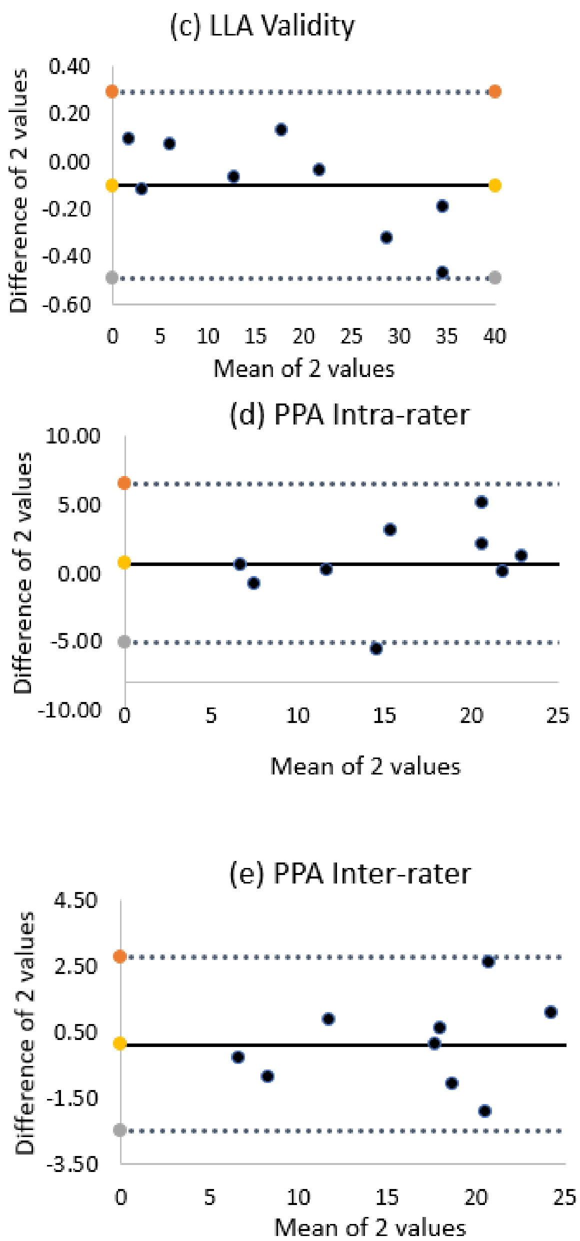
	Mean (SD)	ICC	95% Confidence Interval		SEM	MDC	CV %
			Upper limit	Lower limit			
Intra-rater							
Reading 1 Reading 2	16.06 (6.82) 16.09 (6.98)	0.88472	0.97294	0.56439	1.18491	3.28441	143.55
Inter-rater							
Rater 1 Rater 2	16.35 (6.22) 16.22 (5.88)	0.97781	0.99495	0.90484	0.20032	0.55527	162
Validity							
WinTrack DT-walk	17.54 (5.47) 16.35 (6.22)	0.87747	0.97039	0.58193	0.98608	2.73327	82.68

SD: standard deviation; ICC: Intraclass coefficient; SEM: standard error of mean; MDC: Minimum detectable change; CV: Coefficient of variance.

Test-retest reliability

The test-retest reliability was calculated for intra-rater and inter-rater readings using the mean of tworeadings for the same rater and different raters in intra-rater and inter-rater reliability, respectively. At95% of the confidence interval, DT-walk showed excellent intra-rater reliability with ICC > 0.9, (SEM=0.00668, MDC= 0.01852, CV=5.43%), and inter-rater reliability with ICC > 0.9, (SEM=0.002,MDC= 0.00556, CV= 13.15%) for LLA in KOA. Whereas DT-walk showed good reliability with ICC = 0.884 (SEM=0.00668, MDC= 0.01852, CV=5.43%) and excellent reliability inter-rater reliability with ICC = 0.977 (SEM=0.002, MDC= 0.00556, CV= 13.15%) for PPA in KOA. For each measure, Bland-Altman plots with the bias and limits of agreement between the repeated assessments are reported in Figure 5.





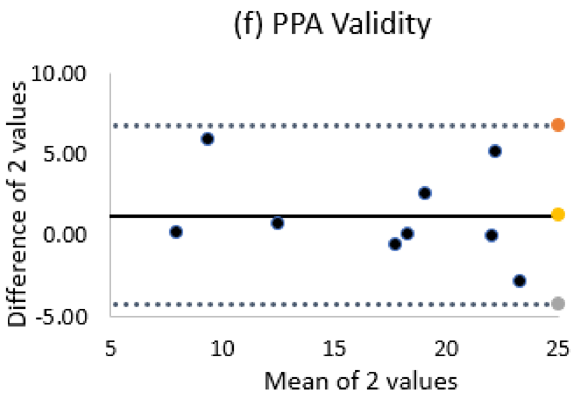


Fig. 6. Bland Altman plot for (a) intra-rater reliability, (b) inter-rater reliability, (c) validity ofDT-walk for limb load asymmetry and (d) intra-rater reliability, (e) inter-rater reliability, and (f) validity of DT-walk for plantar pressure asymmetry.

Concurrent Validity

The DT-walk showed excellent validity against the WinTrack platform with ICC > 0.9 at a 95% of the confidence interval, SEM=0.00234, MDC= 0.00648, and CV= 2.31% for static LLA. Similarly, DT-walk showed good to excellent validity against the WinTrack platform with ICC = 0.877 at a 95% confidence interval, SEM=0.98608, MDC= 2.73327, and CV= 82.68% for dynamic PPA. For each measure, Bland-Altman plots with the bias and limits of agreement between the repeated assessmentsare reported in Figure 5

4. Discussion

The objective of this study was to assess the validity and reliability of DT-walk for assessing asymmetries in limb loading and plantar pressure distribution in KOA. Each participant performed two trials for intra-rater reliability and three for inter-rater reliability and validity testing at an intervalof 15-20 minutes between the trials for static and dynamic assessment. Asymmetrical limb loading in weight-bearing has been identified as the primary biomechanical alteration in KOA. Traditionally, limb loading assessment is performed using force and pressure platforms with a limited walking area, considered gold standards but expensive. Technological advancement has led to the development of low-cost wearable sensors and insole-based devices for assessing limb loading in an indoor and outdoor environment. Various wearable sensor and insole-based devices have been made and are available in the market. However, their validity and reliability remain the primary source of concern for the acceptance of technology in clinical practice.

The result of this study suggests that DT-walk demonstrated excellent test-retest reliability and validity for the assessment of LLA in KOA with ICC ≥ 0.9996. On the other hand, DT-walk showedgood to excellent test-retest reliability and validity for PPA assessment in KOA, with ICC ranging between 0.877 and 0.977. This study's findings align with other studies examining the test-retest reliability of wearable sensors and insole-based devices. [20]–[34] However, the differences in the typeof sensors, variables, and the population used do not allow a direct comparison of the results.

Recently, Parker et al. (2023) found excellent between day reliability of XSENSOR for measuringplantar pressure in controlled environment. [24] Similarly, Khandakar et al. (2022) also developed insole-based device for monitoring plantar pressure and foot temperature in real-time using FSRs, piezoelectric sensor and velostat for early detection of diabetic foot complication [21]. In 2020, Zhaoet al. developed a flexible sensor matrix film using 16 piezoresistive cell sensors for detecting plantarpressure and found it effective in assessing average pressure, maximum pressure, pressure distributions and variations over time. [30] However, these devices have not been validated for use inclinical cases.

In 2021, Barratt et al. found moderate to strong test–retest reliability (ICC = 0.57–0.92) of Moticon and Pedar-X insoles for mean and peak plantar pressure and reaction force. [33] Antti et al. (2021) correlated the highest GRF recorded using MoveSole ® with Kistler force plate and found a strong correlation (.875). [22] Cramer et al. (2022) found excellent reliability of Insole3 (Moticon) for estimating GRF during walking (ICC > 0.941) and during running for the single vGRF peak (ICC = 0.942) and impulse (ICC = 0.940). [26] Peebles et al. in 2018 studied the validity and repeatabilityof the single-sensor Loadsol insoles during single-hop and stop-jump landing and they foundmoderate to excellent repeatability ICC between 0.616 and 0.928. [34] Price et al. in 2016 tested the test-retest reliability of three in-shoe pressure measurement devices (Medilogic, Pedar, and Tekscan), finding high between-day repeatability (ICC ≥ 0.859). [28] During the same period, Lin et al. (2016)used eTextile fabric sensor technique to obtain the high-resolution pressure foot map with 48 sensingpoints and was able to interpret clinically significant data, but clinical studies were recommended to establish its validity. [25]

In 2014, Godi et al. examined gait using a plantar pressure system along linear and curved pathways found excellent reliability (ICC > 0.90) for peak pressure. [32] In another study, Castro et al. (2014) found the WalkinSense ® device to have good-to-excellent accuracy and repeatability (ICC ≥ 0.90) for plantar pressure variables. [31] Crea et al. (2014) developed wireless flexible sensorized insole (PSP2.0) using optoelectronic transduction principle and validated it with a force platform andfound a Pearson’s correlation ≥ 0.88 between the reading. [23] Low and Dixon (2010) found good reliability of Footscan pressure insoles (ICC > 0.75) with poor accuracy when compared with AMTIforce plate (*p < 0.05)*. [27] Alfonso et al. (2007) found good to excellent reliability of BioFoot ® for peak and average pressure between sessions with ICC ranging between 0.78 and 0.94. [20]

The type of technology and sensors used in these devices for plantar pressure and limb loading are velostat [21], FSR [21], piezoelectric sensor [20], [21], [27], [30], [31], pressure sensing pad [23], capacitive force sensor [24], [26], [28], [33], [34], and eTextile sensor [25]. In addition, 3D printed flexible insole with plantar pressure sensing capability are also being developed. [35] The finding ofthe present study indicates that DT-walk has good to excellent validity and reliability in assessing limb loading and plantar pressure distribution and its asymmetries in KOA. These findings are essential for expanding the usability and applicability of DT-walk in research and clinical practice.

Current Limitations and future perspective

The present device also has some limitations, like any other new technology, as it is early. The pressurevalues have not been calibrated in the international system of units. The size of the controller unit needs to be further reduced and make it cosmetically sound. The mobile computing application can be developed for smartphones to allow the user and their clinician to track their movement pattern in real time and improvement over time. The study has tested the validity and reliability of DT-walk forassessing static limb loading and plantar pressure asymmetry but not the spatiotemporal variables of gait. However, all this can be achieved in the later stage.

5. Conclusion

The present device was effective in the real-time assessment of LLA and PPA in standing and walking, respectively, in KOA. Future studies using DT-walk should focus on dynamic limb loading, gait pattern, and asymmetries. When used by clinicians, the device will help in assessment, training, and prognosis. It can also help in the early diagnosis of conditions in which limb loading patterns and balance are affected. Once the customized smartphone application is developed, the patients using this device will be able to track their performance in real-time and over time and improve their performance based on the visual feedback provided by the computing device and the instructions given by their clinicians. Therefore, this study recommends that clinicians may use the proposed device or other similar devices to assess foot mapping, plantar pressure distribution, gait, and limb loading pattern identification in their clinical practice for early identification of gait and balance disturbances.

Funding

The project was mostly self-funded. However, the Division of Research and Development partiallyfunded this research vide SEED grant number *LPU/DRD/SEED/SAC/060622/22315.*

Acknowledgments

The author acknowledges the support of Mr. Prabin Kumar Das and Mr. Biwajyoti Roy, who developed the user interface for data accusation and visualization, and Mr. Ram Kishan, who made the leather pouch for the insole.

Conflict of interest

The authors do not have a conflict of interest to declare.

Contribution of authors

All the authors contributed to the study. Amber Anand performed the initial literature search and identified the gap and drawbacks of the existing studies. Amber Anand, Suresh Mani, Senthil NS Kumar, and Rajesh Singh developed the pressure-sensitive matrix based on the identified gaps and drawbacks. Amber Anand and Suresh Mani tested the prototype device and prepared the manuscript for the study. Senthil NS Kumar and Rajesh Singh did the proofreading of the final manuscript.

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