DEVELOPMENT, AND CONCURRENT VALIDITY AND RELIABILITY OF A NEW WEARABLE DEVICE FOR ASSESSMENT OF LIMB LOAD ASYMMETRY IN KNEE OSTEOARTHRITIS

Thesis Submitted for the Award of the Degree of

DOCTOR OF PHILOSOPHY

in

Physiotherapy

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Declaration

I, hereby declared that the presented work in the thesis entitled "Development and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis" in fulfilment of degree of **Doctor of Philosophy (Ph. D.)** is outcome of research work carried out by me under the supervision of Dr. Suresh Mani, working as Professor, in the Department of Physiotherapy, School of Allied Medical Sciences of Lovely Professional University, Punjab, India. In keeping with general practice of reporting scientific observations, due acknowledgements have been made whenever work described here has been based on findings of other investigator. This work has not been submitted in part or full to any other University or Institute for the award of any degree.

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CERTIFICATE

This is to certify that the work reported in the Ph. D. thesis entitled "Development and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis" submitted in fulfillment of the requirement for the reward of degree of **Doctor of Philosophy (Ph.D.)** in the Department of Physiotherapy, is a research work carried out by Amber Anand, 11816286, is bonafide record of his original work carried out under my supervision and that no part of thesis has been submitted for any other degree, diploma or equivalent course.

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Dedication

To my parents

for their endless love, support, and encouragement throughout my journey of education.

I hope this achievement will fulfill the dreams they have envisioned for me.

-Amber Anand

Abstract

Background: Osteoarthritis (OA) is the most common progressive degenerative joint disorder that occurs due to degenerative changes in the joint structures resulting from the breakdown of bones, and cartilage. According to the Global Durden of Disease Study, 2017, OA is the second most common cause of disability among musculoskeletal disorders affecting nearly 303.09 million people globally. The knee is the most affected joint in osteoarthritis of the lower limb, followed by the hip, affecting nearly 263.08 million people globally. Several potential biomechanical alterations can occur due to the changes in joint structure, which may lead to altered weight-bearing patterns, and further contribute to the development of knee osteoarthritis (KOA) and its progression. In KOA patient's limb loading pattern, and gait are severely affected due to pain. These changes can be assessed using an advanced gait and motion analysis system, which is expensive, limitedly available, and primarily used for research purposes. The existing approaches and technologies are not effective enough to assess early changes in limb load asymmetry, and biomechanical deviations of the lower limb in patients with KOA in real-time scenarios. Studies going on in this direction have gained significant development in recent times. Although many new wearable devices have been made to the market, they lack assessment capabilities due to limited sensor configuration. Thus, there is still a need for a new low-cost technology that can effectively assess limb load, and plantar pressure asymmetry in patients with KOA, and allow the clinicians to monitor the patient's condition in real-time and progress over time.

Objective: The aims of this study were to evaluate the prevalence of limb load asymmetry among patients with knee osteoarthritis, to understand clinician's perspective towards the need, content, function, structure, and applicability of wearable device for KOA, and to develop and validate a new wearable technology for assessment of limb load asymmetry in KOA.

Methods: The study was conducted in four phases- need assessment (Phase I), prevalence study (Phase II), device development (Phase III) and validation (Phase IV). For need assessment, a focus group discussion was conducted. The focus group discussion was conducted via an online videoconferencing platform, which included 25 physiotherapists working in rehabilitation facility (group size=8, sessions=3); the data

was analyzed thematically using Microsoft excel. The prevalence study was conducted at Physiotherapy OPD, Uni Hospital, LPU, Phagwara, to evaluate the prevalence of limb load and spatiotemporal gait asymmetries among patients with KOA using WinTrack System (sample size=95); the data was analyzed descriptively and statistically using SPSS software. The prototype device was developed based on the recommendations of FGD and it was tested for concurrent validity and reliability against the WinTrack System, at Physiotherapy OPD, Uni Hospital, LPU, Phagwara (study population= Knee Osteoarthritis, sample method= systematic random sampling, sample size=9).

Results:

Phase I

A total of 25 physiotherapists participated in one of the three FGD sessions to reach data saturation. The participants included 15 male and 10 female physiotherapists with a minimum clinical experience of three years. However, their years of experience range from a minimum of 3 years to a maximum of 29 years, with a mean of 11.8 years of experience. The majority (23 out of 25) of the participants had master's degree in different specialties of physiotherapy, and two participants had a doctorate degree in physiotherapy. Participants were in favor of using wearable devices for assessment, telemonitoring, feedback, activity tracking, and adherence to exercise. The appearance, comfort and easy to use, cost of device, and easy-to-understand user interface with local and cloud storage were the primary factors responsible for acceptance of wearable technology among the participants. The device should assess and give real-time feedback to users for asymmetries in limb loading, plantar pressure, and spatiotemporal gait parameters.

Phase II

A total of 95 subjects were included, of which 72 were female, and 23 were males, with the majority being moderately active (93.7%) with an active lifestyle (90.5%). The mean age of included subjects was 47.69 (± 6.99), out of which 12 (12.6%) were aged < 40 years, 55 (57.9%) were aged between 41-50 years, 24 (25.3%) were aged between 51-60 years, and 4 (4.2%) were aged > 60 years. In terms of BMI, 54 (56.8%) subjects

were either overweight (40%) or obese (16.8%). Whereas 38 (40%) subjects had normal BMI, 3 (3.2%) subjects were underweight. The limb involvement varied among the subjects, 70 (73.7%) subjects (13 male and 53 female) had bilateral KOA, and 25 (26.3%) subjects (6 male and 19 female) had unilateral KOA. Out of 95 subjects, two male and two female subjects had a history of injury to the lower limb. The mean (SD) age, weight, height, and BMI of the subjects were 47.69 (± 6.99), 63.42 (± 11.77), 1.55 (± 0.07), and 26.29 (± 4.15), respectively.

The prevalence of asymmetries in limb loading, step length, step duration, swing phase duration and plantar pressure were 53%, 41%, 55%, 33%, and 86%, respectively. In unilateral KOA, the mean asymmetry ± SD in limb loading, step length, step duration, swing phase duration and plantar pressure were 12.24% ± 10.27, 11.39% ± 11.38, 20.73% ± 25.30, 10.66% ± 10.88, and 22.31% ± 13.11, respectively. A strong and significant correlation was observed among the asymmetries ($r \geq .557$, $p < 0.01$, and $r \geq .494$, $p < 0.05$). Whereas, in bilateral KOA, the prevalence of asymmetries in static limb loading, step length, step duration, swing phase duration, and plantar pressure were 55.71%, 38.57%, 57.14%, 32.86%, and 84.29%, respectively. Significant correlation was found among some of the asymmetries, such as static limb loading asymmetry with step length asymmetry (r=0.327) and step duration asymmetry (r=0.528), and step length asymmetry with step duration asymmetry (r=0.716) at $P < 0.01$, and plantar pressure asymmetry with swing phase duration asymmetry (r=0.214) at $P < 0.05$.

Phase IV

The test-retest reliability was calculated for intra-rater and inter-rater readings using the mean of two readings for the same rater and different raters in intra-rater and inter-rater reliability, respectively. At 95% 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. 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. The DT-walk showed good to excellent validity and reliability for the assessment of PPA with ICC > 0.87. The Pearson correlation suggest that the reading of DT- walk by same and different rater have strong correlation with each other (r > 0.891, CI=95%). Further, the paired samples t-test showed insignificant difference between the reading of SLLA and PPA taken by same or different rater using DT-walk and between reading taken from DT-walk and WinTrack on same subject (p > 0.05, CI= 95%).

Conclusion:

The prevalence study suggests that a significant proportion of population with KOA exhibit asymmetries in their gait pattern and standing posture. Whereas the focus group discussion helped us in understanding the clinicians' perspective towards the design, content, structure, features, and clinical application of wearable device for KOA. Lastly, the validity and reliability study suggest that DT-walk was equally effective in assessing asymmetries in limb loading and plantar pressure compared to the platform-based device. The DT-walk showed excellent validity and reliability for the assessment of SLLA with ICC > 0.9. The DT-walk showed good to excellent validity and reliability for the assessment of PPA with ICC > 0.87. The Pearson correlation showed strong positive correlation for reliability and validity of DT-walk (r > 0.891, CI=95%). The paired samples t-test showed insignificant difference between the reading of SLLA and PPA taken by same or different rater using DT-walk and between reading taken from DT-walk and WinTrack on same subject (p > 0.05, CI= 95%). Therefore, null hypothesis is accepted, and alternate hypothesis is rejected. Hence, it can be concluded that DT-walk is effective in the real-time assessment of LLA and PPA in standing and walking in KOA.

Future Recommendations

The DT-walk should be upgraded by integrating telemonitoring feature and motion sensing units for the assessment of kinematic parameters of gait as recommended by

the clinicians in focus group discussion. The device, when used by clinicians, will help in assessment, training, and prognosis. Additionally, 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. The future study using DT-walk should focus on dynamic limb loading, gait pattern and asymmetries in different target populations to evaluate its efficacy. Therefore, this study recommends that clinicians may use the proposed device or other similar devices for the assessment of foot mapping, plantar pressure distribution, gait, and limb loading pattern identification in their clinical practice for early identification of gait and balance disturbances.

Keywords: Knee osteoarthritis, limb load asymmetry, wearable device, DT-walk.

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List of Abbreviations

OA	Osteoarthritis
KOA	Knee Osteoarthritis
HR	Heart Rate
WHO	World Health Organization
NHM	National Health Mission
GBD	Global Burden of Disease
IMU	Inertial Motion Sensor
GRF	Ground Reaction Force
ROM	Range of Motion
DT-walk	DiagnoTrain Walk
ACR	American College of Rheumatology
AAOS	American Association of Orthopedic Surgeons
NICE	National Institute for Health Care Education
KOOS	Knee Injury and Osteoarthritis Outcome Score
SLLA	Static Limb Load Asymmetry
PPA	Plantar Pressure Asymmetry
SLA	Step Length Asymmetry
SDA	Step Duration Asymmetry
SPA	Swing Phase Asymmetry
LLA	Limb Load Asymmetry
KAM	Knee Adduction Moment
CTRI	Clinical Trial Registry India
ICC	Intraclass Correlation Coefficient
SD	Standard Deviation
SEM	Standard Error of Measurement
CV%	Coefficient of Variance percent
MDC	Minimal Detectable Changes

FGD	Focus Group Discussion
OPD	Outpatient Department
BMI	Body Mass Index
ACL	Anterior cruciate ligament
MCL	Medial collateral ligament
ROL	Rate of loading
MRI	Magnetic Resonance Imaging
COM	Center of Mass

Operational Definitions

Osteoarthritis:

Osteoarthritis (OA) is a long-term chronic disease characterized by the deterioration of cartilage in joints which results in bones rubbing together and creating stiffness, pain, and impaired movement.

Knee Joint:

The knee joint joins the thigh with the leg and consists of two joints: one between the femur and tibia (tibiofemoral joint), and one between the femur and patella (patellofemoral joint).

Biomechanics:

Biomechanics is the study of a living body and its mechanics. This includes the forces exerted by both gravity and muscles on the skeleton.

Spatial:

Relating to the position, area, and size of object.

Temporal:

Relating to time duration an object stays in a position.

Stride:

Relates to time duration between two consecutive right/left heel strikes.

Stride length:

Distance between two successive placements of the same foot. It consists of two step lengths, left and right, each of which is the distance by which the named foot moves forward in front of the other one.

Step length:

Distance between two successive placements of the opposite foot

Cadence:

Total number of full cycles of stride or step taken within a given period of time, often expressed in steps or cycles per minute.

Assessment:

Refers to the wide variety of methods or tools that evaluators use to evaluate, measure, and document performance, readiness, learning progress, skill acquisition, or other needs of subjects.

Gait:

Bipedal, biphasic forward propulsion of center of gravity of the human body, in which there are alternate sinuous movements of different segments of the body with least expenditure of energy.

Lower limb:

The lower limb refers to the part of the body from the hip to the toes. It includes the hip, knee, and ankle joints, and the bones of the thigh, leg, and foot.

Limb load:

Refers to weight bearing by the foot during motion and standing.

Asymmetry:

The lack of equality or equivalence between parts or aspects of something; lack of symmetry.

Balance:

Balance is an ability to maintain the line of gravity (vertical line from center of mass) of a body within the base of support with minimal postural sway.

Sensor:

A device which detects or measures a physical property and records, indicates, or otherwise responds to it.

Velostat:

Velostat is made of a polymeric foil impregnated with carbon black to make it electrically conductive. Velostat is a piezoresistive material, meaning its electrical resistance decreases when pressured.

Microcontroller:

A microcontroller is a compact integrated circuit designed to govern a specific operation in an embedded system. A typical microcontroller includes a processor, memory and input/output (I/O) peripherals on a single chip.

Wi-Fi:

A facility allowing computers, smartphones, or other devices to connect to the Internet or communicate with one another wirelessly within a particular area.

Plantar Pressure:

The pressure field that acts between the foot and the support surface during everyday locomotor activities.

Foot pressure mapping:

Method of measuring pressures on the surface of the foot during standing or walking.

Joint Angle:

The angle between the two segments on either side of the joint, usually measured in degrees and often converted to clinical notation.

CHAPTER I

INTRODUCTION

1.1 Background

Standing and walking are two primary functional positions for performing activities of daily living, but they are complex tasks for humans as they require muscle activity. Human gait can be defined as “a translatory progression of the body as a whole, produced by coordinated, rotatory movements of body segments” [1]. Normal human gait aims to facilitate translation of the body from one place to another with minimum effort while maintaining optimal stability in different walking conditions. Stable gait can be achieved by a well synchronized communication between central, and peripheral nervous system for coordinating the movements of the musculoskeletal system [2]. Walking requires a high amount of balance, and stability along with the complex synchronized oscillatory movement of different joints of the body [3]. The body's stability, balance, and motion are facilitated by the oscillatory movement of the joints. The synchronized activity of the neuronal, and musculoskeletal systems with the environment is required for a good standing balance, and stable gait [4]. The pattern of walking can get affected by various medical conditions. Any change in musculoskeletal structures of the lower limb, and trunk can result in abnormal limb load distribution which leads to abnormal standing posture, and gait patterns. A good static, and dynamic posture, that is, standing, and walking, not only reduces the burden on foot, ankle, knee, and hip but also enhances one’s appearance. The standing and walking pattern can get affected due to injury or degenerative and infectious joint disease of lower limb.

Osteoarthritis (OA) is the second the most prevalent musculoskeletal disorders that result in disability among adults, affecting both weight-bearing, and non-weight-bearing joints. The World Health Organization (WHO) defined OA as “a long-term chronic disease characterized by the degeneration of cartilage in joints which results in bones rubbing together, and creating stiffness, pain, and impaired movement” [5]. According to the Global Burden of Disease (GBD) study 2017, OA is the second most

common cause of disability globally among musculoskeletal disorders that affect nearly 303,096,500 people [6]. According to World Health Organization (WHO), 18.0% of women, and 9.6% of men aged over 60 years develops symptomatic OA globally out of them 80% have limitations in movement, and 25% cannot perform their day-to-day activities [7]. Among OA, knee osteoarthritis (KOA) is the most common degenerative disease that affects 4% population worldwide [8].

The GBD study (2017) reported that knee joint is the most affected joint in OA, affecting nearly 263.08 million people globally with higher prevalence among females [6]. According to National Health Mission (India), OA is the second most common rheumatologic problem, and it is the most frequent joint disease, with a prevalence of 22% to 39% in India [9]. It is evident from prior studies conducted in India that women are affected more than men, with similar prevalence among the urban, and rural populations [10–12]. Study evaluating epidemiology of KOA in India, and related factors found that the prevalence of KOA is 28.7% and is highly prevalent in people with higher BMI who do not exercise and have a sedentary lifestyle [12]. A recent study conducted in rural area of Ballabgarh, Haryana reported a significantly higher prevalence of KOA of 64.3% among elderly older than 65 years [11]. The probability of developing KOA increases substantially with each decade after the age of 45 years, but it may develop even at an early age [13]. However, a study conducted in Gurdaspur, Punjab reported that the prevalence of KOA among women between the of 30-60 years was 21.6% out of which 35.3% were in the age group of 30-40 years [10].

The exact mechanism of KOA is still unknown; certain factors like over 50 years of age, female gender, increased BMI over 25 kg/m2, previous history of a knee injury, arthritis of other joints, and occupational or physical activities have been identified as predisposing factors for the development of KOA [14]. In 2020, Raud et al. found that the BMI is directly proportional to the severity of KOA and hence the treatment strategies should vary based on obesity severity [15]. Further, Chen et al. (2020) proposed an obesity-related OA model that establishes the effect of obesity on pathological changes on the osteochondral unit and surrounding connective tissues in OA and obesity-related asymmetrical loading, joint malalignment, and muscular

weakness [16]. On the other hand, several studies have found that history of previous trauma or injury around the knee joint has direct relationship with the risk of developing OA of knee [17–19]. Among the injuries of knee, anterior cruciate ligament (ACL) is most associated with the development of KOA in later stage. Webster and Hewett (2022) from their systematic review and meta-analysis concluded that ACL injury significantly increases the risk of KOA in both surgical and non-surgical cases of ACL injury [20].

The history of knee pain is common in KOA, which is exacerbated by physical activity, and worsens by the end of the day. The pain can be localized to one area of the knee joint or generalized to the whole knee joint [21]. Pain and stiffness are common in the morning and may occur after sitting or prolonged rest was reported in OA of hip [22]. The pain severity severely affects the ability to perform activities of daily living (ADL) and participate in physical activity. In KOA patients, the connection between avoidance of activities and limitation of activities is substantially contributed by muscle weakness [23–24]. As a result of pain and fear avoidance patients with KOA tend to spend lesser time and put lesser weight on the affected leg to avoid pain. The asymmetrical limb loading between the legs leads to altered gait mechanics, and further joint degeneration. Furter, Wieland et al. (2005) postulated that alteration in joint alignment can results in cartilage destruction and subchondral bone sclerosis [25]. In addition, many possible biomechanical deviations may develop because of articular changes in joint structure which leads to abnormal weight-bearing patterns, and further contribute to progression of KOA [26].

In the study conducted by Robadey et al., (2018) to evaluate over-ground asymmetry in kinematic parameters in KOA subjects, it was found that 1) there is lower knee flexion in the affected limb as a result of the body's protective mechanism against knee pain; 2) during the vertical movement of the body, significantly high amount of forces act on the knee joint contributes to pain in the affected limb which causes avoidance behavior that leads to limb load symmetry; 3) shorter duration of heel-toe motion in affected limb implies a flatter landing position of foot [27], and although the ground reaction forces are not high during heel strike, increased strike pattern is evident

[27–28]. Thus, patients with KOA may prefer a faster transition from toe touch to decrease knee flexion moment and increase in rate of loading (ROL) which enhances degeneration and progression of the knee joint in KOA.

Changes in the way the knee joint bears weight and where pressure is placed during walking have been detected in the early stages of KOA. This is manifested by increased forces on the knee during contact and a displacement of the center of pressure. Dynamic loads on the joints and limbs during physical activity primarily contributes to biomechanical pathophysiology and progression of KOA [29]. As joint degeneration progresses, deviations in biomechanics of gait lead to increased overall joint loading, affecting both medial and compartments of the knee joint [30]. Compensatory movement and overloading other joints have been identified as potential predisposing factors for developing KOA [31–34].

Measuring the pressure on the sole of the foot can provide information about how the foot functions during walking, as it has to bear and adjust to changes in force direction and magnitude. This is important for analyzing a person's gait, as well as for medical purposes like diagnosis [35–38], rehabilitation [39–41] and sports [40, 42] is widely acknowledged. There are two types of equipment used to measure limb load and plantar pressure: platform-based systems and in-shoe systems. The most common method for analyzing ground reaction force is through the use of force platforms. It has a high repeatability, a wide pressure range, is sensitive to minute changes, and can record at extremely high sampling rates. However, when it comes to analyzing gait from a comprehensive perspective, force plates have some limitations. While they provide an accurate measure of force, they cannot detect the pressure on a specific area of the foot, which is a critical factor when analyzing plantar pressure. These platforms are expensive, bulky and can only be used in a laboratory setting, and they can typically record only one or two steps, which is not enough to obtain statistically significant results [43–44]. Moreover, the subject must be barefooted during the assessment, which is not true representation of how the foot behaves when wearing shoes, thus limiting the data collected [45–46].

To address these limitations, wearable sensors have emerged as an alternative method of analyzing gait. This method is cost-effective and can be used both inside and outside of the laboratory setting, making it an increasingly popular option. Inertial motion units and pressure sensors are applied on various body parts to analyze gait using wearable technology. The sensors used in wearable devices are gyroscope, magnetometer, eTextile, accelerometer, piezoelectric pressure sensor, inclinometer, and many others for assessing different parameters of gait [47]. A brief description of these sensors are given below:

- Gyroscope sensors are devices that, when mounted to a frame, can detect the speed of angular velocity when the frame rotates [48].
- A magnetometer sensor directly senses magnetic fields, helpful in determining direction [49]
- E-textiles are fabrics that can be integrated with electronic components such as batteries, light emitting diodes, sensors, and microcontrollers [50].
- An accelerometer sensor is a device that monitors the acceleration of any body or object at rest [51].
- A piezoelectric pressure sensor is a device that measures changes in pressure, acceleration, strain, or force by converting them to an electrical charge via the piezoelectric effect [52].
- An inclinometer is a device that measures the angles of slope (or tilt), elevation, or depression of an object with regard to gravity [53].

The wearable devices made from thesis sensors exist in different forms- sensor units, sensor embedded clothing, and in-shoe systems.

In-shoe or insole-based systems are more versatile than platform systems. Prior studies have shown the effectiveness of theses in-shoe or insole-based systems in plantar pressure measurement systems for diagnosis, rehabilitation, and daily activity tracking [42, 45–46, 54–58]. There are different brands of smart in-sole devices available in the market for plantar pressure assessment, namely F-Scan (Tekscan, Inc., Massachusetts, USA) [59], Movesole (Movesole, Paulaharjuntie 22, Oulu, Finland) [60], Walkasin (RxFunction Inc. Eden Prairie, Minnesota, United States) [61],

Evalu.Run (Evalu, Munich, Germany) [62], Xsensor (XSENSOR Technology Corporation, Calgary, Canada) [63], Insole3 (Moticon ReGo AG, München, Germany) [64], and Pedar (Novel GmBH Inc., Munich, Germany) [65]. Although the sensors may operate differently, the underlying principle of these systems remains the same. In evaluating plantar pressure using these devices, a matrix of multiple sensors or sensing unit is employed to measure the force exerted on each sensor while the foot is in contact with the supporting surface. The pressure level is then determined by dividing the measured force by the known area of the sensors activated while the foot was in contact with the supporting surface. These devices cost 10-20 times cheaper than platform-based force and plantar pressure systems. Still, the cost of these in-shoe devices is very high for most clinicians and public. The existing approaches, and technologies are not effective enough to assess early changes in limb loading pattern, and biomechanical deviations of the lower limb in patients with KOA in real-time scenarios. Studies going on in this direction have gained significant development in recent times. Although many new wearable devices have been made to the market, they are either expensive or lack in their assessment capabilities due to their sensor configuration.

From the current literature review, it is evident that various external, and internal factors affect the limb loading pattern, and gait parameters in KOA. Limb load asymmetry, the earliest clinical manifestation in KOA, is the key to prevention, diagnosis, and disease progression prevention. The pain and modifiable risk factors should be reduced to correct these changes. Further, early diagnosis of limb load asymmetry and spatiotemporal gait parameter should be given importance in clinical practice along with corrective exercises for these changes. For assessment of these parameters force platform, baropodometry or an insole-based system is required, which is very expensive, limitedly available, and mainly used for research purposes but not in general practice. So, due to the lack of such technology, early diagnosis of these changes is impossible. Thus, there is still a need for a new low-cost wearable technology which is small, light, and portable and that can effectively assess limb load, and plantar pressure asymmetry in patients with KOA, and allow the clinicians to monitor the patient's condition in real-time and improve over time.

1.2 Research Problem

The literature review suggests that the prevalence of KOA is significantly high and is increasing with aging population, affecting nearly 263.08 million people globally [6]. Osteoarthritis being the most common progressive degenerative joint disorders that occurs due to degenerative changes in the joint structures resulting from the breakdown of bones, and cartilage [66]. Many possible biomechanical deviations may develop because of articular changes in joint structure which leads to abnormal weight-bearing patterns, and further contribute to progression of KOA [26]. In KOA patient's limb loading pattern, and gait are severely affected [67]. Limb load symmetry, and gait are closely related, so even a slight asymmetry in limb load can lead to altered gait mechanics [68]. Force platform-based systems, and gait lab systems based on motion sensing cameras, along with wearable sensors or reflective markers, have been in use for a long time for clinical assessment of gait, and limb load symmetry [69]. However, these technologies are not available in most clinical practices due to their cost and infrastructure requirement. Therefore, most clinicians rely on observation assessment which is highly subjective and inaccurate. Studies going on in this direction have gained significant development in recent times. Various wearable technologies have been developed by the researcher and are available in the market. However, they lack assessment capabilities due to their sensor configuration and associated cost of equipment. The existing approaches, and technologies are not effective enough to assess early changes in limb load asymmetry in patients with KOA in real-time scenarios. Thus, there is still a need for a new low-cost technology that can effectively assess limb load, and plantar pressure asymmetry in patients with KOA, and allow the clinicians to monitor the patient's condition in real-time and improvement over time.

1.3 Research Significance

Limb load symmetry, and gait are closely related, so even a slight asymmetry in limb load can lead to altered gait mechanics [68]. Force platform-based systems, and gait lab systems based on motion sensing cameras, along with wearable sensors or reflective markers, have been in use for a long time for clinical assessment of gait, and limb load symmetry [69]. To date, no cost-effective device is commercially available in the market for a complete assessment of lower limb load symmetry, and gait parameters using wearable sensor technology, which can be used outside the clinical setting, and analyze the performance in real-time, except a few which are highly expensive, and cannot be used by patients directly. Gait analysis lab systems available in the market are costly, non-portable, require ample space, and consist of multiple components with limited walking space, and an expert operator [69].

Therefore, to address these limitations, wearable sensors have emerged as an alternative method of analyzing gait. This method is cost-effective and can be used both inside and outside of the laboratory setting, making it an increasingly popular option. Inertial motion units and pressure sensors are applied on various body parts to analyze gait using wearable technology [70]. As stated, earlier sensors like gyroscope, magnetometer, eTextile, accelerometer, pressure sensor, inclinometer, etc. is being used the researchers for assessing different parameters of gait [47]. Various shoe/insole-based devices are also available in the market, which claims that they can analyze gait. However, they only analyze the gait phases [69].

The developed prototype device (DT-walk) assesses static limb load asymmetry (SLLA) and plantar pressure asymmetry (PPA) using a computer-based application. The DT-walk is an insole-based device which is very lightweight, easy to use, and susceptible for any application that requires quantitative evaluation limb load and plantar pressure asymmetry without requiring a sophisticated laboratory setup, and ability to be used in any environment. The DT-walk is based on a custom-made pressure-sensitive matrix made up of one layer of velostat sheet sandwiched between two layers of copper strips. One layer of copper strips is placed in the horizontal

direction, and the other layer in the vertical direction. Each cross-sectional area formed by the velostat and copper layers act as a pressure-sensing unit. This results in a lightweight, flexible, and high-resolution insole that can be worn and carried easily. Additionally, a separate layer consisting of five force-sensitive resistors was placed at key locations on the plantar surface of the foot for accurate gait phase identification. For spatiotemporal gait parameters, two inertial motion sensors with attitude and heading reference system (AHRS) were also incorporated into our device for accurate spatial and temporal gait detection. A detailed description of DT-walk device development is mentioned in section 4.3.

The DT-walk can be used for assessment by medical practitioners, physiotherapists, occupational therapists, podiatrists, and orthotists, as well as for training purposes by physiotherapists, trainers, patients, and athletes if the training component is also developed in later stages. Moreover, based on cost of materials, and technologies used in this device, costs at least 50-100 times cheaper than traditionally platform-based systems with similar accuracy when produced in bulk.

1.4 Rationale

KOA is the most common degenerative disease that affects 4% population worldwide [8]. In KOA, abnormal gait is reported to be associated with limb load asymmetry [67]. Asymmetrical limb loading is the primary response to knee pain in the early stage of KOA which activates due to pain and fear avoidance belief. Individuals with knee pain tend to avoid pain provoking activities like weight bearing on affected knee which results in joint and limb loading asymmetry. Hence, limb load symmetry, and other gait parameters in static, and dynamic postures are important aspects of assessing KOA in clinical practice. Prior studies have primarily focused on kinetic and kinematic alteration of gait in KOA like joint angle and joint torque/moment. However, there is scarcity of literature on limb loading pattern in KOA. Asymmetrical limb loading leads to gait changes, further enhancing joint degeneration [71]. Early detection, and training for limb load asymmetry, and gait parameters is the key to preventing further progression of KOA [67]. Currently available devices are expensive, sophisticated, non-portable, and require trained operators, and ample space. Due to the lack of such devices assessment of limb load asymmetry, and spatiotemporal gait parameters in real-time scenarios remains unassessed in its early stages of KOA [66, 72]. In postoperative cases of KOA, training of correct limb loading pattern, and biomechanical strategies is essential for a good prognosis. With the development of the new wearable device, the current demands of assessment technology and rehabilitation of limb load asymmetry in KOA were addressed. The DT-walk is very light, easy to use, and track results over time using a mobile computing application. It can be used by healthcare practitioners like physicians, physiotherapists, occupational therapists, orthopedics, neurologists, orthotists, prosthetists, podiatrists, patients, athletes, and the footwear industry for assessment. DT-walk is effective in assessing the patient's limb load symmetry, and thereby delaying the progression of KOA due to the following reasons:

- The commercially available platform-based systems are not affordable for clinicians since they are expensive, non-portable, require significant space, and consist of multiple components with limited walking space [73]. In contrast, this device is cost-effective, portable, and wearable.

- The DT-walk uses an innovative wearable sensor-based technology that can be used by anyone, anywhere, and efficiently for assessing limb load asymmetry, and plantar pressure asymmetry in real-time in KOA.
- The DT-walk can assess limb load, and plantar pressure asymmetry, display results, and give visual feedback to the patients.
- The DT-walk allows continuous assessment of the patient's limb loading, and plantar pressure distribution pattern.
- Clinicians and patients can use the DT-walk inside and outside the lab.

1.5 Research Questions

- What is the prevalence rate of limb load and plantar pressure asymmetry in KOA?

- What is the clinician's perspective towards wearable technology for assessment and rehabilitation in KOA?

- Can a wearable device be as equally effective as a platform-based device for assessing limb load asymmetry, and plantar pressure asymmetry in KOA?

1.6 Research Objectives

The objectives of this research are as follows:

General Objective

To develop and validate a new wearable device for assessing limb load, and plantar pressure asymmetry in KOA.

Specific Objective

1. To ascertain the content, structure, and design of DT-walk for assessing limb load asymmetry, and plantar pressure asymmetry in standing, and walking based on clinician's perspective. (Phase I)
2. To evaluate the prevalence of limb loading, plantar pressure, and spatiotemporal gait asymmetry among patients with KOA using WinTrack, a platform-based system. (Phase II)
3. To develop DT-walk based on recommendations of focus group. (Phase III)
4. To evaluate the validity, and reliability of a new wearable device, DT-walk, for limb load asymmetry, and plantar pressure asymmetry in standing, and walking in patients with KOA against the WinTrack, a platform-based system. (Phase IV)

1.7 Research Hypothesis

Null Hypothesis : DT-walk is a valid, and reliable tool for assessing limb load asymmetry, and plantar pressure asymmetry in KOA.

Alternate Hypothesis : DT-walk is not a valid, and reliable tool for assessing limb load asymmetry, and plantar pressure asymmetry in KOA.

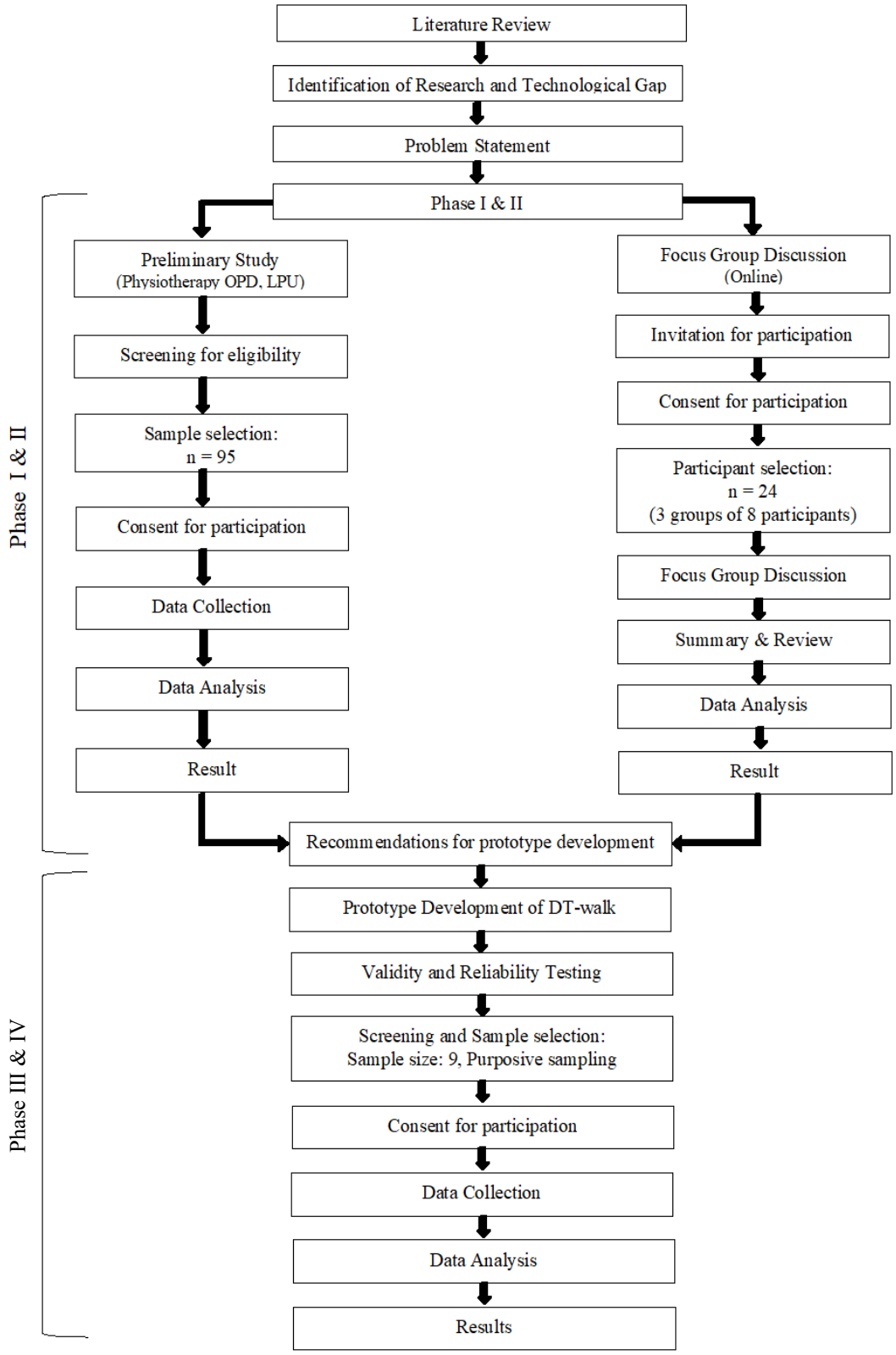


Figure 1. 1 Study flowchart.

CHAPTER II

LITERATURE REVIEW

Overview

This review of literature is designed to explore the extent to which KOA affects the population, and how it is being treated. This attempt also significantly consolidates the existing assessment, and treatment approaches for KOA. The review focuses on the theoretical concepts of limb loading, and gait, and how it affects KOA. This chapter has considered all these directions to narrow down the research question.

The aims of this chapter are to:

- Review the KOA, and its pathology to provide clearer insights into clinical findings, and associated problems the patients face.
- Review the existing approaches for clinical assessment of KOA, and their limitations.
- Review the existing approaches for the treatment of KOA, and their limitations.
- Review the relevant literature related to the theories of limb loading for a clear understanding of limb loading patterns, and asymmetry that occurs in KOA.
- Review the relevant literature related to the theories of gait for a clear understanding of biomechanical deviations that occurs in KOA.
- Synthesize the review to form a conceptual framework for effectively assessing and treating KOA.

2.1 Knee Osteoarthritis

Among the musculoskeletal disorders OA is the second the most prevalent disorders that result in disability among adults, affecting both weight-bearing, and non-weight-bearing joints. WHO defined OA as “a long-term chronic disease characterized by the degeneration of cartilage in joints which results in bones rubbing together, and creating stiffness, pain, and impaired movement” [5]. The Osteoarthritis Research Society International defines OA as “a disorder involving movable joints characterized by cell stress and extracellular matrix degradation initiated by micro- and macro-injury that activates maladaptive repair responses including pro-inflammatory pathways of innate immunity. The disease manifests first as a molecular derangement (abnormal joint tissue metabolism) followed by anatomic, and/or physiologic derangements characterized by cartilage degradation, bone remodeling, osteophyte formation, joint inflammation, and loss of normal joint function), that can culminate in illness” [74–75].

According to the GBD study (2017), OA is the second most common cause of disability globally among musculoskeletal disorders that affect nearly 303,096,500 people [6]. According to WHO, symptomatic OA affects 18.0% of women and 9.6% of men over 60 in the world; of these, 80% have mobility restrictions and 25% are unable to carry out their activities of daily living [7]. The National Health Mission (India) reports that in India, OA is the most common joint disease and the second most prevalent rheumatologic issue, affecting 22% to 39% of the population. [9].

KOA is the most common degenerative disease that affects 4% population worldwide [8]. The GBD study (2017) reported that the knee is the most affected joint in OA, affecting nearly 263.08 million people globally [6]. It is evident from prior studies conducted in India that women are affected more than men, with similar prevalence among the urban, and rural populations [10–12]. Study evaluating epidemiology of KOA in India, and related factors found that the prevalence of KOA is 28.7% and is highly prevalent in people with higher BMI who do not exercise and have a sedentary lifestyle [12]. A recent study conducted in rural area of Ballabgarh, Haryana reported a significantly higher prevalence of KOA of 64.3% among elderly older than 65 years [11]. The probability of developing KOA significantly increases with each decade after 45 years of age, but it may develop even at an early age [13].

However, a study conducted in Gurdaspur, Punjab reported that the prevalence of KOA among women between the of 30-60 years was 21.6% out of which 35.3% were in the age group of 30-40 years [10]. It is evident from the reports of the GBD study in 2017 that women have a higher risk of developing KOA [6]. Prevalence of OA has been associated with menopause [76–78] for a long time due to estrogen deficiency [77] and osteoporotic changes in the bone.

KOA typically presents with a history of chronic progressive joint degeneration [12]. A history of knee pain is common in KOA, which is exacerbated by physical activity, and worsens by the end of the day. Wieland et al. (2005) postulated that alteration in joint alignment can results in destruction of joint cartilage and sclerosis of subchondral bone. Pain initiates because of mechanical and chemical nociceptor activation, impairing the quality of life and frequently leads to disability, stigma, and isolation from social circle [25]. In KOA, the pain can be localized to one area or generalized to the whole of the knee joint [21]. Pain, and stiffness are common in morning, and may occur after sitting or prolonged rest [22]. Stiffness, and crepitus are also prominent features of KOA. The swelling of knee joint occurs secondary to synovitis, and formation of osteophyte along the joint [21]. Joint locking, and instability are common symptoms in KOA that develop due to weakness of quadriceps and hamstring muscles resulting from underuse of these muscles [21–22].

The exact mechanism of KOA is still unknown; certain factors predispose a person to develop KOA. Silverwood et al. (2015) from their systematic review concluded that individuals over than 50 years of age, female gender, BMI over 25 kg/m2, history of injury to knee joint, arthritis of other joints, and occupational or physical activities are predisposing factors for the development of OA of knee joint [14]. The symptoms of KOA increase significantly with every decade of life, with the highest incidence between 55-66 years [79]. OA is not merely a basic physical wearing down and deterioration of cartilage, but rather a dynamic biological process in which cells within the joint play a role in mediating the degeneration of cartilage [80]. Chen et al. (2020) identified pathological changes associated with obesity-related OA and proposed a hypothetical model of obesity-related osteoarthritic changes based on biomechanical factors as shown in Figure 2.1. The model demonstrates how obesity

impacts the pathological alterations to the osteochondral unit and the connective tissues surrounding it in cases of OA, as well as the uneven loading, joint misalignment, and muscle weakness that are associated with obesity [16]. Raud et al. (2020) found that the BMI score is directly proportional to the severity of KOA and hence the treatment strategies should vary based on obesity severity [15].

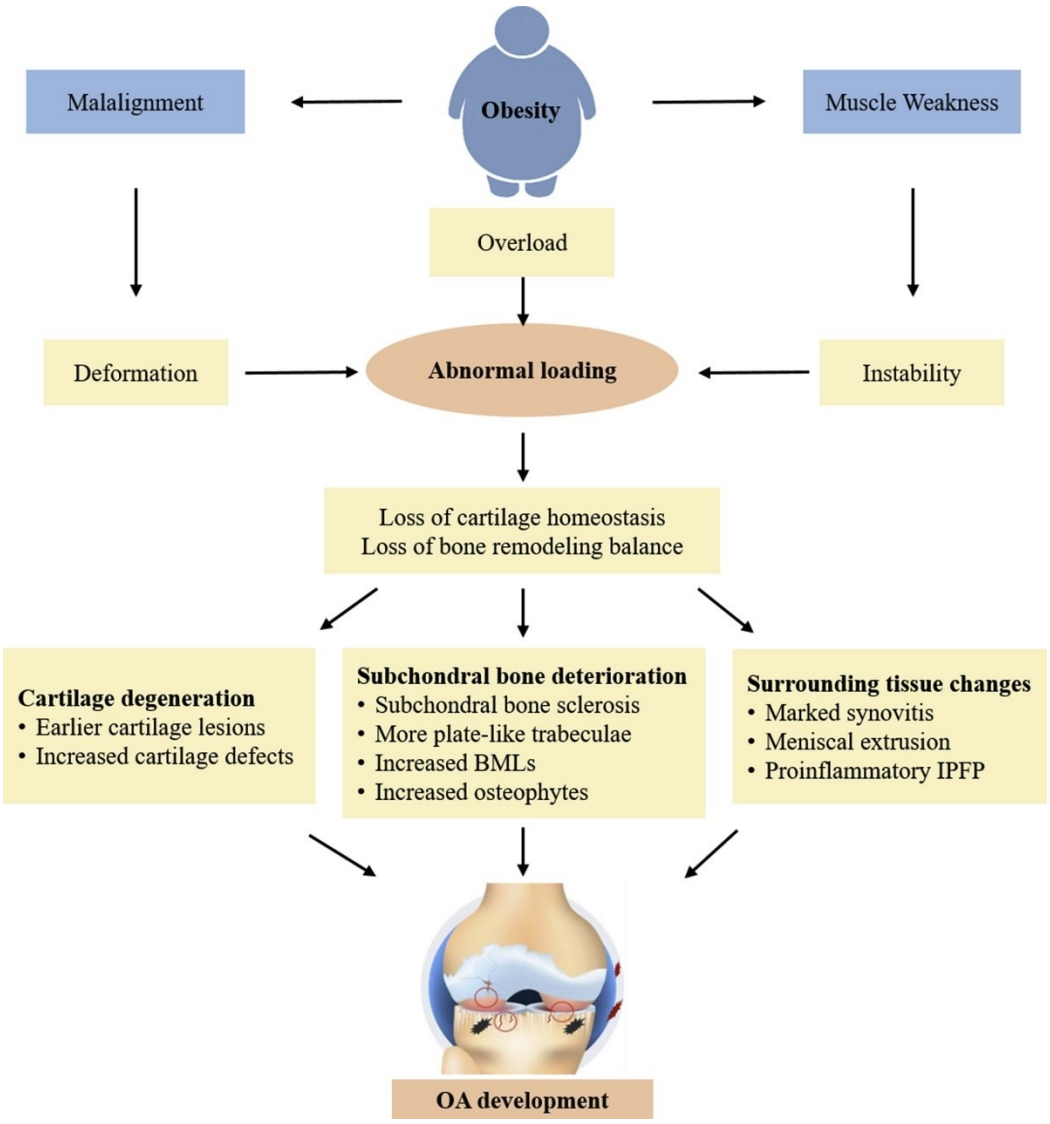


Figure 2. 1 A model of obesity-related osteoarthritis.

BMLs: bone marrow lesions; IPFP: Infrapatellar fat pad; OA: osteoarthritis

(Source: Chen L, Zheng JJY, Li G, Yuan J, Ebert JR, Li H, Papadimitriou J, Wang Q, Wood D, Jones CW, Zheng M (2020) Pathogenesis and clinical management of obesity-related knee osteoarthritis: Impact of mechanical loading. J Orthop Translat

24:66–75.) (Available under Creative Commons Attribution-Non-Commercial-No Derivatives License (CC BY NC ND) at https://doi.org/10.1016/j.jot.2020.05.001)

The genetic composition can predispose an individual to the development of OA. Various genetic factors like COL11A1, COL11A2, COL1A1, COL2A1, Interleukin- 1, 4, 6, and 17, ASP, HLA, BTNL2, and many more have also been identified which are closely linked with the occurrence of OA [81–83]. However, certain genes have been identified to have a genetic association with KOA, namely GDF5, DVWA, HLA-DQB1, BTNL2, C0G5, DUS4L, MCF2L, GLT8D, TP63, and some others [84]. A recent review has concluded that genome-wide association scan of DNA variants using alleles mapping has identified 124 single nucleotide polymorphisms that significantly correlates with higher risk of developing OA [85]. Thus, it can be concluded that individuals having one of these genes have higher chances of developing KOA.

In several studies, the history of previous trauma or injury around the knee joint has been postulated to have a direct relationship with the development of KOA. Injured joints may be susceptible to the development of KOA because of the initiation of pathogenic processes within the joint at the time of injury. These processes can be linked to long-term alterations in the way the joint is loaded and functions dynamically. [18] because of the body's defense and protective mechanism. Sustaining injuries to the anterior cruciate and medial collateral ligament (MCL) which can result in rupture and tear of ligament and meniscal, are significant risk factors for the development of KOA. [17–19]. Bone fractures proximal or distal to the knee joint also significantly impact the early development of KOA. These fractures may include tibial, femoral, fibular, patellar, and stress [86]. Webster and Hewett (2022) from their systematic review and meta-analysis concluded that ACL injury significantly increases the risk of KOA in both surgical and non-surgical cases of ACL injury [20].

Occupation-related physical activities that involve frequent sitting, and standing, prolonged standing or walking, and vigorous physical activity like sports, and athletic events predispose the individual to develop KOA at an early age [87]. Occupations that require prolonged standing or walking up, and down stairs puts the knee joint under continuous compression, which causes early degeneration of joint

cartilage, whereas weight lifting puts additional load on the knee joints that further compresses the meniscus, and may potentially damage the ACL, and MCL which may predispose the knee joint to adapt to an altered limb loading pattern [17, 88] which may further contribute to the development of OA of knee joint [71].

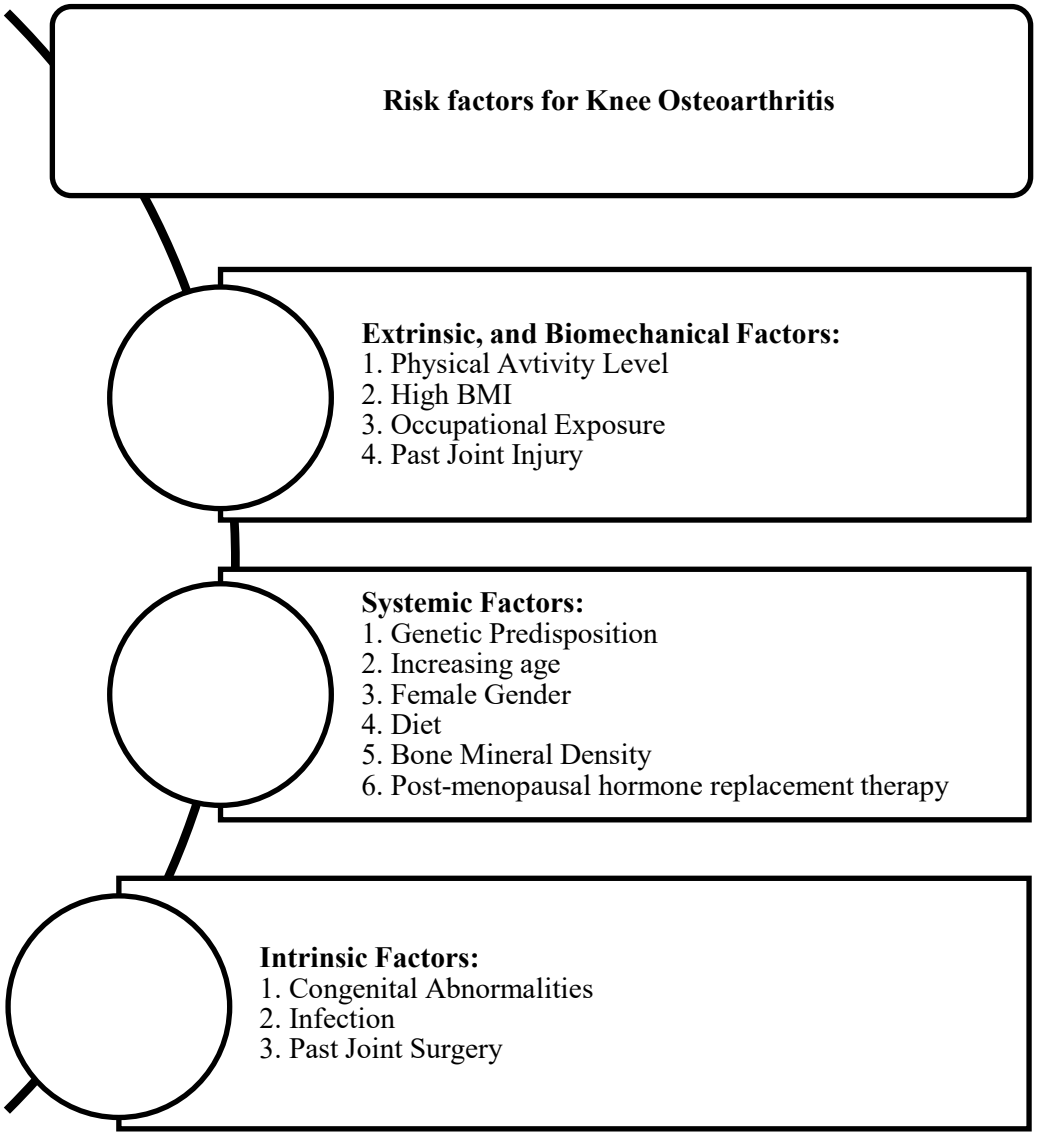


Figure 2. 2 Risk factors for developing KOA.

2.2 Clinical and Advanced Assessment

The primary indications of KOA are pain in the knee, stiffness of knee joint, and altered joint function which often worsen with weight-bearing activities such as standing and walking during the initial stage [5, 13, 14, 17, 18, 84, 89–91]. As the condition advances and cartilage loss leads to direct contact between bones, OA can result in constant pain both during the day and at night [5, 90]. Compared to other inflammatory arthritis, like rheumatoid arthritis, which is associated with prolonged morning stiffness, and worsened pain in the morning, OA is associated with stiffness that worsens by the end of the day [92]. The stiffness experienced by those with OA is referred to as "inactivity stiffness," which is different from the extended "morning stiffness" often seen in rheumatoid arthritis. In OA of joints in the lower limbs, inactivity stiffness can last for as long as 10 minutes and typically occurs when a person attempts to stand up and put weight on the joint after a prolonged period of inactivity [12, 92–95].

According to the American College of Rheumatology (ACR), clinical OA of the knee can be defined as “knee pain and at least three out of six of the following criteria: age > 50 years, morning stiffness < 30 min, crepitus, bony tenderness, bony enlargement, and no palpable warmth” [96]. On physical examination, cartilaginous crepitus or a crackling feeling can be felt on palpation of the knee with movement. As the condition progresses into later stage, a coarser bone-on-bone crepitus can be felt, where the ends of the articular bone, which have lost their cartilage, seem to rub against each other [13, 21, 30, 76, 86, 93, 97–99]. With the progression of KOA, there is frequently a noticeable reduction in the range of motion of the affected knee. The loss of cartilage within the knee joint can result in the leg becoming misaligned, with an observable varus or valgus deformity in the leg's positioning [18, 26, 90, 100]. Varus deformity commonly applies to the angulation of the knee towards the medial compartment in KOA [86, 92, 101].

Table 2. 1 The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the knee.

Clinical and laboratory	Clinical and radiographic	Clinical †
Knee pain + at least 5 of 9: - Age > 50 years - Stiffness < 30 minutes - Crepitus - Bony Tenderness - Bony enlargement - No palpable warmth - ESR <40 mm/hour - RF <1:40 - SF OA 92% sensitive 75% specific	Knee pain + at least 1 of 3: - Age > 50 years - Stiffness < 30 minutes - Crepitus + Osteophytes 91% sensitive 86% specific	Knee pain + at least 3 of 6: - Age > 50 years - Stiffness < 30 minutes - Crepitus - Bony Tenderness - Bony enlargement - No palpable warmth 95% sensitive 69% specific

ESR = erythrocyte sedimentation rate (Westergren); RF = rheumatoid factor; SF OA = synovial fluid signs of OA (clear, viscous, or white blood cell count <2,000/mm3). † Alternative for the clinical category would be 4 of 6, which is 84% sensitive and 89% specific.

(Source: R. Altman, E. Asch, D. Bloch, G. Bole, D. Borenstein, K. Brandt, W. Christy, T. D. Cooke, R. Greenwald, M. Hochberg, D. Howell, D. Kaplan, W. Koopman, S. Longley III, H. Mankin, D. J. McShane, T. Medsger Jr., R. Meenan, W. Mikkelsen, R. Moskowitz, W. Murphy, B. Rothschild, M. Segal, L. Sokoloff, F. Wolfe (1986) Development of criteria for the classification and reporting of osteoarthritis-Osteoarthritis of the Knee. Arthritis Rheum 29:1039–1049. https://doi.org/10.1002/art.1780290816.) (Permission available at:

https://s100.copyright.com/CustomerAdmin/PLF.jsp?ref=5f276151-5de3-4e84-a1db-cc41ec06f6c3 vide permission to use License Number 5605320245563)

The National Institute for Health, and Care Excellence (NICE) recommends a holistic approach to the assessment of persons with OA that includes social assessment in terms of lifestyle, and impact on life, occupational assessment in terms of ability to work, and home or workspace adjustments, the mood in terms of stress, and depression, quality of sleep, other musculoskeletal pain, altitudes to exercise, and physical activity, influence of comorbidities, and pain assessment. Nonetheless, NICE also suggests that OA can be diagnosed through clinical evaluation alone, without the need for further tests, in individuals who are 45 years of age or older, experience joint pain during

activity, and have either no joint stiffness in the morning or morning stiffness that lasts for no more than 30 minutes [21, 102].

However, to confirm the diagnosis of KOA, the clinician might recommend the patient for a radiological examination as recommended by ACR. The primary role of radiography in diagnosing OA is to evaluate the joint space width. An X-ray is most recommended for patients with suspected osteoarthritic changes in the knee joint. A knee X-ray can provide a reliable indication of KOA through the narrowing of the joint space, according to several studies [12, 17, 21, 76, 92, 97, 103] but the osteophytes can only be seen in advanced stages of KOA [22, 97, 103]. An MRI may also be recommended if the patient has severe pain to rule out other causes of pain or is in advanced stages of KOA for planning a total knee replacement surgery [21, 97, 103].

Since asymmetrical limb loading leads to altered gait mechanics, further enhancing joint degeneration [71, 104], a functional assessment. Alterations in gait mechanics significantly impact the ankle and hip joint moment, coronal arc, and range of motion. Individuals with KOA tend to have reduced range of motion and a stiffer gait pattern. [101]. Knee adduction moment (KAM) was also higher in patients with KOA compared to normal subjects [101, 105].

For assessment of limb load asymmetry, force platform, pressure platform system or advanced gait analysis lab is required, which is available in a limited number of healthcare institutions due to its heavy investment, and infrastructure requirements [69, 106]. These systems are highly accurate and considered as gold standard. The force and pressure platform can be used alone or in conjunction with motion analysis system. Force and plantar pressure platforms are primarily used for assessment of GRF and/or plantar pressure distribution between and within the foot. These platforms are expensive, bulky and can only be used in a laboratory, and they can typically record only one gait cycle. Further, the subject must be barefooted during the assessment, which is not a true representative of how the foot behaves when wearing footwear. On the other hand, a gait lab typically consists of (1) infrared video-cameras; (2) inertial sensor; (3) force platform; (4) wireless EMG; (5) data analysis and interpretation system; (6) video recording system; (7) Display screen; and (8) data acquisition system. The commercially available platform-based systems are not affordable for clinicians

since they are expensive, non-portable, require significant space, and consist of multiple components with limited walking space [73].

Figure 2. 3 BTS Gait Lab configuration. (1) infrared video cameras; (2) inertial sensor; (3) GRF measurement walkway; (4) wireless EMG; (5) workstation; (6) video recording system; (7) TV screen; (8) control station.

(Source: Muro-de-la-Herran A, Garcia-Zapirain B, Mendez-Zorrilla A. Gait Analysis Methods: An Overview of Wearable and Non-Wearable Systems, Highlighting Clinical Applications. Sensors. 2014; 14(2):3362-3394. https://doi.org/10.3390/s140203362 Available via Common Creative License: CC BY 3.0)

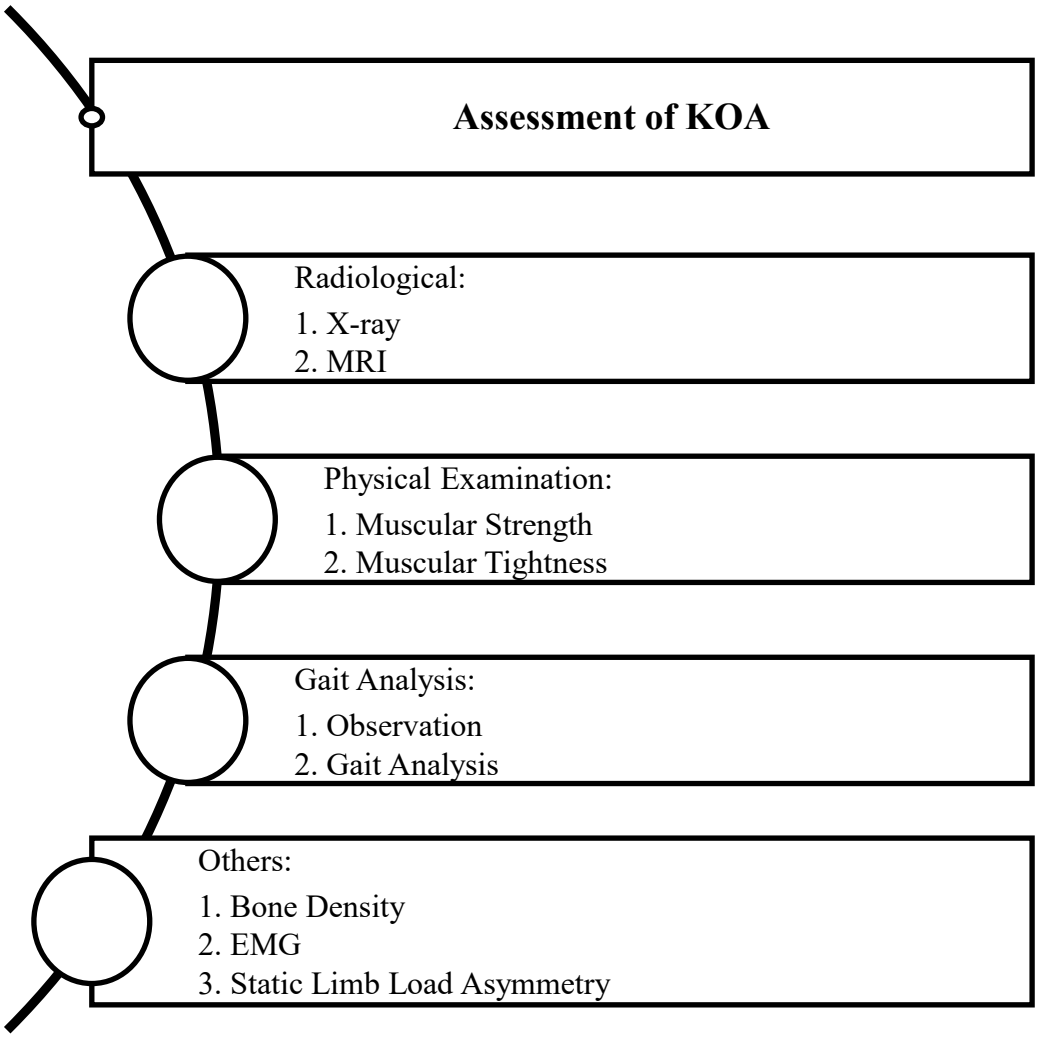


Figure 2. 4 Clinical assessments of KOA

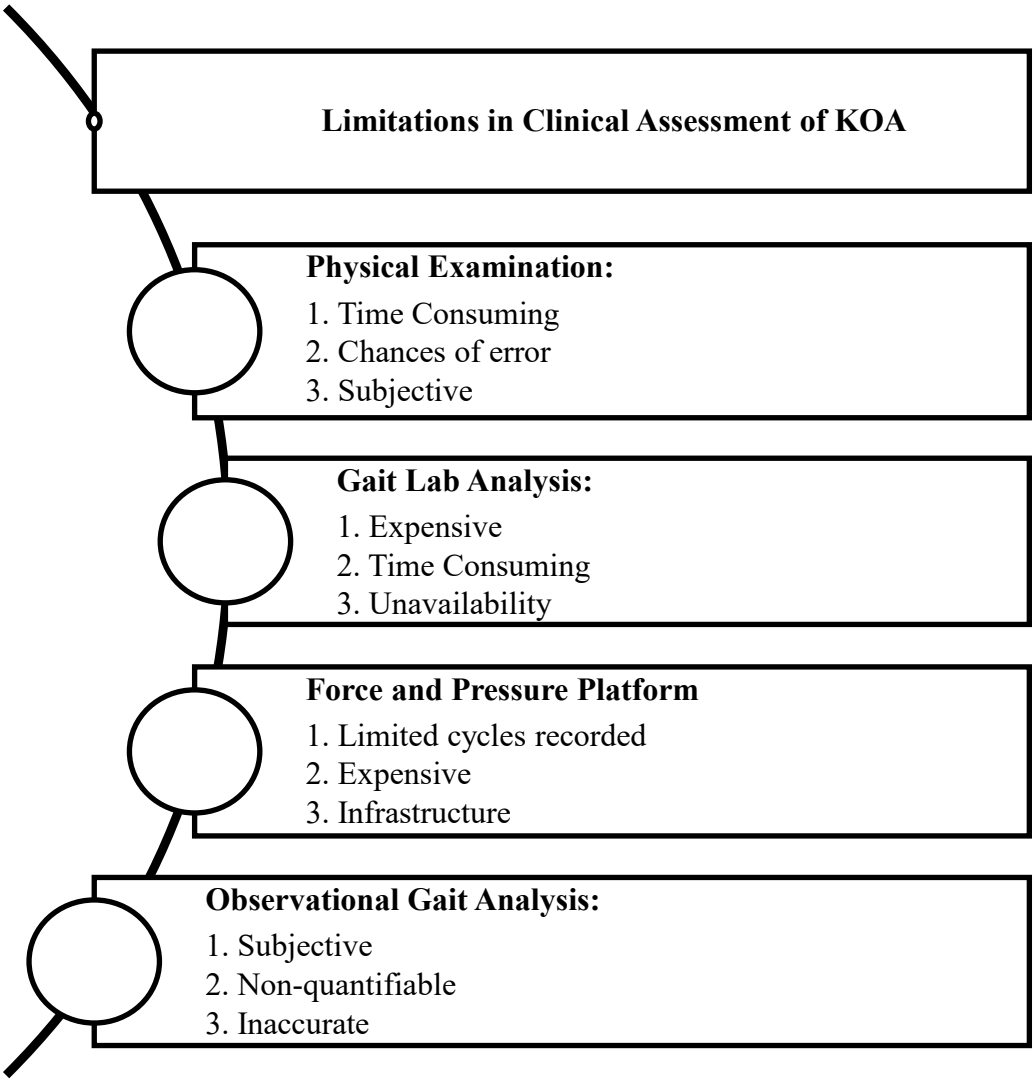


Figure 2. 5 Limitations of existing assessment approaches

2.3 Theoretical Concepts of Gait, Balance, and Limb Loading

The movement of a human body from one location to another commonly referred to as human gait is a complicated process that includes intricate interactions between the pelvis, hips, knees, and ankles. Human gait can be defined as “bipedal, biphasic forward propulsion of center of gravity of the human body, in which there are alternate sinuous movements of different segments of the body with least expenditure of energy” [107]. Normal human gait aims to facilitate translation of body from one place to another with minimum effort and maintain optimum stability in different walking conditions. To achieve stable gait, the movement of musculoskeletal system must be coordinated by a complex network of central and peripheral neural pathways [2, 108].

Determinants of Gait

Saunders et al. (1953) introduced a theory of gait that has had significant and enduring impact. Commonly known as the "six determinants of gait," the theory proposes that there are six key factors that influence how people walk. These factors include the rotation and tilt of the pelvis, as well as the flexion of the hips, knees, and ankles. Another determinant is the interaction between the knees and ankles, and the final determinant is the lateral displacement of the pelvis [109]. This theory was later contradicted when subjected to scrutiny by many researchers who concluded that it should be called kinematic features of gait [110]. In 1997, Gracovetsky developed the "spinal engine" theory of human gait, which focuses on observing and analyzing the biomechanics of the thoracic-lumbopelvic region. This theory proposes that the human body has a fundamental coupled motion mechanism that drives walking and that the lower extremities have a supportive, functional role that aligns with theories of human evolution. Gracovetsky also suggests that the legs are like "instruments of expression" that extend from the spinal engine. Essentially, the spinal engine theory posits that there is a biomechanical mechanism at the core of human ambulation and that the legs play a supportive and expressive role in this mechanism. [111].

Dynamic Walking Model

The concept of dynamic walking is a theoretical framework for bipedal motion that relies on basic dynamical models and considers behavior across multiple steps rather than just one, with the aim of understanding and enhancing stability and energy conservation during walking [112]. Dynamic walking takes advantage of the passive dynamics of the legs to drive the majority, if not all, of the gait. This approach involves the stance and swing legs moving in a pendulum-like manner, similar to a ballistic motion, and extending this motion to create a fully periodic gait. During each step, the leading leg collides with the ground, causing a redirection of the body's center of mass (COM) and initiating the next step [112–114].

Inverted Pendulum Model

The dynamic walking model establishes the applicability of how the stance phase in inverted pendulum can be used to minimize energy usage during walking by focusing on how leg works in step-to-step transition, and it establishes relationships between step length and step frequency [115–116]. The inverted pendulum is the most used model for studying the biomechanics of biped walkers [117]. Walking can be thought of as the motion of two coupled pendula as the stance leg acts like an inverted pendulum that moves around the stance foot, while the swing leg behaves like a regular pendulum that swings around the hip [118]. Typically, the motion of the mass in an inverted pendulum model is constrained to the sagittal plane, which is the plane perpendicular to the ground and contains the direction of the walker's movement [112–114, 118–119].

Stability Model

In order to maintain balance and conserve energy, it is important to keep the center of mass within the base of support. In 1985, Nashner & McCollum studied how this is achieved and identified three common strategies: the ankle strategy, the hip strategy, and the stepping strategy [120]. The theory is supported by various researchers [120–123]. The ankle strategy involves minimal movement of the hip or knee joint and instead rotates the body about the ankle joints to shift the center of mass in response to small anterior-posterior sway perturbations. The hip strategy is used for larger

perturbations and involves flexion and extension of the hips to shift the center of mass. The stepping strategy is reserved for the most significant perturbations and involves quickly realigning the base of support under the center of mass through steps, hops, or stumbles in the direction of the perturbation source [120, 123].

To maintain a stable posture, a combination of active and passive mechanisms at the muscle and spinal level, as well as visual and vestibular system, is necessary. Active torques are produced by the contraction of muscles in response to the commands send by central nervous system (CNS) and reflex mechanisms, whereas passive torques are produced by the intrinsic stiffness and viscosity of the muscle and surrounding tissues, like ligaments and tendons [108]. Researchers commonly use the Inverted Pendulum model to analyze postural sway stabilization. This model represents the musculoskeletal system as a single rigid segment that rotates about the ankle joint, influenced by the force of gravity and the net torque generated by the musculo-tendon complex surrounding the ankle joint [113, 115, 117, 122]. In this model, the total stiffness, which is the sum of ankle-joint and gravitational stiffness, must be greater than zero for local asymptotic stability. An equal weight distribution on each leg is required for a stable static or dynamic posture and uneven weight distribution can lead to postural instability [124]. Increased limb loading asymmetry in standing posture is due to the asymmetrical contribution of both legs to control [125], which may lead to an asymmetrical gait pattern [126].

Ankle Push-off Model

Based on biomechanical evidence, Zelik & Adamczyk, (2016) concluded that ankle push-off primarily affects the mechanics of the body's center of mass (COM) by increasing speed through the localized action of the push-off limb. This limb, which is responsible for generating kinetic energy, may have a small mass in comparison to the rest of the body, but its velocity change significantly contributes to the body's overall dynamics. Therefore, the movement of the limb plays a critical role in changing the body's COM and energy changes. To understand the relationship between the movement of the limb and the COM, the entire body can be viewed as a system of segments that can be divided into the push-off limb and the rest of the body [127].

Rate of Loading

The body can experience repetitive stress, and associated complications at the initial contact of the foot with the ground due to the cyclic nature of walking, and the ROL. Due to change in gait kinematics, ROL increases at initial contact and a repetitively high ROL can lead to various joint disorders like OA of hip and knee. Proprioceptive feedback signals related to limb position and movement play crucial role in understanding how the foot strikes the ground, and, thus, affects the ROL [128]. ROL can get affected if an individual tries to slow down or stops the foot before landing on the ground or if they allow the ground to stop their foot along with downward velocity or acceleration of the foot and knee joint [129]. Walking velocity positively affects coordinative stability in relative phase dynamics but not on changes in amplitude [130].

Fear Avoidance Beliefs

According to Crombez et al. (2012), individuals experiencing acute pain may follow a trajectory that leads to chronic disability and suffering, which is described by the fear-avoidance (FA) model [131]. The FA model suggests that pain-related fear triggers avoidance mechanisms that result in reduced movement and activity, which can be adaptive in the context of acute pain but harmful in the long term. Zale and Ditre (2015) conceptualized that the fear of experiencing pain, fear of pain-inducing activities, fear of movement or re-injury, and pain-related anxiety are all aspects of pain-related fear [132]. The FA model suggests that pain-related fear avoidance mechanisms result in reduced movement and activity, which can be adaptive in the context of acute pain but harmful in the long term. Long-term avoidance of physical activity can negatively affect functioning, leading to reduced participation in daily activities, increased negative mood, and physical deconditioning [133]. Hence, it is crucial to note that pain-related fear may contribute to the transition from acute injury/pain to chronic pain and disability. Overall, the FA model proposes that the mutual reinforcement of pain-related fear and avoidance behaviors may contribute to the development and progression of disability.

2.4 Altered Weight Bearing Pattern in Knee Osteoarthritis

Individuals with KOA typically presents with a history of chronic progressive joint degeneration [12]. History of pain in the knee is common in KOA, which is exacerbates with physical activity, and worsens as the day progresses. The pain can be localized to one area of knee joint or generalized to whole of knee joint [21]. It is typical to experience pain and stiffness after periods of prolonged rest, particularly in the morning [22]. Stiffness, and crepitus are also prominent features of KOA. The swelling of knee joint in KOA occurs after the formation of osteophytes and inflammation of joint synovium [21]. The weakness of knee flexor muscles (hamstrings) and extensor muscles (quadriceps) develops due to underuse of these muscle results in joint locking, and instability associated with KOA [21–22].

A longitudinal study evaluating the prevalence of pain-related avoidance of activities in early symptomatic KOA states that knee pain and low vitality were associated with a subsequent increase in avoidance of activities. This pain-related avoidance of activities was found to be linked with activity limitations not only at the onset of symptoms, but also in the years that followed [134]. The study involving Malaysian population with KOA reported that moderate to severe intensity knee pain was associated with decreased ability to perform instrumental activities of daily living (crude RR = 2.00; 95% CI = 1.29–3.11) [24]. Muscle weakness significantly contributes to the connection between avoidance and limitation of activities in KOA patients [23]. As a result of pain and fear avoidance patients with KOA tend to spend lesser time and put lesser weight on the affected leg to avoid pain. The asymmetrical limb loading between the legs leads to altered gait mechanics, and further joint degeneration. The changes in joint structure associated with KOA can cause a variety of biomechanical alterations, including alteration in weight-bearing patterns, which may contribute to the progression of the disease [26]. In KOA, The osteoarthritic changes in KOA are more frequently reported in medial compartment than the lateral compartment of the tibiofemoral joint [93, 135]. The most evident gait deviations in patients with medial KOA are increased knee adduction moments, and decreased flexion of knee joint, associated with varus alignment, and weakness of quadriceps muscles [105, 136–137].

Due to reduced knee flexion, the impact load is increased on joint cartilages [138], as seen in individuals with KOA who usually experience stiffness of knee joint during weight acceptance [136, 139]. Muscles, and ligaments around the knee joint forms the passive structures the protects the joint cartilage by regulating the fine joint motion and shear forces acting on the joint [140–142]. Nevertheless, in individuals with KOA, these passive structures are ineffective as there is excessive frontal plane laxity due to muscle weakness, and articular changes within the joint. The gait deviation stated above occurs due to the degeneration of the articular structure that results in uneven load distribution within the knee joint of the affected leg, and between the two legs.

Due to change in gait kinematics, ROL increases at initial contact and a repetitively high ROL can lead to various joint disorders like OA of hip and knee. Proprioceptive feedback signals related to limb position, and movement play a crucial role in understanding how foot strikes the ground, and, thus, affects the ROL [128]. Knee proprioception is thought to be significant for joint injury prevention since it is necessary for protection against excessive movements, stability during static posture, and movement coordination [143]. In KOA, proprioception is usually impaired in presence of pain and muscle weakness [144] which may result in increased ROL. Further, the weakness of quadriceps muscle has been associated with dynamic balance stability in the more painful KOA. The reduced proprioception and muscle strength positively correlates with static and dynamic balance and sway of center of pressure in KOA [145].

Changes in the way the knee joint bears weight and where pressure is placed during walking have been detected in the early stages of KOA. This is manifested by increased forces on the knee during contact and a displacement of the center of pressure. Dynamic loads on the joints and limbs during physical activity primarily contributes to biomechanical pathophysiology and progression of KOA [29]. As joint degeneration progresses, deviations in biomechanics of gait lead to increased overall joint loading, affecting both medial and compartments of the knee joint [30]. Compensatory movement and overloading other joints have been identified as potential predisposing factors for developing KOA [31–34].

Bilateral KOA patients exhibit significant limb load asymmetry [67]. Whereas patients with unilateral hip OA tend to put more load on the contralateral limb, which leads to early degeneration of knee joint structure due to asymmetries in dynamic joint loading at the knee associated with peak external knee abduction moment [146]. The patients with severe unilateral KOA have abnormal joint loading in both lower limbs. The knee abduction moment, at peak and mid-stance associates with the load on medial compartment, is predictive factor for development and progression of KOA [32]. In KOA, the peak abduction moment during gait is evident in the medial compartment of the knee [26, 105, 147].

In the study conducted by Robadey et al., (2018) to evaluate over-ground asymmetry in kinematic parameters in KOA subjects, it was found that 1) there is lower knee flexion in the affected limb as a result of the body's protective mechanism against knee pain; 2) during the vertical movement of the body, significantly high amount of forces act on the knee joint contributes to pain in the affected limb which causes avoidance behavior that leads to limb load symmetry; 3) shorter duration of heel-toe motion in affected limb implies a flatter landing position of foot [27], and although the ground reaction forces are not high during heel strike, increased strike pattern is evident [27, 28]. Thus, patients with KOA may prefer a faster transition from toe touch to decrease knee flexion moment and increase in rate of loading (ROL) which enhances degeneration and progression of the knee joint in KOA.

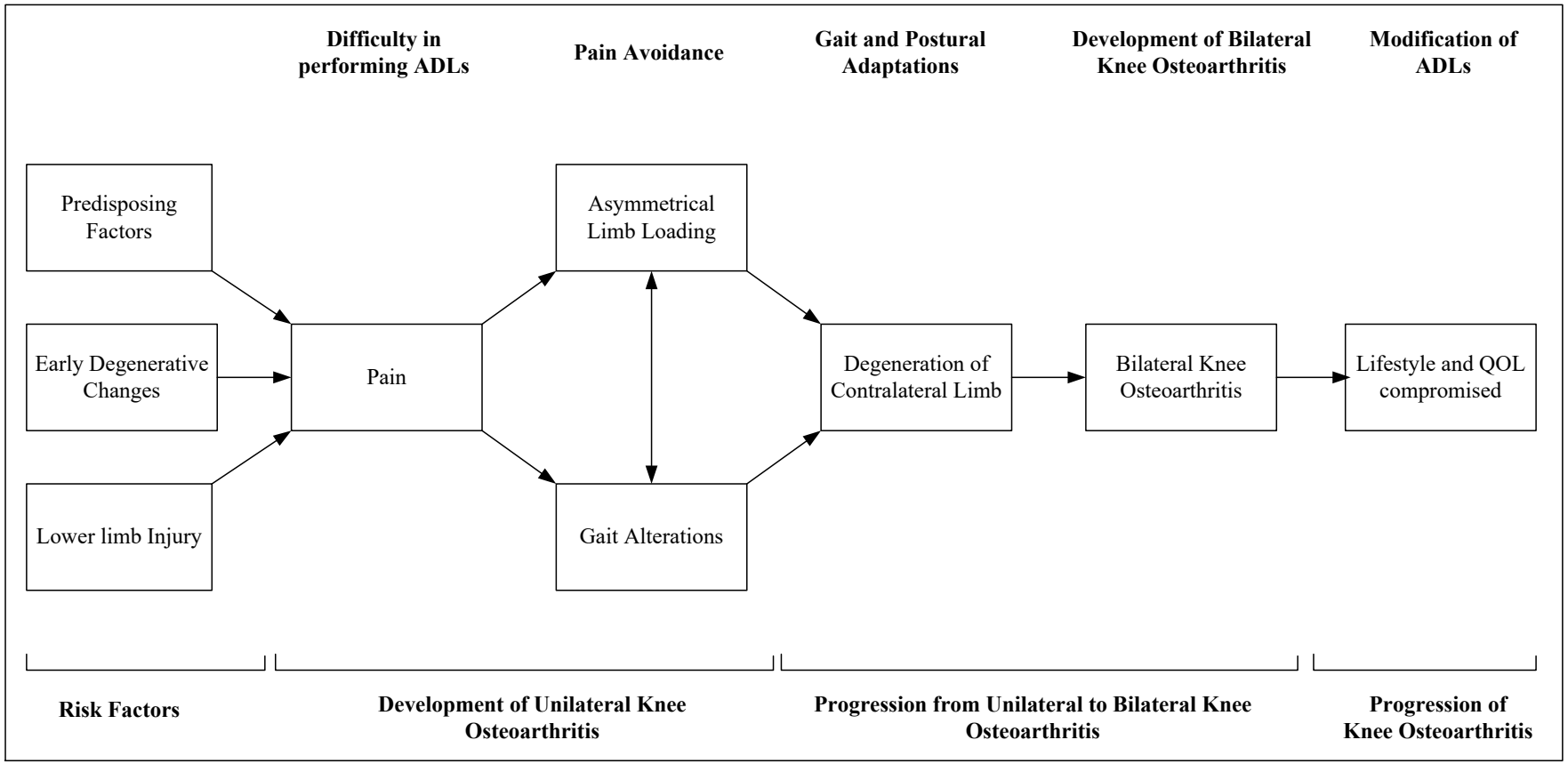


Figure 2. 6 Conceptual framework for development, and progression of knee osteoarthritis.

2.5 In-Shoe System for Limb Load and Plantar Pressure Assessment

Measuring the pressure on the sole of the foot can provide information about how the foot functions during walking, as it has to bear and adjust to changes in force direction and magnitude. This is important for analyzing a person's gait, as well as for medical purposes such as diagnosis [35–38], rehabilitation [39–41] and sports [40, 42] is widely acknowledged. There are two types of equipment used to measure limb load and plantar pressure: platform-based systems and in-shoe systems. The most common method for analyzing ground reaction force measurement is through the use of force platforms. It has a high repeatability, a wide pressure range, is sensitive to minute changes, and can record at extremely high sampling rates. However, when it comes to analyzing gait from a comprehensive perspective, force plates have some limitations. While they provide an accurate measure of force, they cannot detect the pressure on a specific area of the foot, which is a critical factor when analyzing plantar pressure. An alternative to this issue is to use an optical pedobarograph, which displays a graphical representation of pressure applied during walking in real-time. The device is highly precise and capable of detecting even minor pressure variations. Nevertheless, the device requires appropriate calibration to ensure accurate measurement of the pressure magnitude. These platforms are expensive, bulky and can only be used in a laboratory setting, and they can typically record only one or two steps, which is not enough to obtain statistically significant results [43–44]. Moreover, the subject must be barefooted during experiments, which is not representative of how the foot behaves when wearing shoes, thus limiting the data collected [45–46].

In-shoe or insole-based systems are more versatile than platform systems. Prior studies have shown the effectiveness of theses in-shoe or insole-based systems in plantar pressure measurement systems for diagnosis, rehabilitation, and daily activity tracking [42, 45–46, 54–58]. There are different brands of smart in-sole devices available in the market for plantar pressure assessment, namely F-Scan (Tekscan, Inc., Massachusetts, USA) [59], Movesole (Movesole, Paulaharjuntie 22, Oulu, Finland) [60], Walkasin (RxFunction Inc. Eden Prairie, Minnesota, United States) [61], Evalu

Run (Evalu, Munich, Germany) [62], Xsensor (XSENSOR Technology Corporation, Calgary, Canada) [63], Insole3 (Moticon ReGo AG, München, Germany) [64], and Pedar by Novel (Novel GmBH Inc., Munich, Germany) [65]. Although the sensors may operate differently, the underlying principle of these systems remains the same. In evaluating plantar pressure using these devices, a matrix of multiple sensors or sensing unit is employed to measure the force exerted on each sensor while the foot is in contact with the supporting surface. The pressure level is then determined by dividing the measured force by the known area of the sensors activated while the foot was in contact with the supporting surface. A comparison of the cost of these systems are given in Table 2.1. These devices cost 10-20 times cheaper than platform-based force and plantar pressure systems. Still, the cost of these in-shoe devices is very high for most clinicians and the public.

Figure 2. 7 Wearable in-shoe device available in market: a. Movesole, b. Walkasins, c. F-scan, d. Evalu, e. Pedar.

Source:
a. MoveSole - MoveSole n.d. https://www.movesole.com/en/ (accessed August 7, 2023).
b. Walkasins by RxFunction | A Peripheral Neuropathy Device n.d. https://rxfunction.com/ (accessed August 7, 2023).
c. F-Scan GO System | In-Shoe Pressure Measurement Foot Function Gait Analysis System | Tekscan n.d. https://www.tekscan.com/products-solutions/systems/f-scan-system (accessed August 7, 2023).
d. Finde heraus wie Du läufst - running coach | evalu n.d. https://evalu.com/ (accessed August 7, 2023).
f. Footwear pressure distribution measurement- pedar| novel.de n.d. https://novel.de/products/pedar/ (accessed August 7, 2023).

Table 2. 2 Comparison of cost of insole and platform-based system for plantar pressure and limb load assessment.

S. No.	Name and country	Type	Price	Price (INR)
1	Pedar, Novel, Germany [65]	Insole Based	27809 Dollars	23,01,041
2	F-scan, Tekscan, US [59]	Insole Based	> 250000 Dollars	20,69,125
3	WalkinSense, Kinematix, UK [148]	Insole Based	Commercially unavailable	NA
4	Stridalyzer Prism Insole, ReTiSense, Delaware [149]	Insole Based	699 Dollars	57,838
5	Stridalyzer Forceplate Sensor Board, ReTiSense, Delaware [149]	Insole Based	999 Dollars	82,661
6	Move Sole, Finland [60]	Insole Based	Commercially unavailable	NA
7	Runvi, Germany [62]	Insole Based	Commercially unavailable	NA
8	OpenGo, Moticon, USA [64]	Insole Based	1895 Dollars	1,56,800
9	XSENSOR, Canada [63]	Insole Based	Unavailable	NA
10	Force Plate Quattro Jump, Kristler, Switzerland [150]	3-axis force plate	25000 - 30000 Dollars/ Force plate	20,69,125 - 24,82,335 per Force plate
11	AccuPower-O, AMTI, USA [151]	3-axis force plate		
12	Bertec Force Plate FP4060-08, Bertec Corporation, USA [152]	3-axis force plate		
13	GAITRite Platinum Plus Classic, GAITRite, USA [153]	Baropodometric	25815 Euros	22,79,412
14	WinTrack, Medicapteurs, France [154]	Baropodometric	9000 Euros	7,94,681
15	Strideway, Tekscan, USA [155]	Baropodometric	25000 Dollars	20,69,125
16	Pasport, Pasco Scientific, USA [156]	2-axis force plate	1525 - 2127 Dollars	1,26,185 – 1,75,997
17	Force Platform Biosignalsplux, Plux biosignals, Portugal [157]	1-axis force plate	2750 Euros	2,42,819
18	Bilateral Force Plate, Hawkins Dynamic, USA [158]	1-axis force plate	5000 Dollars	4,13,722

2.6 Conceptual Framework

From the current literature review, it is evident that various external, and internal factors affect the limb loading pattern, and gait parameters in KOA. The Global Burden of Disease study reported that the KOA affects nearly 263.08 million people globally, with a higher prevalence among females. The history of knee pain is common in knee osteoarthritis, which is exacerbated by physical activity and worsens by the end of the day. The pain severity severely affects the ability to perform activities of daily living and participate in physical activity. As a result of pain and fear avoidance, patients with knee osteoarthritis tend to spend less time and put less weight on the affected leg to avoid pain. This asymmetrical limb loading between the legs leads to altered gait mechanics and vice-versa, which furthers joint degeneration. Joint alignment alteration can result in cartilage destruction and subchondral bone sclerosis. In addition, several potential biomechanical alterations may occur due to the changes in joint structure, leading to altered weight-bearing patterns and contributing to the further progression of knee osteoarthritis. As structural degeneration progresses, alterations in gait mechanics lead to increased overall joint loading, affecting the medial and lateral compartments of the knee. Compensatory movement and overloading other joints have been identified as potential predisposing factors for developing knee osteoarthritis. The pain and modifiable risk factors should be reduced to correct these changes. Further, early diagnosis, limb load asymmetry and spatiotemporal gait parameter should be given importance in clinical practice along with corrective exercises for these changes. Limb load asymmetry, the earliest clinical manifestation in KOA, is the key to prevention, diagnosis, and disease progression prevention. This framework recommends early assessment of limb load asymmetry in all individuals with predisposing factors of knee osteoarthritis to prevent the development and progression of knee osteoarthritis.

For assessment of these parameters force platform, baropodometry or an insole-based system is required, which is very expensive, limitedly available, and mainly used for research purposes but not in general practice. So, due to the lack of such technology, early diagnosis of these changes is impossible. Therefore, it can be said that there is a great need for a low-cost wearable device that is small, light, and portable for

assessment. The development of such wearable device can be achieved in the following steps:

1. The clinical profile of KOA patients' needs to be verified.
2. The current needs of technology in the assessment of KOA are to be identified.
3. Based on the need assessment, new technology/devices should be developed
4. The reliability of the new device should be tested.
5. The validation of new devices against the gold standards

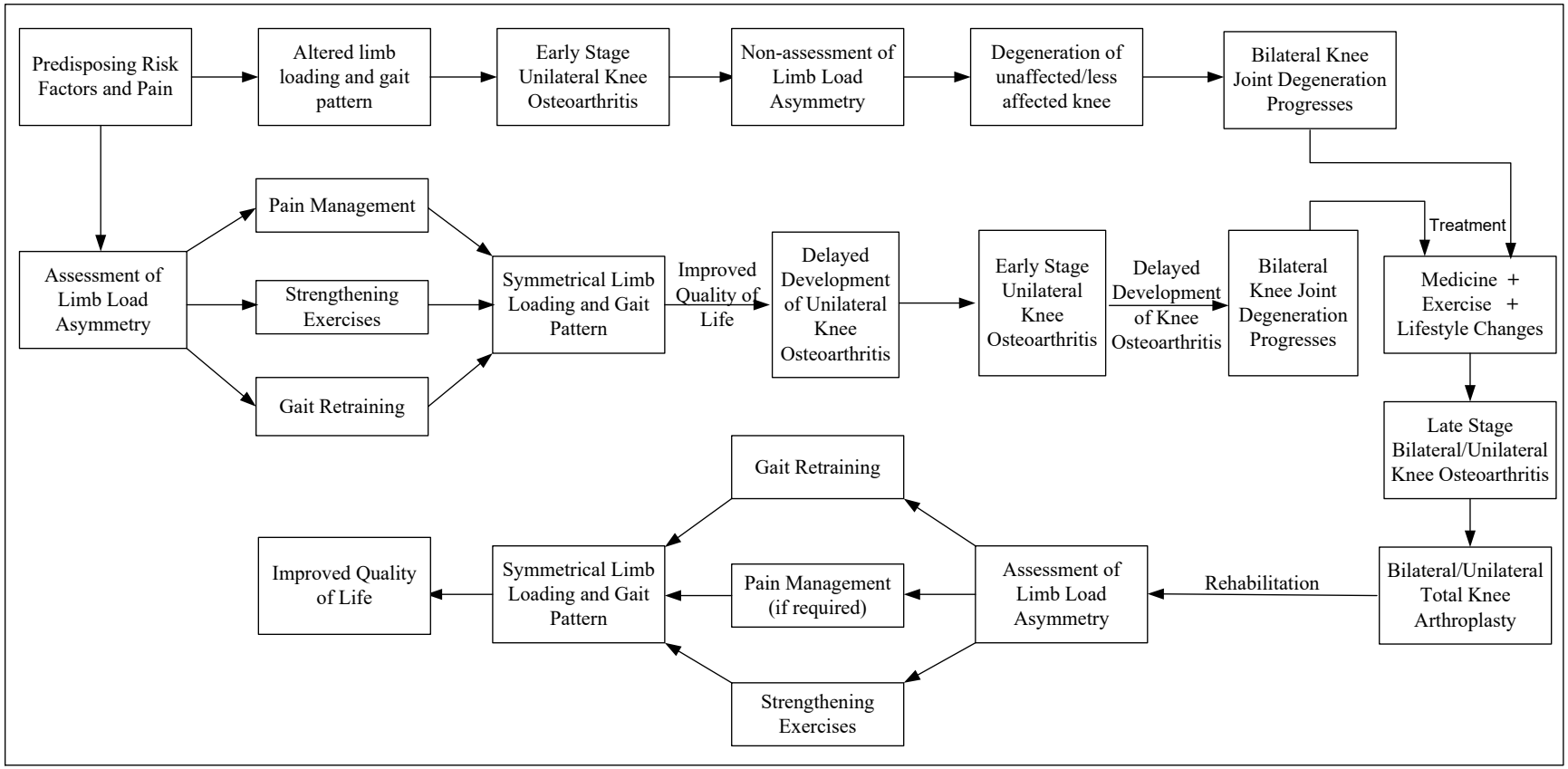


Figure 2. 8 Conceptual framework for assessment, prevention, and management of knee osteoarthritis based on limb load asymmetry.

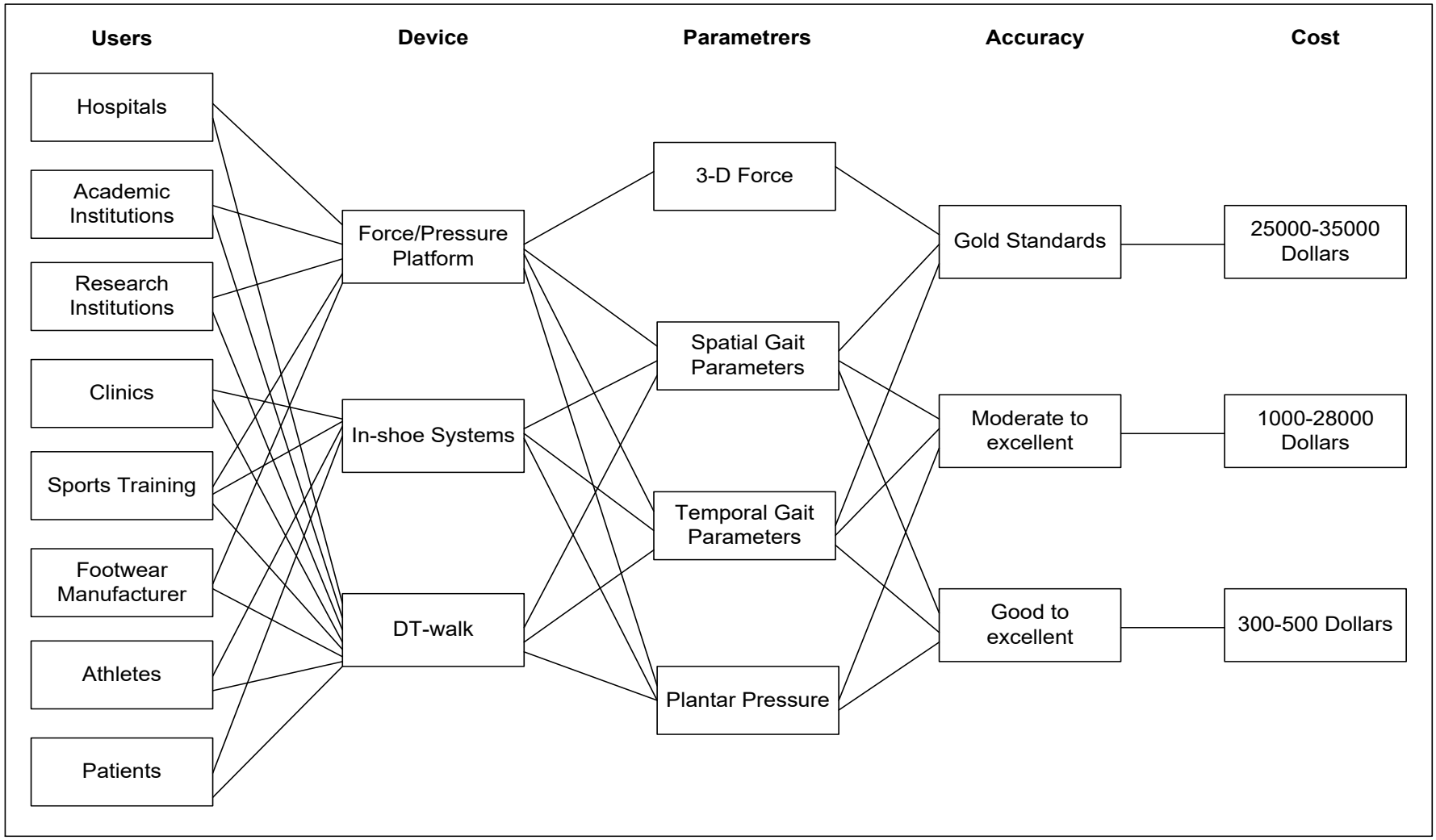


Figure 2. 9 Relative applicability and cost effectiveness of DT-walk.

CHAPTER III

METHODOLOGY

Overview

This chapter aims to provide the outline for the methodology used in this study. The study was conducted in four phases. The first phase was designed to identify and discuss the clinical problems in KOA with the focus group, and to develop the device based on the focus group's recommendations. The second phase was designed to evaluate the prevalence of asymmetries in limb loading, plantar pressure, and spatiotemporal gait parameters in KOA. The third phase was designed for development of DT-walk. The fourth phase was designed to assess the validity, and reliability of DT-walk against gold standards. Each phase has its methodology, which is explained in this chapter.

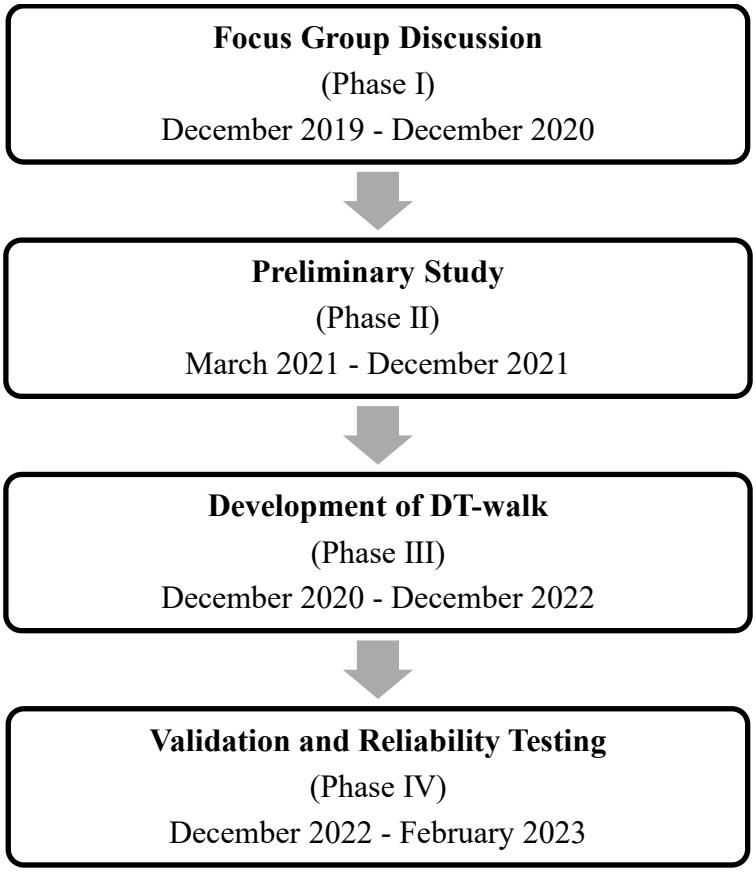


Figure 3. 1 Phases of this study

3.1 Focus Group Discussion (Phase I)

Based on the literature review, we understand the fact that there is a need for a new wearable technology for the assessment of limb load asymmetry in KOA. A focus group discussion was conducted to conceptualize the need, content, structure, and design of the DT-walk based on clinician's perspective. Finally, based on the recommendations made by the focus group regarding the needs, content, structure, and design of the alpha prototype, a functional prototype was made in collaboration with the Division of Research and Innovation, Lovely Professional University.

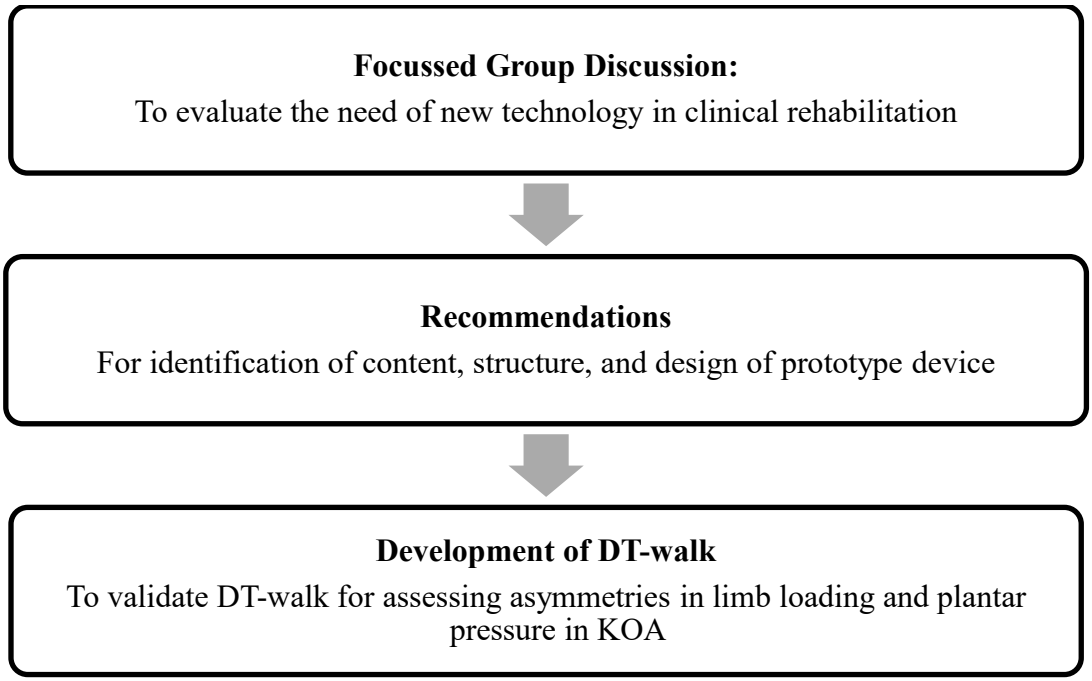


Figure 3.2 Components and outcomes of the need assessment study

The focus group discussion was planned with a panel of clinical experts. Focused group discussion was conducted between August 2020 and October 2020 via an online video-conferencing platform like Google meet or Zoom meetings. The FGD included twenty-four physiotherapists working at different clinics, hospitals, and academic institutions in one of the three focus group discussions where each discussion included six – eight participants. Focused group discussion covered different aspects of KOA, including prevalence, clinical features, assessment techniques, and treatments available for KOA.

The primary focus of this discussion was on the clinical assessment of asymmetrical limb loading, which ultimately leads to alteration in gait patterns and the strategies or technologies being used in clinical practice for such assessment in patients with KOA. Secondly, this discussion was focused on assessment and rehabilitation techniques or technology they use in clinical practice. How effective is the current approach? Is there any need for new technology? What kind of technology do they want to see in the future? What parameters should be incorporated in such devices?

Methodology

Study Design: Qualitative Study Design using Focus Group Discussion (FGD).

FGDs were used for generating information on collective views, and the meanings that lie behind those views. It is useful in generating a rich understanding of participants' experiences and beliefs [159].

Study population: Physiotherapist

The study population included only the physiotherapists working in a clinical setting with a minimum experience of three years for homogeneity of samples based on the guidelines given by Morgan (1997) and Krueger (2002) [159–160].

Sample Size: Twenty-four

Based on the recommendations for group size of focused group discussion given by [159, 161, 162], the optimal focus group size should include six to ten participants, and an additional 20% non-participants who would miss the discussion. A total of three focus group discussion sessions were conducted to identify the key themes.

Study Location: Online video-conferencing platform

It was conducted via video-conferencing platforms like Google meet or Zoom meetings. The participants can join the discussion from their own location at the scheduled time of the meeting.

Procedure

The focus group discussion was conducted based on the guidelines given by [159] for planning, observation, analysis, and reporting a focus group discussion. The focus group discussion required a moderator and an assistant moderator. The researcher took the role of moderator, and an assistant moderator was appointed who assisted the moderator in the discussion, took notes, and recorded audio and video of the whole session.

Due to the prevailing COVID-19 pandemic, the FGD was conducted online mode via cloud meeting. The potential participants were approached via email and personalized text message with an invitation to participate in one of the three FGDs. All the participants provided consent via Google form prior to taking part in the study. A total of 29 physiotherapists had consented to participation in the FGD, out of which four physiotherapists could not make it to the FGD, and the remaining 25 physiotherapists participated in one of the three FGD sessions conducted via online videoconferencing. Ultimately, 25 physiotherapists with a minimum experience of three years in treating KOA with good English communication skills volunteered to participate in this study. The duration of each discussion was between 90 and 120 minutes. Two moderators (AA and SR) facilitated the discussion based on a semi-structured topic guide.

Table 3.1 shows the flow of discussion with associated questions. At the start of each focus group discussion (FGD), an introduction was given to explain the discussion format and rules, followed by a guarantee of confidentiality for all exchanged information. The discussion objectives were thoroughly clarified, along with the definitions of KOA and wearable technology. To aid in later analysis, each FGD session was recorded on video and transcribed verbatim. The thematic analysis of the FGD was performed individually by the two moderators, and the outputs were cross-checked for validity before the results were categorized. Key themes were identified from which concepts were derived, and these themes were used to compare responses between focus groups and to map and interpret data. The physiotherapists' responses were organized into different themes and concepts using Microsoft Excel spreadsheets.

Table 3. 1 Semi-structured topic guide for focus group discussion

1. Introduction • Moderators, and participants introduce themselves. • Setting the ground rules, and format of discussion, and its aim • Confidentiality Assurance
2. Knee Osteoarthritis • Definition- KOA • What is their opinion about KOA and its prevalence in our society? • What is the most common complaint of patients with KOA from their perspective? • Do they think the assessment of limb load asymmetry is important in KOA? • How do they assess limb load asymmetry? • What are the challenges with the current technologies?
3. Wearable technology • Definition- wearable technology • Ask if they know or use any wearable devices or have seen a demonstration of any developed prototype. • Ask if they like wearable technology, and, if so, why: o Would you use it? o How often would you like to wear it? • Ask what they do not like about wearable technology, and if so, why? o What would put you off from using such technologies? • Ask if they know of any alternative to wearable sensor technology.
4. Feelings about wearable medical technology • How are they doing in general in dealing with KOA? • Do they think wearable technology would help their patient's situation? If so, how? • How do they view this technology in comparison to conventional forms of treatment? And why? • Do they see themself using this kind of technology? If so, how? • Would they use this technology for monitoring their patient's rehabilitation practice from their home rather than going to clinical practice?
5. Features & Functionality • What features would they like to include in such a device for KOA? • What parameters would you like to include in such a device for KOA?
6. Impact on relationships • If they did decide to use this technology, how do they think it would impact their clinical practice? • Do they think it would change how they interact with patients? • What are their views on data privacy?
7. Closing • Is there anything else they would like to say about what we have discussed? • What are their expectations from the new technology, and its cost? • Summarize the discussion. • Thank everyone for their time, and participation

An invitation, along with the objectives of the focused group discussion, was sent via email to the physiotherapists working in a rehabilitation facility to participate in the discussion. They were asked to give their consent electronically via email/personal message for participation in the focus group discussion. Once consent was received from all the participants, the structure of the focus group discussion was finalized. In this study, three sessions of focused group discussion were conducted. The first focus group discussion was guided in the identification of current approaches used in clinical practice, problems being faced in assessment and training, and the need for technologies for the future- their design, content, and structure. The successive sessions of focus group discussion were helpful in confirming of structure, content, and design of the future device.

Before the commencement of the discussion, all the necessary preparation were done, including the selection of a suitable online video-conferencing platform, selection of participants, presentation, and video recording. The background details of each participant, including demographic details, area of interest, specialty, experience, and informed consent stating their willingness to participate actively, were collected. As soon as the discussion started, the assistant moderator began the audio and video recording of the session and took notes from the discussion.

During the discussion, the moderator addressed the participants with a warm welcome note and briefing about the purpose of this focus group discussion and set out the discussion rule. The moderator initiated the discussion with the set of questions he had prepared in advance based on the objective of the focus group discussion. One by one, the question was presented before all the participants, and the response of each participant for each question was recorded as they discussed. All the participants were encouraged to express their views and concerns that were relevant to the core objectives of the discussion. At the end of discussion, the moderator thanked all the participants for their valuable time in participation and comments.

Immediately after the end of the discussion, the moderator and the assistant moderator debriefed the contents of the discussion and labeled and stored the recorded data document, audio, and video files in a password-protected storage device. The moderator and assistant moderator prepared a report on the outcomes of the focus group

discussion. The successive focus group discussions were conducted based on the findings of the first focus group discussion. In a similar manner, successive focus group discussions were scheduled and conducted via videoconferencing with a different group of participants.

Data Analysis

The comments of each participant were recorded and carefully analyzed using systematic and verifiable methods. The focus group discussions were analyzed thematically using Microsoft excel, based on the framework given by Gale et al., (2013) for the analysis of qualitative data in multi-disciplinary health research [163]. For quantitative analysis of qualitative data, the data has to go through multiple stages, which include transcription, familiarization, coding, development of an analytical framework, application of the analytical framework, and summarization.

To transcribe accurately, a high-quality audio recording was necessary, and the transcripts generated were formatted with wide margins and line spacing to allow for future annotations and coding. It was crucial to become familiar with the entire interview by utilizing the audio-video recording, transcript, or other notes taken during the focus group discussion to interpret the content effectively. After gaining familiarity with the discussion, the researcher carefully reviewed the transcript line by line and applied codes or paraphrases to convey their interpretation of the text. Following the coding process, the researcher developed a practical analytical framework that was utilized to analyze the complete data. The transcript, coding, and analytical framework were then applied to Microsoft Excel, and the analysis was conducted. The focus group discussion was summarized, and recommendations were generated based on the findings of the analysis [164].

3.2 Prevalence Study (Phase II)

The preliminary study was conducted understand the extent to which limb load asymmetry and gait parameters are affected in KOA, a preliminary study using the WinTrack system is required. The preliminary study evaluated the prevalence of limb load asymmetry and biomechanical deviations among KOA patients using WinTrack system based on the basic framework given by Smith et al., (2015) for carrying out a preliminary study [165].

Methodology

Research Design: Cross-sectional Study

To evaluate the prevalence of limb load asymmetry and spatiotemporal gait changes in KOA was conducted using a cross-sectional study design.

Study Population: KOA

Patients with the diagnosis of KOA were included in the study.

Sampling Method: Purposive Sampling

Since this was a prevalence study, no randomization was required. Therefore, all the samples meeting the selection criteria were included in the study.

Sample Size: 95

The total sample size for this study was calculated using G*Power version 3.1 [166] using a two-tailed t-test for the correlation point biserial model with an effect size of 0.3, error prob 0.05, and power of 0.8, which was 82. Considering 15% dropouts (including both those who enrolled but couldn't come on the day of the assessment and those who came for the assessment but could not complete the assessment due to some other health problem) in the total sample, 13 more samples were included in the study. Therefore, the total sample size comes out to be 95, which was included in this study (Figure 3.2).

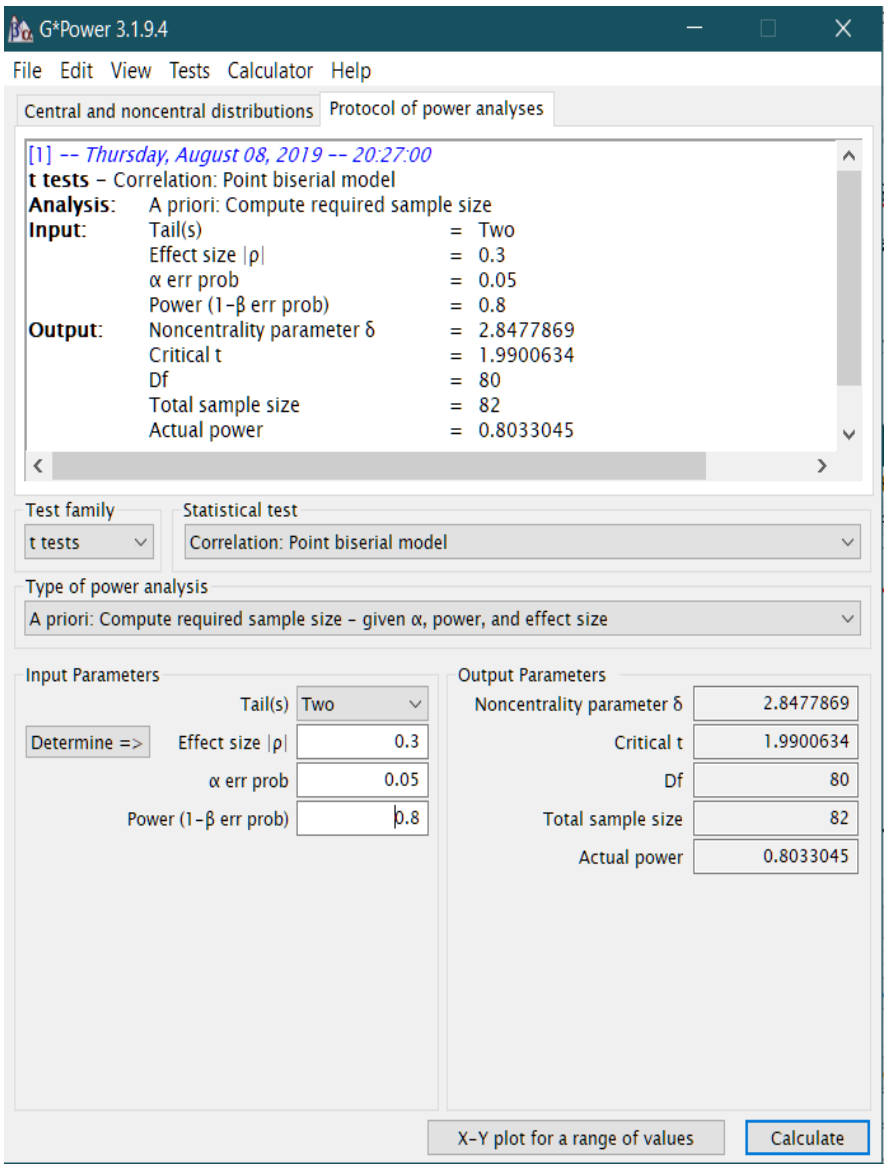


Figure 3. 2 G*Power Package Software program displays the statistical power, effect size, and alpha for the sample size used in the calculation. The calculated total sample size is displayed in the Protocol of power analyses.

Selection Criteria:

Inclusion Criteria:

- Fulfilment of American College of Rheumatology criteria for diagnosis of knee osteoarthritis.
- Gender: Both males, and females

Exclusion Criteria:

- Injury to the leg (< 6 months)
- History of fracture in lower limb
- Deformities of the spine and lower limb
- Musculoskeletal disorders of the trunk and upper limb
- Diagnosed cases of cardiac arrhythmias
- Diagnosed cases of Neurological Disorder
- Diagnosed cases of Psychosomatic Disorder

Study Location: Physiotherapy OPD, Uni Hospital, LPU, Phagwara

Patients coming to Uni Hospital, and Physiotherapy OPD of Lovely Professional University were asked to participate in the study and were included after getting the signed consent from them.

Equipment: WinTrack platform, Laptop with WinTrack Software, Weighing scale, and Stadiometer.

The assessment of limb loading, and spatiotemporal gait parameters was performed using the Win-Track platform (Medicapteurs Technology, France) which is a valid and reliable tool for these assessment barefooted [167]. The platform has a dimension of 1610 mm × 652 mm × 30 mm (length/width/height). It has a thickness of 9 mm, and it has a total of 12 288 sensors of resistive type. Each sensor has a dimension of 7.8 × 7.8 mm^2, with an acquisition frequency of up to 200 images/s. The WinTrack data accusation software allows the clinician to upload the assessment data to a computer on which it is installed, and it automatically identifies the footstep and calculates the parameters in three modes static, dynamic, and postural. The WinTrack system

provides the clinician with quantitative information about the patient's static loading, plantar pressure, postural instability, and spatiotemporal gait parameters.

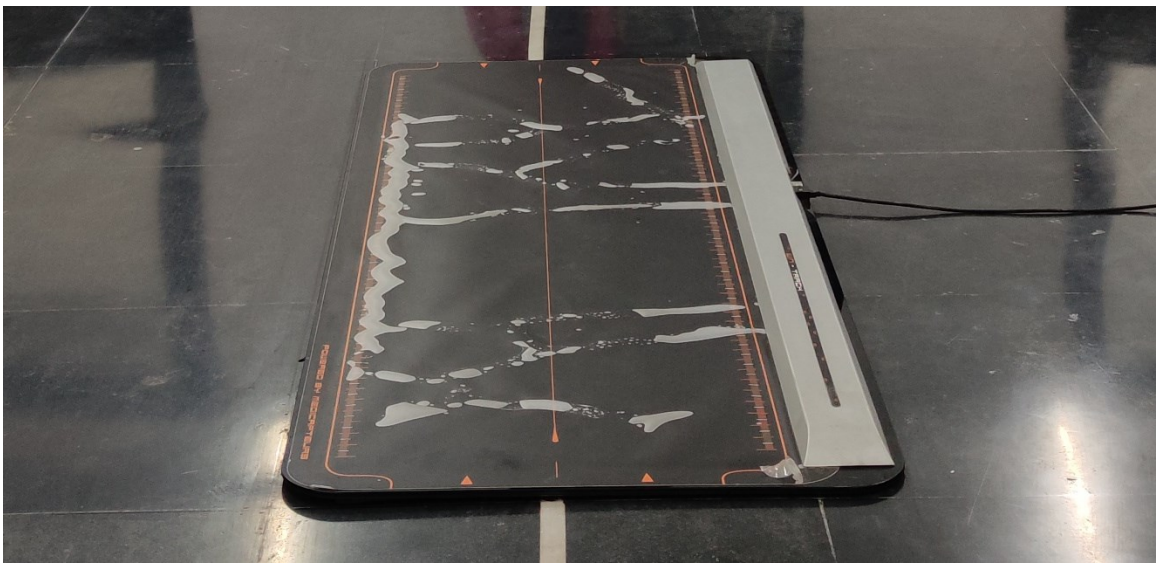


Figure 3. 3 WinTrack platform

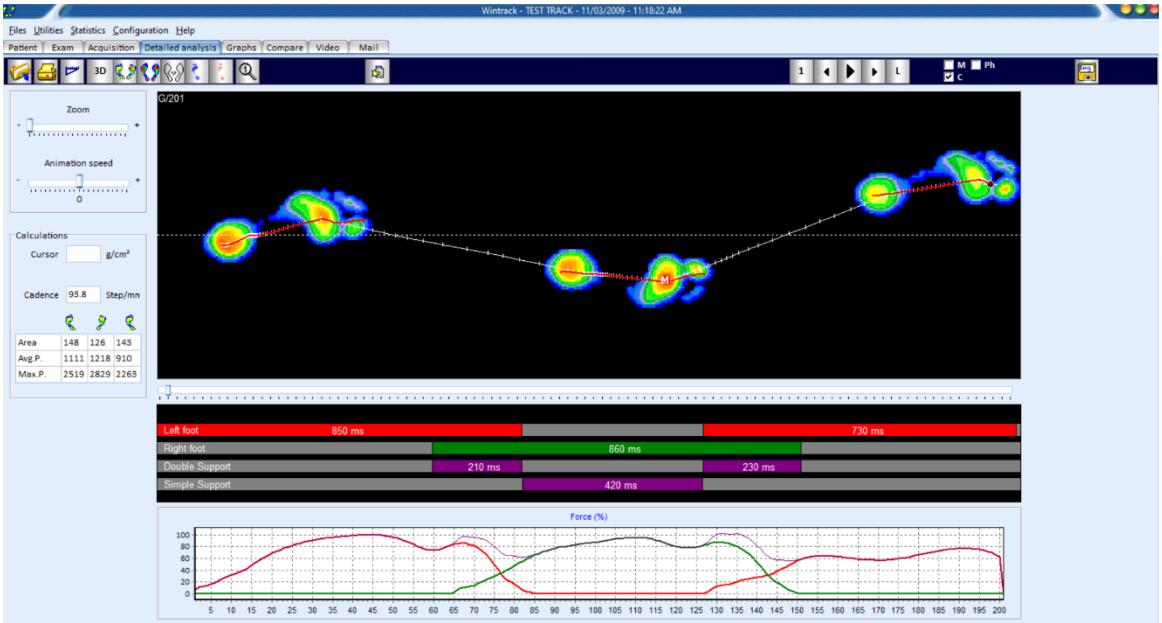


Figure 3. 4 WinTrack application for data acquisition from WinTrack platform.

Figure 3. 5 Computers with Wintrack application.

Figure 3. 6 Stadiometer and weighing scale used in the study.

Outcome measures:

Temporal

Swing Duration- left (ms), Swing Duration- right (ms), Stance Duration- left (ms), Stance Duration- right (ms), Step Duration- Left (ms), Step Duration- Right (ms) and Stride Duration (ms).

Spatial

Step Length- Left (mm), Step Length- Right (mm), Gait Velocity (m/s) and Stride Length (mm).

Load Distribution

Limb Load- Left (kg), Limb Load- Right (kg), Maximum Plantar Pressure- Left (kPa) and Maximum Plantar Pressure- Right (kPa).

Asymmetry

Limb Load Asymmetry (%), Step Length Asymmetry (%), Step Duration Asymmetry (%), Swing Phase Asymmetry (%) And Plantar Pressure Asymmetry (%).

Procedure

Samples were selected based on the inclusion and exclusion criteria (self-reported based on medical record). Subjects fulfilling the inclusion criteria were asked to participate in the study. The aims and objectives of the study were explained to them. The procedure was explained to the patients to make them understand the importance of the study and how they will benefit from it. Patients were asked to give their consent for participation in the study. After getting consent from the patient, the general assessment was done. Then the patient was taken to the lab for assessment where we explained the assessment procedure and showed them what the data looks like on the system interface. The assessment outcome was explained to each patient and relevant self-care exercises and measures were explained to them post assessment.

For the assessment of spatial and temporal parameters of gait using WinTrack, a certain procedure recommended in the user manual needs to be followed. Firstly, the WinTrack platform needs to be placed on the floor; then, a start/end line was marked on the floor. The WinTrack platform was connected to a computer on which the WinTrack analysis application was installed. Then a new case was created for each subject, and the basic information like name, age, gender, foot size, weight, and height were fed into the system for each subject, and the data acquisition system was turned on and activated. Secondly, subject preparation was done that included an explanation of the procedure, and they were instructed to stand by the start/end line as marked on the floor and wait for instructions. Thirdly, the patient was asked to follow the instruction during the analysis process while the data was being stored, and the data acquisition profile was generated in a sequential manner that included assessment of static limb load, dynamic limb load, spatiotemporal gait parameter, and postural instability (Figure 3.7).

In this study, the WinTrack platform was used to record static loading and 3-step gait. In static loading assessment, the platform records the position of the foot, weight, and plantar pressure distribution between and within the foot. The participants were instructed to stand barefoot on the platform in their natural posture and look ahead to assess the static loading. The static data was recorded once the participant confirmed their position. For the assessment of the gait parameters, the platform records the first

3 steps of gait once the participant steps on the platform. The start and end points were marked on the floor 2 meters from the edge of the platform to get more accurate and natural gait data. The participants were instructed to stand barefoot with both feet at the start mark and start walking in their natural pattern and pace while looking ahead. Each participant was administered six trials according to multiple dynamic assessment protocol of the WinTrack software wherein they were required to place their dominant foot on the platform and take at least three consecutive steps. The best-recorded gait cycle of the six trials was selected for analysis. On successful completion of the procedure, the patient was thanked for his cooperation. Home exercise rehabilitation protocol was explained to the participants for their knee pain and gait asymmetries. The same procedure was followed for all (n=95) of the patients recruited in this study.

Figure 3. 7 Use of WinTrack system for assessing limb load and spatitemporal asyemmetry.

The system recorded the following gait variable: single stance (%), cadence (steps/minute), step duration (ms), double stance duration (ms), swing duration (ms), stride duration (ms), step length (mm), gait cycle length (mm), area (cm^2) covered by

the first, second, and third footsteps, and average, and maximal plantar pressure (kPa) under the foot during the first, second, and third step of the foot on the platform. Based on variables recorded by the WinTrack system, additional calculations were made to calculate, namely dynamic interlimb maximum pressure difference (kPa), interlimb swing phase duration difference (ms), interlimb step duration difference (ms), interlimb step length difference (mm), step length asymmetry (%), step duration asymmetry (%), and plantar pressure asymmetry (%).

The calculations were made as follows:

1. Dynamic Interlimb Maximum Pressure Difference (DIMPD):

$$\text{Dynamic Interlimb Maximum Pressure Difference (kPa)} = Max.Pressure_{\ Left} - Max.Pressure_{\ Right}$$

Where, Max. Pressure $_{\text{Left}}$, and Max. Pressure $_{\text{Right}}$ are the maximum pressure exerted on the left and right foot, respectively, during walking.

2. Interlimb Swing Duration Difference:

$$\text{Interlimb Swing Duration Difference (ms)} = Swing\ Duration_{\ Left} - Swing\ Duration_{\ Right}$$

Where, Swing Duration $_{\text{Left}}$ and Swing Duration $_{\text{Right}}$ are the duration of the swing phase of the left and right foot respectively, during walking.

3. Interlimb Step Duration Difference:

$$\text{Interlimb Step Duration Difference (ms)} = Step\ Duration_{\ Left} - Step\ Duration_{\ Right}$$

Where, Step Duration $_{\text{Left}}$ and Step Duration $_{\text{Right}}$ are the duration of the left and right steps respectively, during walking.

4. Interlimb Step Length Difference:

$$\text{Interlimb Step Length Difference (mm)} = Step\ Length_{\ Left} - Step\ Length_{\ Right}$$

Where Step Length $_{\text{Left}}$ and Step Length $_{\text{Right}}$ are the length of the left and right steps, respectively, during walking.

5. Step Duration Asymmetry:

Step Duration Asymmetry (%)

$$= \left(\frac{\sqrt{(Step\ Duration_{\ Left} - Step\ Duration_{\ Right})^2}}{Step\ Duration_{\ Left} + Step\ Duration_{\ Right}} \right) * 100$$

where, Step Duration $_{\text{Left}}$ and Step Duration $_{\text{Right}}$ are the duration of the left and right steps respectively, during walking.

6. Step Length Asymmetry:

Step Length Asymmetry (%)

$$= \left(\frac{\sqrt{(Step\ Length_{\ Left} - Step\ Length_{\ Right})^2}}{Step\ Length_{\ Left} + Step\ Length_{\ Right}} \right) * 100$$

where, Step Length $_{\text{Left}}$ and Step Length $_{\text{Right}}$ are the length of the left and right steps, respectively, during walking.

7. Plantar Pressure Asymmetry:

Plantar Pressure Asymmetry (%)

$$= \left(\frac{\sqrt{(Max.Pressure_{\ Left} - Max.Pressure_{\ Right})^2}}{Max.Pressure_{\ Left} + Max.Pressure_{\ Right}} \right) * 100$$

where, Max. Pressure $_{\text{Left}}$, and Max. Pressure $_{\text{Right}}$ are the maximum pressure exerted on the left and right foot, respectively, during walking.

8. Limb Load Asymmetry:

$$\text{Limb Load Asymmetry (\%)} = \left(\frac{\sqrt{(Limb\ Load_{Left} - Limb\ Load_{Right})^2}}{Limb\ Load_{Left} + Limb\ Load_{\ Right}} \right) * 100$$

where, Limb Load $_{\text{Left}}$ and Limb Load $_{\text{Right}}$ are the weight under left and right foot, respectively, during standing.

9. Swing Phase Asymmetry

Swing Phase Asymmetry (%)

$$= \left(\frac{\sqrt{(Swing\ Duration_{\ Left} - Swing\ Duration_{\ Right})^2}}{Swing\ Duration_{\ Left} + Swing\ Duration_{\ Right}} \right) \times 100$$

The data acquired for all the samples were calculated using the above formula to evaluate asymmetries in static loading, step duration, step length, and plantar pressure.

Statistical analysis

The data was 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 also first analyzed descriptively to evaluate the prevalence of asymmetry in limb loading and spatiotemporal gait parameters among patients with KOA based limb involvement. The main outcome measure obtained from this cross-sectional study was prevalence, which can be calculated using the following equation:

$$\textbf{Prevalence} = \frac{\textbf{Number of cases in a defined population at one point in time}}{\textbf{Number of persons in a defined population at the same point in time}}$$

The data were then analyzed statistically for correlation between the prevalence of limb load asymmetry and asymmetries in spatiotemporal gait parameters in patients with KOA, and the risk factors, namely age, gender, obesity, and history of trauma, using the test for correlation of co-efficient to measure how strong a relationship is between two variables. This helped us understand the relationship between patient profile, limb load asymmetry and spatiotemporal gait deviations in KOA. One of the most used formulas for assessing correlation of co-efficient in statistics is Pearson's correlation coefficient formula, which can be calculated using the following equation:

$$r = \frac{n(\sum xy) - (\sum x)(\sum y)}{\sqrt{[n\sum x^2 - (\sum x)^2][n\sum y^2 - (\sum y)^2]}}$$

where, r = Pearson's correlation coefficient, n= number of samples, x, and y are variables.

3.3 Development of DT-Walk (Phase III)

Based on the recommendations of the expert panel from the focused group discussion, an outline for the development of the prototype was made. The prototype development outline includes information related to the assessment parameters to be incorporated, the type of technology to be used, and the applicability of the device for other areas. The device outline was explained to the technical experts- Dr. Rajesh Singh and Mr. Prabin Kumar Das, Division of Research and Innovation, Lovely Professional University regarding the needs, demands, and applicability of the new device mentioned below:

- The DT-walk should address clinical issues like scarcity of low-cost assessment technology, thereby helping in early diagnosis of the asymmetries in limb loading and gait.
- The device should assess limb loading pattern, limb load asymmetry, foot mapping, arch index, arch type, and spatiotemporal parameters of gait.
- The DT-walk should be easy to use, a product that is wearable, lightweight, portable, and cost-effective, and it should have storage and cloud computing abilities.
- The device should be useful for clinicians, patients, and trainers for real-time assessment, feedback, and telemonitoring.

Based on framework for health-related wearable device development and recommendations regarding the structure, contents, and design of the prototype of the DT-walk, the device was developed in collaboration with technical experts.

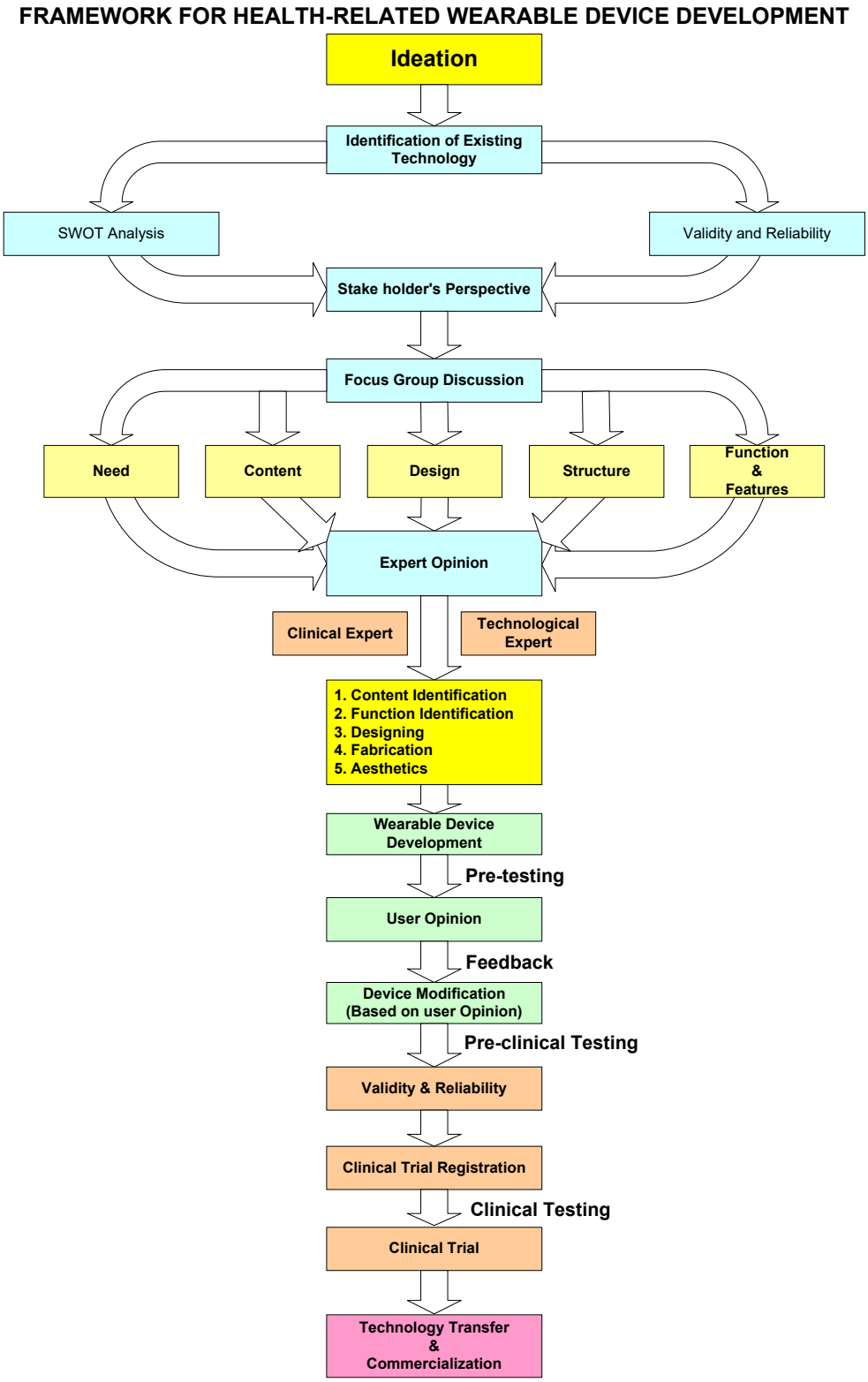


Figure 3. 8 Framework for health-related wearable device development

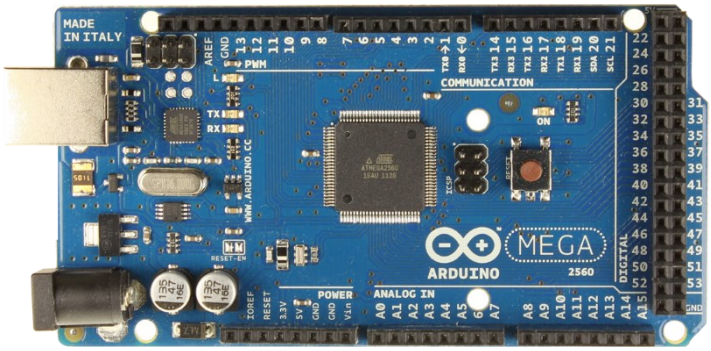
Development Team:

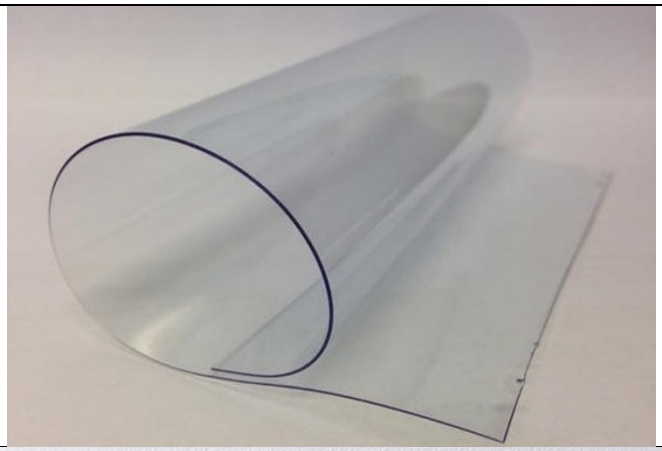
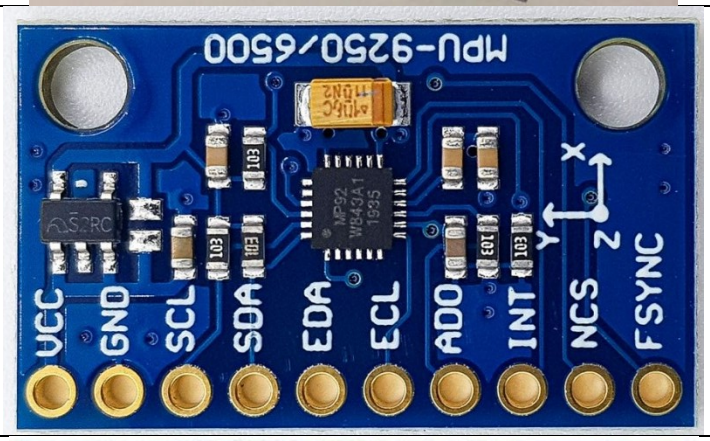
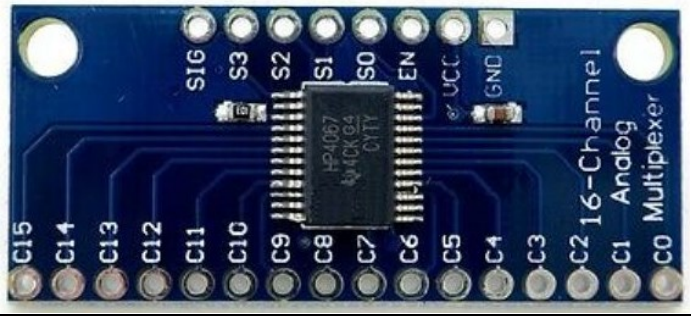
1. Amber Anand
2. Dr. Suresh Mani
3. Dr. Senthil NS Kumar
4. Dr. Rajesh Singh
5. Prabin Kumar Das

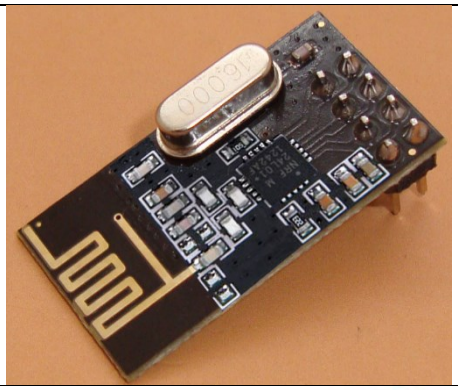
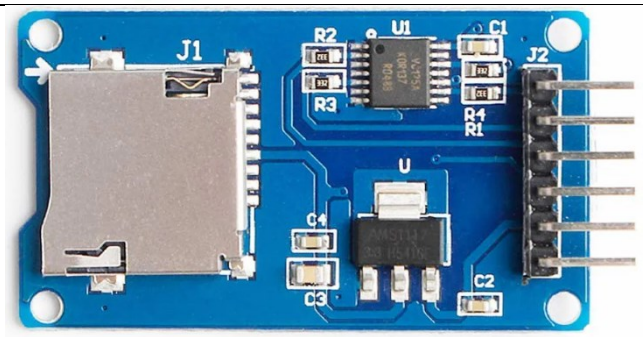
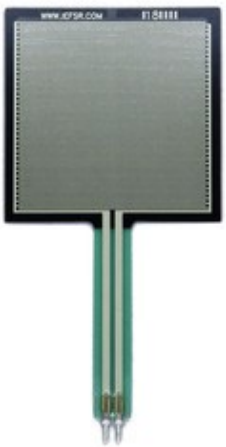
Study Location: Innovation Studio, Block 39, Lovely Professional University

Equipment:

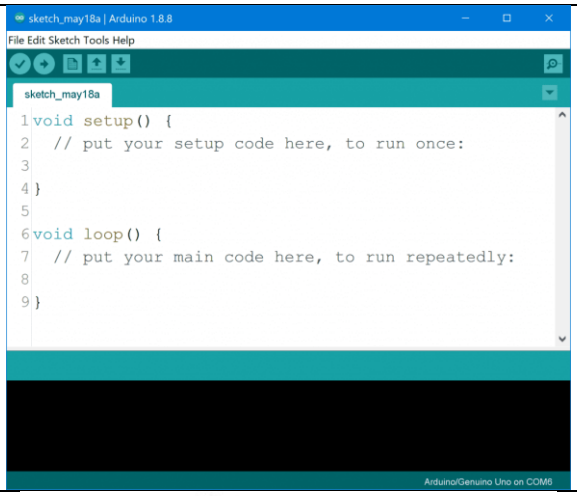
Table 3. 2 Equipment used in development of DT-walk.

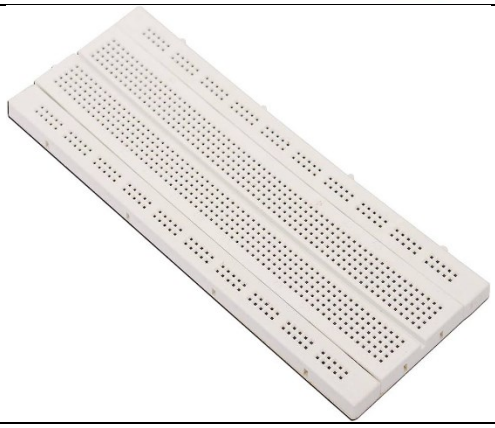
S. No.	Equipment	Image
1.	Microcontroller-Arduino Mega 328	
2.	Velostat-Adafruit	

3.	Copper tape- Sparkfun	
4.	Insulating layer	
5.	Inertial Motion Unit sensor- MPU 9250	
6.	16-channel multiplexer	

7.	Wi-Fi communication module- Sunrom	
8.	Rechargeable battery- Samsung 3.7 volts battery	
9.	SD card module	
10.	Force-sensitive resistor sensor	

11.	Flexible wires	
12.	Solder	
13.	Solder paste	
14.	Solder element	

15.	Hot air gun	
16.	Laptop	
17.	Arduino application	
18.	Heat Shrink Sleeve Tube	

19.	Wire cutter	
20.	Breadboard	

Procedure:

The development of DT-walk device was carried out in the Innovation Studio, Block 39, Lovely Professional University under the supervision of Dr. Rajesh Singh. The device development was a continuous process which faced many ups and downs and was developed based on trial-and-error method. Eventually, the prototype of DT-walk was developed. Detailed development procedures and outcome is explained in result section.

Description of DT-walk

The DT-walk is an insole-based wearable device which consists of a custom-made pressure-sensitive matrix made up of one layer of velostat sheet sandwiched between two layers of copper strips. One layer of copper strips is placed in the horizontal direction, and the other layer in the vertical direction. Each cross-sectional area formed by the velostat and copper layers act as a pressure-sensing unit. This results in a lightweight, flexible, and high-resolution insole that can be worn and carried easily. Additionally, a separate layer consisting of five force-sensitive resistors was placed at key locations on the plantar surface of the foot for accurate gait phase identification.

For spatiotemporal gait parameters, two inertial motion sensors with attitude and heading reference system (AHRS) were also incorporated into our device for accurate spatial and temporal gait detection.

3.3 Validation and Reliability Testing of DT-walk (Phase IV)

A validation and reliability study were conducted to evaluate the efficacy of DT-walk in assessment asymmetries in limb loading and spatiotemporal parameters of gait among KOA patients as compared to the gold-standards WinTrack system, based on the basic framework given by Smith et al. (2015) for carrying out validity, and reliability of the instrument [165]. The WinTrack system was selected for assessing the validity primarily due to its valid assessment capabilities [167], similar assessment outcome measures as DT-walk and in-house availability of the equipment. The registration of the validity and reliability study in the Clinical Trial Registry India (CTRI) was done prospectively vide CTRI number- CTRI/2023/01/048920.

Methodology

Research Design: Cross-Sectional Study

A cross-sectional study design was followed for validation and reliability study. Although many researchers suggest that the validation study is itself a separate design, no specific procedure and design have been formalized. So, for the validation and reliability of the developed prototype device against the gold standards, a cross-sectional study design was be followed.

Study Population: KOA

Patients with the diagnosis of KOA were included in the study.

Sample Method: Purposive sampling

Since this was a single-group cross-sectional study, no randomization was required. Therefore, all the samples meeting the selection criteria were included in the study.

Sample Size: 9 (Nine)

Based on the guidelines by NATO, 2018 for validation, and verification of quantitative and qualitative test methods, a minimum of seven replicate measures should be taken [168]. Considering a dropout of 20 %, two more subjects were added to the sample. Thus, a total of nine subjects were included for validation and reliability testing in this study.

Raters: Two

Two qualified physiotherapists with experience of at least three years in a clinical setting.

Selection Criteria: The samples were selected based on the following criteria:

Inclusion Criteria:

- Fulfilment of American College of Rheumatology criteria for diagnosis of knee osteoarthritis.
- Gender: Both males, and females
- Shoe size- 7 (Due unavailability of additional prototype device of different sizes)

Exclusion Criteria:

- History of fracture in lower limb
- Deformities of the spine and lower limb
- Musculoskeletal disorders of trunk and upper limb
- Diagnosed cases of cardiac arrhythmias
- Diagnosed cases of Neurological Disorder
- Diagnosed cases of Psychosomatic Disorder

Study Location: Uni Hospital, LPU, Phagwara

Patients coming to Uni Hospital, and Physiotherapy OPD of Lovely Professional University were asked to participate in the study and were included in the study only after getting consent from them.

Study Tools/Equipment:

- WinTrack System
- DT-walk
- Laptop with DT-walk application
- Laptop with WinTrack application
- General assessment and consent form
- Tripod Stand
- Patient information sheet

- Digital camera

Outcome measures:

- Limb load asymmetry
- Plantar pressure asymmetry

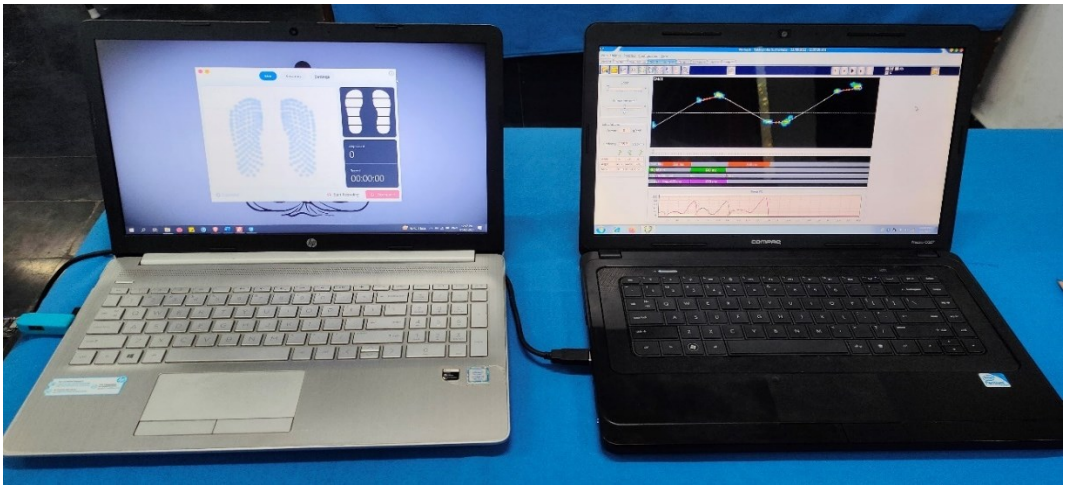


Figure 3. 9 Computers with DT-walk and Wintrack application.

Figure 3. 10 Stadiometer and weighing scale used in the study.

Figure 3. 11 DT-walk device.

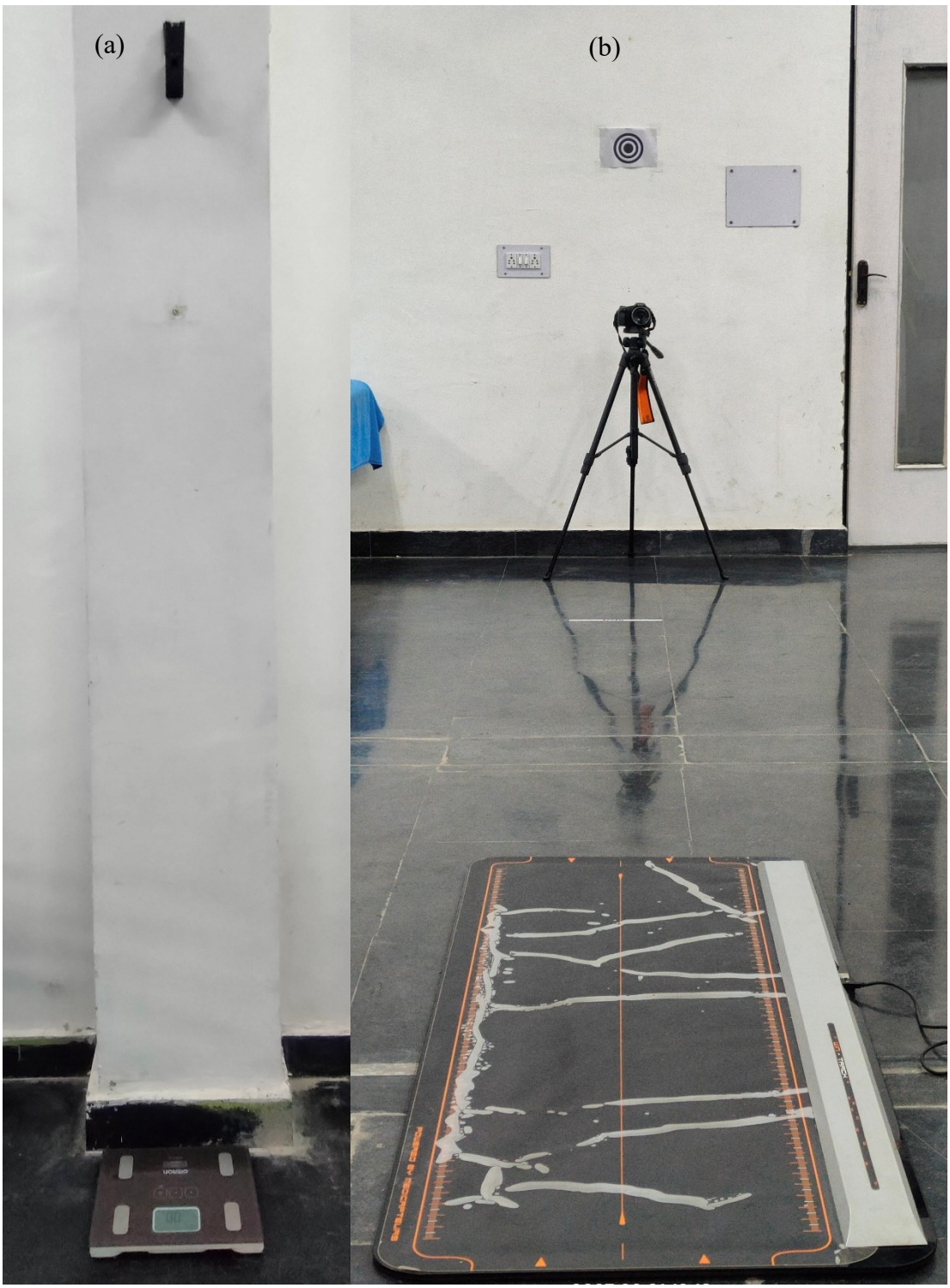


Figure 3. 12 Placement of (a) stadiometer and weighing scale, and (b) WinTrack and tripod with camera used in this study.

Procedure

The samples were selected based on the inclusion and exclusion criteria (self-reported based on medical record). Individuals who met the requirements for participation in the study were invited to take part and were requested to provide their consent to participate in the study. Then the study procedure was explained to the patient, and a general assessment was performed, followed by preparation for assessment of limb load asymmetry using WinTrack System and DT-walk for validity and reliability.

Initially, 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 walk while wearing DT-walk. Sample data were collected for each participant for at least two repetitions. For intra-rater reliability, a five-meter-long walkway was marked on the floor. The researcher applied DT-walk on the patient's foot and connected it with the DT-walk application. The patient was asked to stand close to the starting point marked on the floor and wait for instructions. The researcher then asked the patient to walk through the walkway and reach the end point marked on the floor while data was stored and analyzed. Rest for about 15-20 minutes was given to the patient, and then the patient was asked to walk again through the walkway from the start point towards the end point while data was stored. Similarly, the data was collected for nine samples, and the data collected from the first and second assessment were analyzed for the reliability of the DT-walk.

For inter-rater reliability, a five-meter-long walkway was marked on the floor. Two physiotherapists performed the assessment test using DT-walk on the same patient at an interval of 15-20 minutes. The application process for applying DT-walk was explained to both physiotherapists. The first physiotherapist applied the DT-walk on the patient and connected it with the DT-walk application. Then, the patient was asked to stand close to the starting point marked on the floor and wait for instructions. The physiotherapist then commands the patient to walk through the walkway toward the endpoint and stop while the data was collected by the DT-walk application in real-time. After that, the physiotherapist removed the DT-walk from the patient's body, and the patient was given a rest of 15-20 minutes. After rest, the second physiotherapist applied DT-walk to the patient in a similar manner, and take the assessment, and recorded the

data. The data collected by the two therapists were analyzed for the inter-rater reliability of DT-walk.

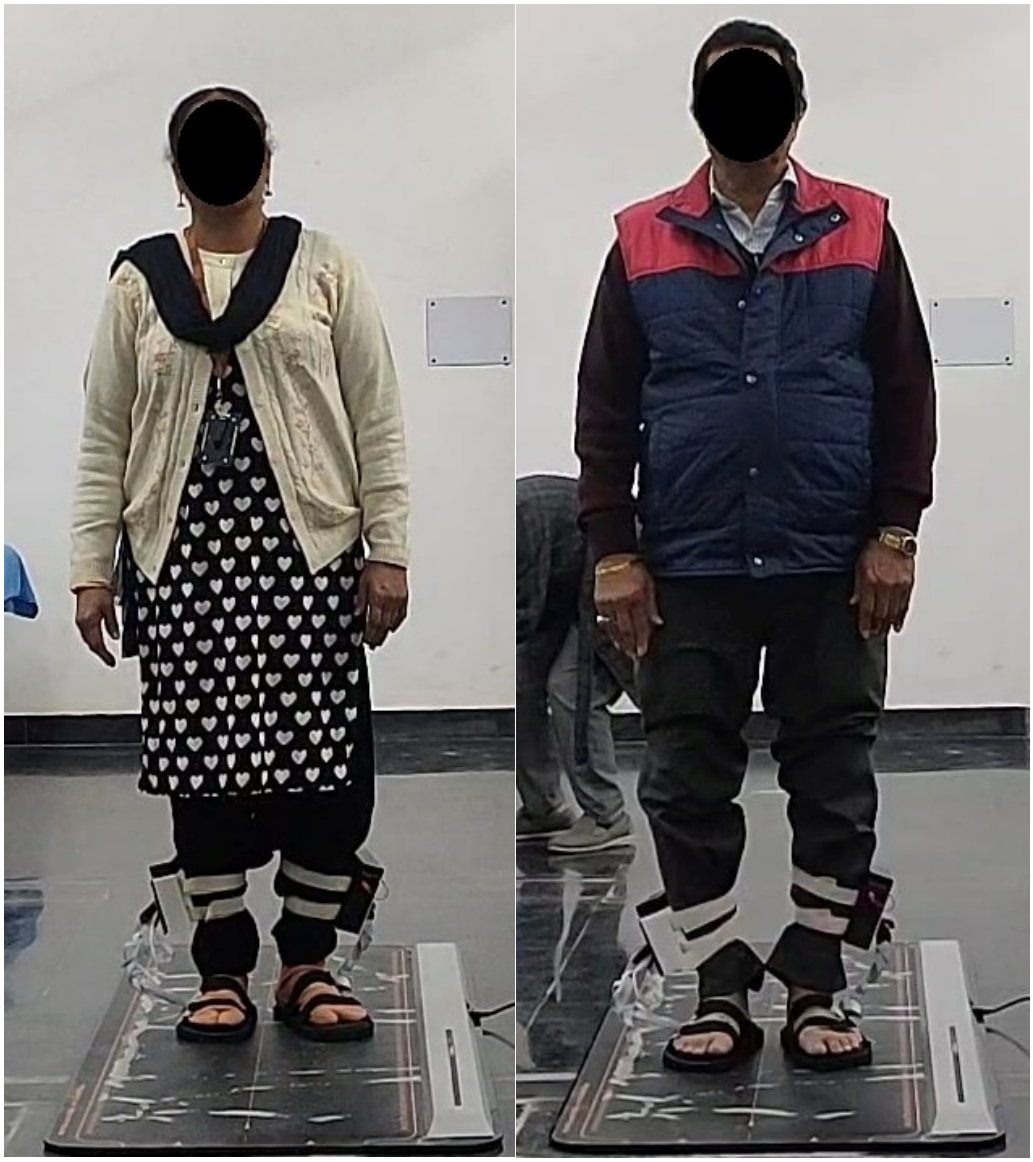


Figure 3. 13 Application of DT-walk device on patient's leg while standing on WinTrack platform for validity and reliability testing of DT-walk in standing position.

For validity, the patient was prepared for the assessment using WinTrack as done in the preliminary study, and the data was collected in a similar manner for six trials according to multiple dynamic assessment protocol of the WinTrack software for each patient. A walkway was marked on the floor of the same length as that of the WinTrack platform. After an interval of 15-20 minutes, the physiotherapist applied DT-walk on the patient

and connected it with the DT-walk application. The patient was asked to stand close to the starting point of the walkway and follow the instruction. The physiotherapist then instructed the patient to walk through the walkway from the starting point to the endpoint while data was collected for three repetitions for each patient.

Figure 3. 14 Application of DT-walk device on patient's leg while standing on WinTrack platform for validity and reliability testing of DT-walk while walking.

At the end of the assessment, outcome was explained to each patient and relevant self-care exercises and measures were explained to them.

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 also first analyzed descriptively to evaluate the prevalence of asymmetry in limb loading and plantar pressure asymmetry among patients with KOA based on criteria like age, gender, obesity, and limb involvement. Data related to outcome measures were analyzed statistically to evaluate the validity and reliability of DT-walk for the assessment of limb load and plantar pressure asymmetry as compared to the gold standards among patients with KOA.

Reliability

To assess the reliability, coefficients of variation percent (CV%), standard error of measurements, minimal detectable changes, and intra-class correlation coefficient (ICC) calculations were selected [169, 170].

The computation of a coefficient of variation gives a quantitative index of the reliability of the testing system [164]. The CV% was calculated using the following formula:

$$CV\ \% = \frac{\sigma}{\mu} \times 100 \quad \text{(i)}$$

Where, σ is sample standard deviation and μ is the sample mean.

Standard error of measurement (SEM) is inversely proportional to the reliability of a test. This implies that larger the SEM, the lower the reliability of the test, and vice-versa [171]. The SEM was calculated using the following formula:

$$SEM = SD \times \sqrt{1 - r} \quad \text{(ii)}$$

Where, SD is sample standard deviation, and r is the reliability of the test.

The minimal detectable changes (MDC) measure the minimum difference in an individual's score which ensures that the observed change is not because of measurement error, with 95% confidence [170]. The MDC was calculated using the following formula:

$$MDC = 1.96 \times SEM \times \sqrt{2} \quad \text{(iii)}$$

Where, SEM is the standard error of measurement.

Intraclass correlation coefficient (ICC) is a statistical measure that assesses the degree of similarity between observations within a group or cluster. It is used to evaluate the consistency or reproducibility of measurements made by different individuals or using different methods. The ICC was calculated using the following formula:

$$ICC\ (2,1) = \frac{MS_R - MS_E}{MS_R + \frac{MS_C - MS_E}{n}} \quad \text{(iv)}$$

$$ICC\ (2,k) = \frac{MS_R - MS_E}{MS_R - (k-1)MS_E + \frac{k}{n}(MS_C - MS_E)} \quad \text{(v)}$$

Where, MS_R is the mean square for rows, MS_E is mean square for error, MS_C is mean square for columns, k is number of raters or measurements, and n is number of subjects.

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" [172]. The ICC selection process is reported in Figure 3.14.

Validity

The Bland-Altman plot, CV%, SEM, ICC, and MDC were employed to assess the validity of the DT-walk [170]. The CV%, SEM, ICC and MDC were calculate using the same formula given in equation (i), (ii), (iii) and (v), respectively. A Bland–Altman graph was employed to analyze the agreement between data sets acquired by two systems in which x-axis and y-axis represents the mean and difference of the two sets of test values, respectively [173]. The Bland-Altman plot was prepared based on following calculations:

$$Upper\ Limit\ of\ Agreement = \bar{d} + 1.96 \times s \quad \text{(vi)}$$

$$Lower\ Limit\ of\ Agreement = \bar{d} - 1.96 \times s \quad \text{(vii)}$$

Where, $\bar{d}$ is mean difference and s is standard deviation of differences.

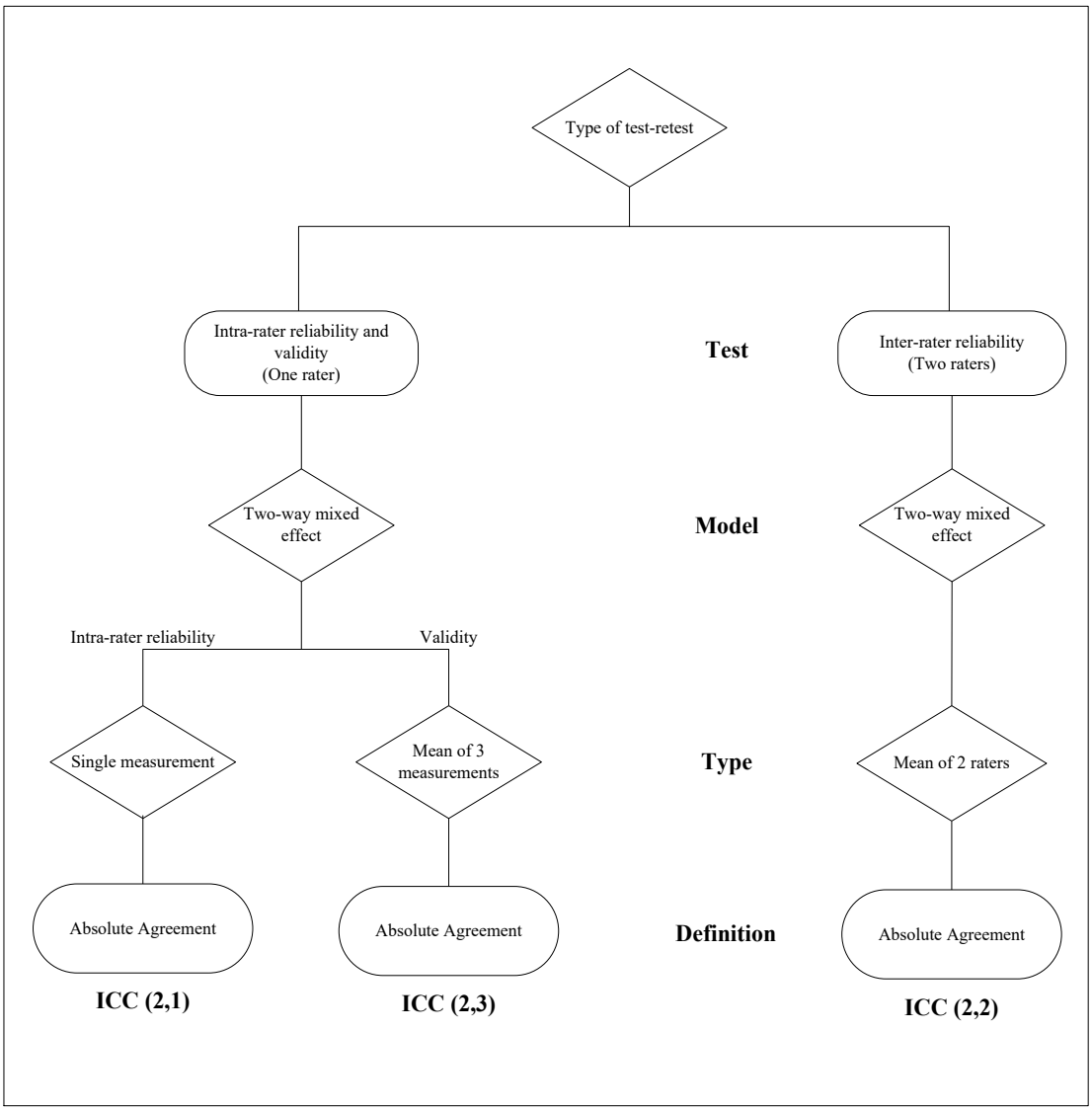


Figure 3. 15 ICC model, type and definition selection process used in this study.

Correlation

Further the data was analyzed statistically for correlation between the data collected from DT-walk and WinTrack system using the test for establish the validity of DT-walk for assessing SLLA and PPA. Correlation coefficients was used to measure how strong is the relationship between two variables. This helped us understand the extent to which the data collected using DT-walk correlates with the data collected by WinTrack system for validity. Similarly, it was used to understand the extent to which the data collected using DT-walk correlates with the data collected by same or different rater

using DT-walk system for reliability One of the most used formulas in statistics is Pearson's correlation coefficient formula, that is:

$$r = \frac{n(\sum xy) - (\sum x)(\sum y)}{\sqrt{[n\sum x^2 - (\sum x)^2][n\sum y^2 - (\sum y)^2]}}$$

where, r is the Pearson's correlation coefficient, n is the number of samples, x, and y are variables. In this study, higher correlation value suggests highly significant and strong association between the reading taken from DT-walk and WinTrack.

Hypothesis Testing

The hypothesis was tested to confirm whether DT-walk is a valid and reliable tool for assessing limb load asymmetry and plantar pressure asymmetry or not. The hypothesis is given below:

Null Hypothesis : DT-walk is a valid, and reliable tool for assessing limb load asymmetry, and plantar pressure asymmetry in KOA.

Alternate Hypothesis : DT-walk is not a valid, and reliable tool for assessing limb load asymmetry, and plantar pressure asymmetry in KOA.

The hypothesis was tested using paired t-test to confirm whether there is a significant difference between the two readings for the same rater and the mean of three readings by different raters and establish the intra-rater and inter-rater reliability of DT-walk for assessing LLA and PPA. It was also used to confirm whether there is a significant difference between the mean of three readings recorded using DT-walk and WinTrack and establish its validity for assessing LLA and PPA.

The formula used for paired t-test in this study is given below:

$$t = \frac{\sum d}{\sqrt{\frac{n(\sum d^2) - (\sum d)^2}{(n-1)}}}$$

where, d is difference per paired variables, n is number of samples.

In this study, no significant difference between the readings signifies high validity and reliability of DT-walk based on the readings used in the test.

CHAPTER IV

RESULTS

4.1 Focused Group Discussion for Need Assessment (Phase I)

Demographic

A total of 25 physiotherapists participated in this study (Figure 4.1). The participants included 15 male and ten female physiotherapists with a minimum experience of three years in clinical setting. However, their years of experience range from a minimum of three years to a maximum of twenty-nine years, with a mean year of experience of 11.8 years. The majority (23 out of 25) of the participants had master's degrees in different areas of expertise in physiotherapy, and two participants had doctorate degrees in physiotherapy (Figure 4.2).

Themes

All twenty-five participants were aware of the topic of discussion, and they were able to provide feedback, and explanations related to various questions raised in the discussion. The discussion with the focus group revealed certain repeated concepts as expressed by participants' views. The findings suggested three major interlinked themes associated with wearable technology in KOA: clinical issues, applicability, features, and functionality. As per the aim of this study, which assesses the clinician's need for a wearable device in KOA, all the themes were discussed in detail (Figure 4.3). The participant's comments are reported along with the acronym FG1-FG3 indicating the focus group number, and P1-P8 indicates the participant number of the respective focus group they attended.

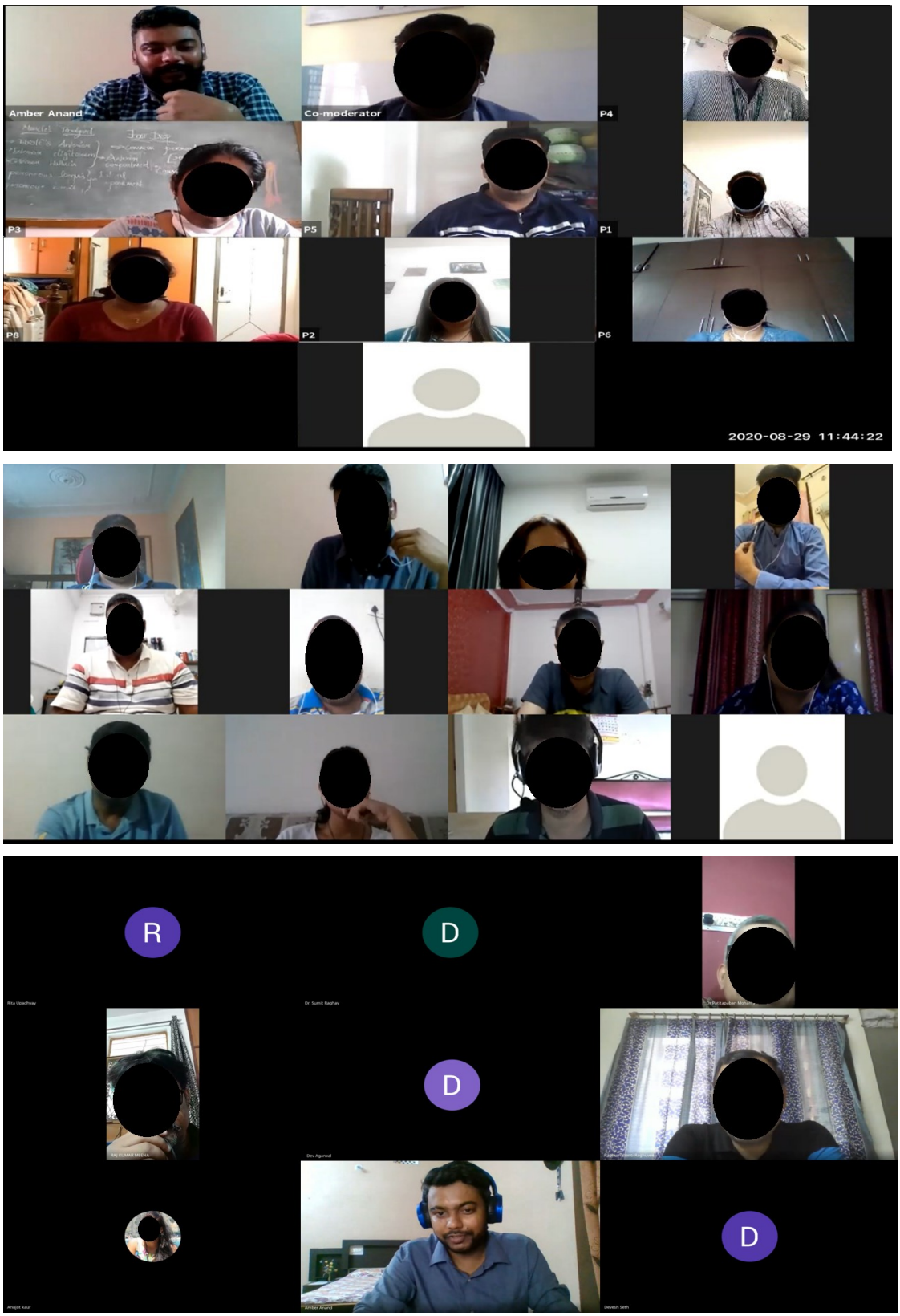


Figure 4. 1 Picture from focus group discussion via video conferencing

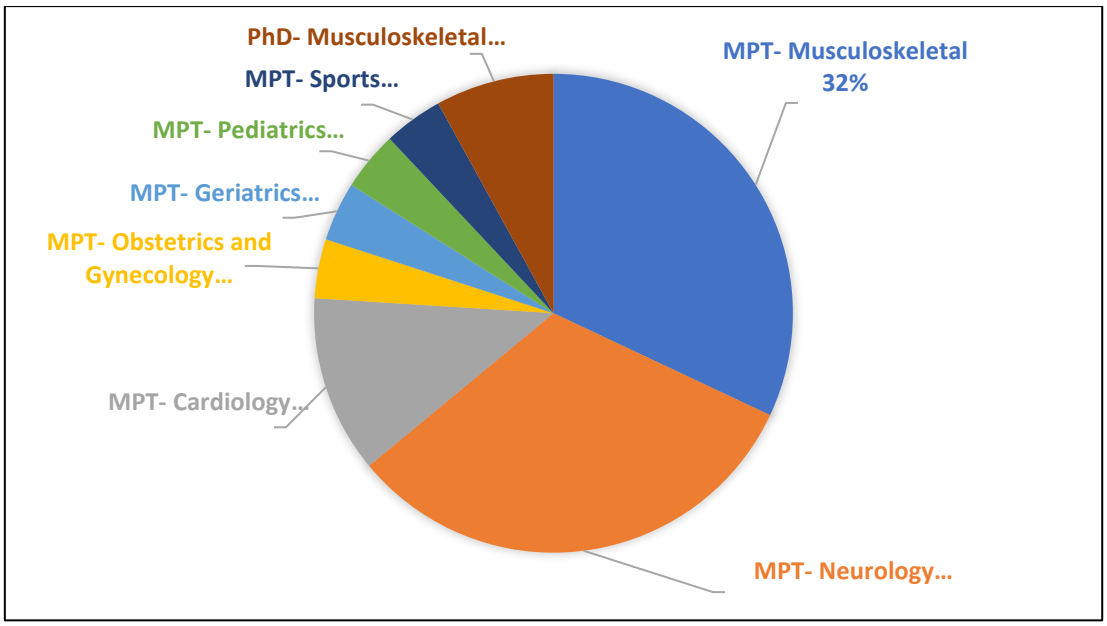


Figure 4. 2 Participant distribution based on the area of expertise.

Figure 4. 3 Mind map for the key findings from the focus group discussion.

Clinical issues

Physiotherapists associated various clinical issues related to KOA, and its impact on prognosis. Their view expressed concerns regarding the prevalence rate, economic burden, scarcity of assessment technology, delayed diagnosis, lack of preventive measures, and non-adherence to exercise related to KOA (Figure 4.4).

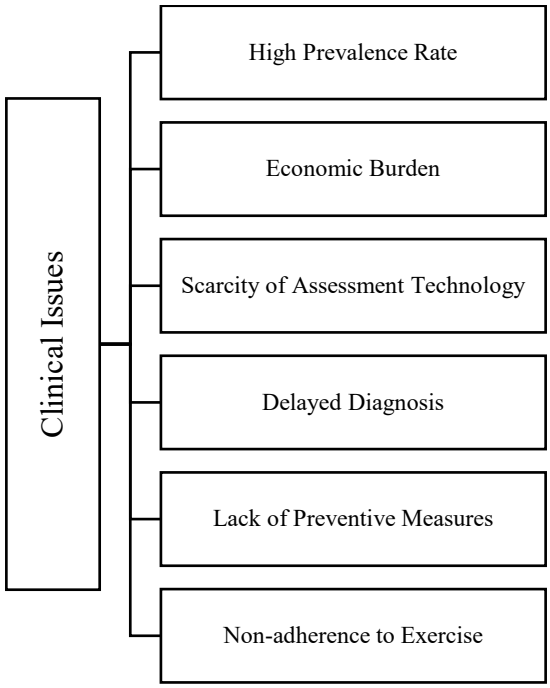


Figure 4. 4 Clinical issues associated with KOA.

Although various clinical issues were identified by different physiotherapists, all of them showed a positive and encouraging attitude towards the necessity of incorporating wearable technology. For instance, some physiotherapists believed that although the prevalence rate is very high, most of the patients visit their clinic at a later stage of KOA:

"If we see the prevalence of OA (2000), it is the 10th leading cause of non-fatal burden in the world. And if we see the global burden of diseases (2017), it was the fourth most common cause of this disability. The overall prevalence of OA in India is 20 to 30% as per the National Health Portal of India." (FG1, P2)

"The prevalence of is has been reported to be more in women as compared to males. It has been reported to be about 10% in individuals over 60 years of age, but I think it would be around 30% or so definitely." (FG2, P5)

"With the changing lifestyle, as we can understand, the prevalence is gradually increasing. The prevalence of OA range is between 22 to 30% of the population that is affected after around 60 years of age." (FG3, P4)

This creates an additional economic burden on the patients as patients rely mostly on medications for their condition rather than exercises which ultimately results in total knee arthroplasty surgery:

"According to the research, in the year 2017, there was a total of 300 million cases of OA, including 15 million new cases. So, we can imagine how much how massive it is, how much impact, how much global health burden it is putting." (FG2, P1)

"Around 303 million people suffer from OA globally, and out of that 263 million are affected by knee osteoarthritis. And in Indian context, it's It is about 27 28%. 28% of elderly have knee osteoarthritis. And in global population, around 4% of total population are affected by knee osteoarthritis globally. And yes, it increases the economic burden for the patient, and their family." (FG2, P4)

"I do agree with everybody that KOA is more prevalent among women because of morphological changes. But one more thing I would like to add to this is that though it has some psychomotor component of this problem, women tend to come out, and seek any type of medication only when their sleep disturbances come because of the pain. When that level of issues raises, only then they come forward. "(FG1, P6)

"The prevalence rate is more among women than men, and they come to the clinicians or visit the physiotherapist only when their condition get severe, and severe. Otherwise, they continue on self-managing their activities of daily living with the pain killer, and all other modalities that are available in their house like with moist heat or everything." (FG1, P7)

On the other hand, a few physiotherapists suggested that some of the patients visit their clinic at an early stage of KOA as soon as symptoms set in. However, these patients do not adhere to the exercises prescribed to them.

When discussing gait changes among the patients, the assessment of kinematic and kinetic gait emerged to be a very crucial part of their assessment. However, different views emerged in terms of the assessment of gait changes in clinical practice. Many suggested that due to the unavailability of gait and motion labs in almost all clinical practices. In clinical practice, they mostly rely on observational gait analysis.

"At my clinical, I have one portion of assessment that starts from the foot, and way up. We have all the joints mentioned, and it, and we go for the car. Oh, poster examination of the patient, and with observation only." (FG1, P6)

"According to my knowledge, if we are getting a patient, we are treating only the symptoms. We are not giving importance to how much weight they are giving on the particular joint based on observation, we are not treating based on load. And the reason behind why we cannot assess these things in our is the lack of the device, the labs in our clinics or hospitals due to its cost." (FG1, P1)

"We assess while observing, we see if there is any deformity or factors associated with his deformity, the knee, and other factors. basically, we are doing the observational way to some if there is any deviation, weight shifting, more accepting toward one side. We say that there is asymmetry. But we cannot quantify. We actually assess the shoes, the sole of the shoes to see whether there is any indent. We do not check for limb load asymmetry in clinical practice." (FG2, P2)

All physiotherapists stated that only a few governments, private hospitals, and research organizations have such facilities due to their cost, infrastructure, and manpower requirements.

While discussing the major challenges they face in clinical practice, most of the physiotherapists suggested that the major reason behind poor outcomes in such patients is a lack of preventive measures and scarcity of advanced assessment technology:

"Even if the facility we are implemented, we have to get charges from the patient only. So the patients here are also not ready to pay that much for doing the proper assessment. So, they want only the symptomatic treatment. They don't want to get a full cure for that particular disease. They will not stand with us for a period of time to assess. Everything untreated I have is a view about this. The reason for unavailability regarding the gait lab or the force platform is that it's too costly." (FG1, P7)

Applicability and features

All physiotherapists expressed a supportive attitude towards the need for wearable technology; however, different views emerged on the applicability and features they wish to see in wearable technology (Figure 4.5).

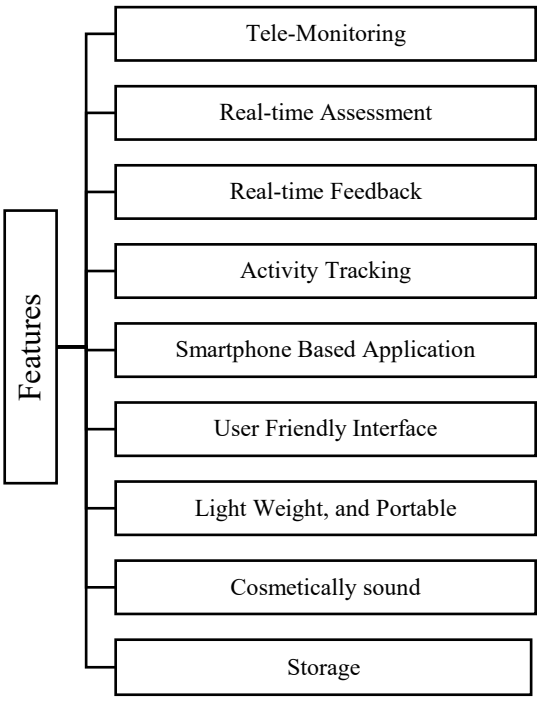


Figure 4. 5 Features expected in future technologies.

For instance, most of them suggested that the device should have a real-time assessment and feedback capability.

"It should be used for better assessments as well as the diagnostic, and for therapeutic purpose." (FG1, P8)

"The device can be used for some of our assessments and diagnosis and even for the progression of the patient. If patients know the progression of their activity, they will be more active, motivated, and involved in active participation. A direct implication of this will be that it will give feedback to the patients in the way the patient follows the exercise." (FG2, P6)

Whereas some suggested that the device should have an activity-tracking feature, and some suggested that it should have both activity-tracking and Telemonitoring features.

"These things should have a storage facility and linkage with their healthcare provider so that we can track progress or monitor how the patient is doing over time. And identify the problems he or she will have in the future time. So, we can have such kinds of things so that we can track the progress or monitor, all the variables of the patient regarding the osteoarthritis of the knee for example. So if he is my patient, I would like to see his progression over the laptop or phone, and it will be easy for us, especially for a patient living in remote areas." (FG3, P2)

Some physiotherapists also suggested that the device should have its own smartphone application with a user-friendly interface.

"The result should be such that both an educated and uneducated people can also interpret and can use it for the biofeedback or self-assessment or to improve their limb loading." (FG1, P4)

"The device can be a single-user device or multi-user device. It should take less time for getting the correct measurements. And application should be easy." (FG2, P7)

A few physiotherapists also suggested that the device should have storage capability so that it can work as a stand-alone device.

"It should be affordable for everyone. If any such type of device is developed, it should be affordable, and should not be dependent on the internet. It can be used anywhere by everyone." (FG2, P6)

In addition, all the physiotherapists suggested that the device should be lightweight, portable, and cosmetically sound.

"The device should be, I think, comfortable, and should be small in size, and lightweight." (FG2, P1)

"The device should have qualities like it should be a small size and looks good cosmetically. Also, people are attracted to type devices that are easy to use. The patient-friendly will come to its features." (FG1, P4)

"I think the design of these devices should be compact, cost-effective, and can be easily charged." (FG3, P2)

Functionality

All physiotherapist expressed their views in terms of the functionality of such wearable devices. However, different views emerged on the functions they wish to see in wearable technology (Figure 4.6).

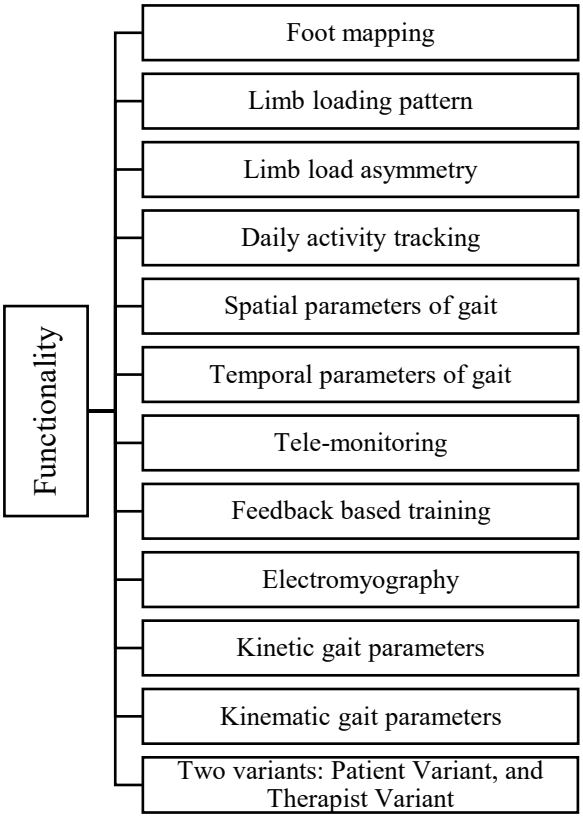


Figure 4. 6 Functions and applications expected in future technologies.

For instance, most physiotherapists suggested foot mapping and plantar pressure measurement as key functions they wish to see in such wearable devices as it allows them to assess the patient's foot arch and plantar pressure distribution within the foot and between the foot.

"There should be foot mapping assessment, so that you can identify which area is getting more pressure- anterior or posterior, medial or lateral, and arch type." (FG 1, P3)

"We can have something like heat mapping similar to what we have seen in other systems." (FG 2, P2)

In addition, some of the physiotherapists suggested that the device should have the ability to assess limb loading patterns which allows them to understand how the load is being distributed on foot during different gait phases.

"The device should have the ability to assess limb load asymmetry as asymmetrical limb loading is the primary response to pain in lower limb which leads to altered gait pattern." (FG 3, P4)

When discussing gait changes among the patients, the assessment of kinematics and kinetics of gait emerged to be a very crucial part of their assessment. However, different views emerged in terms of the assessment of gait changes in clinical practice. Many suggested that due to the unavailability of a gait lab, they are not assessing it.

"Assessment of joint angles, joint alignment, joint line, symmetry index, should be incorporated in the device." (FG 2, P3)

"It can measure joint angles as it one of the most important aspects of assessment, along with joint alignment, joint line, ground reaction force, center of mass, and center of gravity." (FG 2, P3)

However, one physiotherapist agreed that it is practically impossible to incorporate, as it requires 3-dimensional force data, ideally from a force plate, and accurate motion analysis using reflective markers, and motion analysis camera or wearable sensors.

The assessment of spatial and temporal parameters of gait was an important area of concern among physiotherapists. They suggested that the device should also have daily activity tracking and inactivity reminder functions for fitness enthusiasts.

"It should assess step length, stride length, cadence, joint range of motion." (FG 1, P2)

"It should assess all spatial and temporal parameters of gait." (FG 1, P7)

However, only one physiotherapist suggested that electromyography should also be considered for evaluating the muscle activation pattern during different phases of gait.

"It would be great if we see muscle activity or muscle activation pattern during movement." (FG 1, P5)

Many physiotherapists pointed towards having the telemonitoring function in such wearable devices if developed. It is a very useful feature for patients living in remote locations with poor connectivity, longer travel time to reach healthcare facilities, weather, and lack of transport.

"For patients who live in remote areas, who cannot access physiotherapy services on a daily basis, it will be helpful as most of India lives in rural areas. So, having tele function will allow us to monitor the effectiveness and efficacy of the treatment or intervention plan." (FG 2, P5)

When discussing the training feature, all the physiotherapists agreed on having a feedback-based training function in such devices for their patients. However, the type of feedback varied among them; some suggested that there should be auditory feedback, some suggested visual feedback, and a few suggested both auditory and visual feedback functions in such wearable devices.

"It will enhance patient involvement, active participation, performance tracking, and self-awareness." (FG 3, P6)

"Having real-time data will guide them whether they are going the right way, or if any change is required in the treatment." (FG 2, P2)

"It will allow monitoring the effectiveness and efficacy of the treatment or intervention plan." (FG 2, P5)

"The data can be utilized for future studies or research. It would be like evidence-based practice, plus whatever data we are getting from the device, we can show it to the patient. And on the basis of improvement, it will give good feedback to the patients." (FG 2, P4)

"Based on the usage, this device will help in all three aspects- diagnosis, prognosis, and treatment or intervention plan." (FG 2, P8)

In addition, a few physiotherapists suggested incorporating artificial intelligence and machine learning modeling for predicting disease development and risk of falls and tracking their improvement over time.

While discussing the usage of such wearable devices in their clinical practice, all physiotherapists agreed on having two variants of the device- one for patients with basic feature and one for clinicians with advanced features.

"*I think you should develop two models- one for the patients with limited features or features relevant to them, and one for the clinician with more features with higher cost." (FG 1, P6)*

Different views emerged among physiotherapists in terms of the cost of such wearable devices, as some suggested that the price should be under Rs. 5000, and some suggested up to Rs. 10000 for the patient variants with lesser features. For the clinician variants with advanced features, some physiotherapists suggested that the price should be up to Rs. 50000, and only a few were willing to pay up to Rs. 100000 for such devices when developed.

"It should be near Rs. 3000 to Rs. 4000 if you want to give it to a patient with fewer features. For the clinical purpose, it should have all the features we discussed and can range up to Rs. 20000." (FG 1, P2)

"It depends on who is going to buy this device; for a clinician, it can range between Rs. 10000 to Rs. 20000. But for the patient, it should be pocket friendly, like Rs. 3000 to Rs. 4000, that is also too high for patients from villages who would prefer for painkillers." (FG 1, P3)

"I think on an average patient can pay Rs. 10000 to Rs. 12000. And for clinicians, it can be up to Rs. 30000 to Rs. 40000." (FG 2, P1)

"For patients, the cost should be really low with very limited features, and for clinicians, it can range anywhere between Rs. 50000 to Rs. 100000 with all advanced features." (FG 2, P4)

"For institutions, it won't be any problem to fund the device for research purposes so that it can grow up properly. For institutions like hospitals, clinics, and academic institutions, the price can be Rs. 100000 to Rs. 200000. From a patient's perspective, it should be low because it bears the additional cost of mobile plus Internet also. So, Rs. 5000 is the maximum." (FG 3, P4)

4.2 Recommendations for development of DT-walk

Based on the recommendations of the expert panel from the focused group discussion, an outline for the development of the prototype was made. The prototype development outline includes information related to the assessment parameters to be incorporated, the type of technology to be used, and the applicability of the device for other areas. The device outline was explained to the technical experts- Dr. Rajesh Singh and Mr. Prabin Kumar Das, Division of Research and Innovation, Lovely Professional University regarding the needs, demands, and applicability of the new device mentioned below:

- The DT-walk should address clinical issues like scarcity of low-cost assessment technology, thereby helping in early diagnosis of the asymmetries in limb loading and gait.
- The device should assess limb loading pattern, limb load asymmetry, foot mapping, arch index, arch type, and spatiotemporal parameters of gait.
- The DT-walk should be easy to use, a product that is wearable, lightweight, portable, and cost-effective, and it should have storage and cloud computing abilities.
- The device should be useful for clinicians, patients, and trainers for real-time assessment, feedback, and telemonitoring.

Based on recommendations regarding the structure, contents, and design of the prototype of the DT-walk, the device was developed in collaboration with technical experts using the following components:

1. Microcontroller
2. Velostat
3. Copper tape
4. Insulating layer
5. Inertial Motion Unit sensor
6. 16-channel multiplexer
7. Wi-Fi communication module
8. Rechargeable battery-3.7 volts
9. SD card module
10. Force-sensitive resistor sensor
11. Mobile computing application
12. Flexible wires

4.3 Prevalence of Asymmetries in Knee Osteoarthritis (Phase II)

Overview

In this study, a total of 95 subjects were included, of which 72 were female, and 23 were males, with the majority being moderately active (93.7%) with an active lifestyle (90.5%). The mean age of included subjects was 48.01 (± 6.56), out of which 8 (8.42%) were aged < 40 years, 59 (62.1%) were aged between 41-50 years, 24 (25.3%) were aged between 51-60 years, and 4 (4.2%) were aged > 60 years. In terms of BMI, 54 (56.8%) subjects were either overweight (40%) or obese (16.8%). Whereas 38 (40%) subjects had normal BMI, 3 (3.2%) subjects were underweight. The limb involvement varied among the subjects, 70 (73.7%) subjects (13 male and 53 female) had bilateral KOA, and 25 (26.3%) subjects (6 male and 19 female) had unilateral KOA. Out of 95 subjects, two male and two female subjects had a history of injury to the lower limb. The mean (SD) age, weight, height, and BMI of the subjects were 47.69 (± 6.99), 63.42 (± 11.77), 1.55 (± 0.07), and 26.29 (± 4.15), respectively. Frequency distribution of age, BMI, lifestyle, physical activity, injury history, and limb involvement based on gender is summarized in Table 4.1.

KOOS Score

The performance of the subjects in relation to pain, function, and quality of life was evaluated using the KOOS score. The overall KOOS-12 score suggests that, on average, all the subjects experienced pain 34 % of the time in the past week, difficulty performing their daily activities 26% of the time, and difficulty having a good quality of life 67.5 % of the time (Table 4.2).

Regarding the KOOS pain score (Figure 4.7), most subjects (n=53) reported knee pain at least once weekly, whereas the remaining 35 subjects had knee pain at least once monthly, and only 7 reported no pain in knee. The intensity of knee pain experienced by the subjects in the past week while sitting or lying was moderate= 3 subjects, mild= 24 subjects, and no pain = 68 subjects. The amount of knee pain the subjects experienced in the past week while going up or down the stairs were severe= 7 moderate= 51 subjects, mild= 34 subjects, and no pain = 3 subjects. The amount of knee pain experienced by the subjects in the past week while walking on a flat surface was moderate= 13 subjects, mild= 61 subjects, and no pain = 21 subjects.

Table 4. 1 Frequency distribution of age, BMI, lifestyle, physical activity, injury history, and limb involvement based on gender.

n=95		Male (n=23)		Female (n=72)		Total	
		Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
Age (years)	< 40	0	0	8	8.42	8	8.42
	41–50	11	11.6	48	50.5	59	62.1
	51– 60	10	10.5	14	14.7	24	25.3
	> 60	2	2.1	2	2.1	4	4.2
BMI	< 18.5	1	1.1	2	2.1	3	3.2
	18.5-24.9	12	12.6	26	27.4	38	40.0
	25 - 30	7	7.4	31	32.6	38	40.0
	> 30	3	3.2	13	13.7	16	16.8
Lifestyle	Active	15	15.8	71	74.7	86	90.5
	Sedentary	8	8.4	1	1.1	9	9.5
Physical Activity	Moderate	18	18.9	71	74.7	89	93.7
	Low	5	5.3	1	1.1	6	6.3
Injury History	Yes	2	2.1	2	2.1	4	4.2
	No	21	22.1	70	73.7	91	95.8
Limb Involvement	Unilateral	6	6.3	19	20.0	25	26.3
	Bilateral	17	17.9	53	55.8	70	73.7

Note: BMI- body mass index

Table 4. 2 Comparison of descriptive statistics for age, weight, height, BMI, and KOOS score in terms of pain, function, and quality of life-based on limb involvement.

n=95	**Unilateral (n= 25)**				**Bilateral (n= 70)**			
	Mean	**SD**	**SEM**	**Range**	**Mean**	**SD**	**SEM**	**Range**
Age (years)	47.160	7.821	1.564	40.000	47.871	6.616	0.791	34.000
BMI	26.928	3.561	0.712	20.011	26.023	4.789	0.572	22.462
KOOS Global	68.250	13.948	2.790	56.250	67.351	9.629	1.151	54.167
KOOS Pain	66.250	13.578	2.716	56.250	65.804	10.965	1.311	56.250
KOOS Function	76.000	14.650	2.930	56.250	73.839	10.367	1.239	56.250
KOOS QOL	62.500	16.298	3.260	62.500	62.411	11.054	1.321	56.250

Note: SD: standard deviation, SEM- standard error of mean, BMI- body mass index, KOOS- Knee Injury and Osteoarthritis Outcome Score, QOL- quality of life

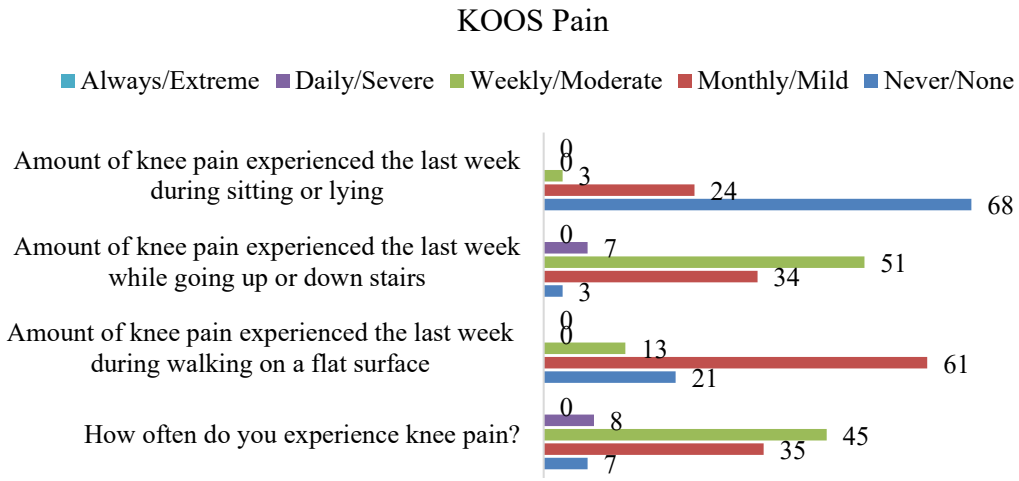


Figure 4. 7 KOOS pain score among the subjects

Regarding the KOOS function score (Figure 4.8), most subjects (n=59) experienced difficulty due to knee while twisting or pivoting on their injured knee. The amount of difficulty the subjects experienced in the past week while getting in or out of car or public transport was severe= 1 subject, moderate= 8 subjects, mild= 52 subjects, and no pain= 32 subjects. The amount of difficulty experienced by the subjects in the past week while standing was severe= 1 subject, moderate= 19 subjects, mild= 58 subjects, and no pain= 17 subjects. The amount of difficulty experienced by the subjects in the past week while rising from sitting was severe= 6 subjects, moderate= 45 subjects, mild= 43 subjects, and no pain= 1 subject.

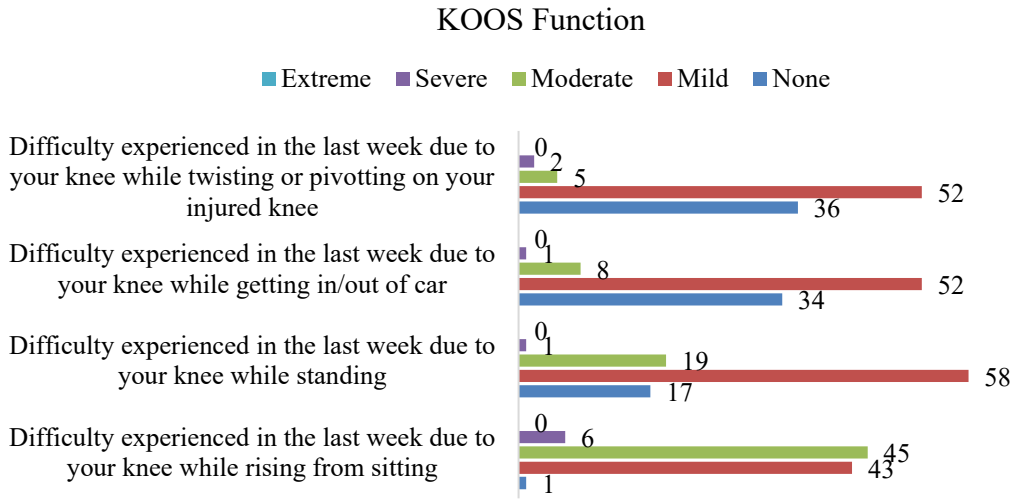


Figure 4. 8 KOOS function score among the subjects

Regarding the KOOS quality of life score, most subjects (n=88) reported that they are aware of their knee pain at least once weekly, and only seven subjects reported it at least once monthly (Figure 4.9). Fifty-eight subjects reported difficulty in their knee at least once monthly, whereas the remaining thirty subjects reported difficulty in their knee at least once weekly, six subjects reported difficulty in their knee daily, and only 1 reported no difficulty in their knee. Furthermore, 86 out of 95 subjects mildly lacked confidence in their daily activities due to their knee, whereas nine subjects did not report any lack of confidence due to their knee. Seventy-four subjects reported modification in lifestyle to avoid potentially damaging activities to their knee; however, 21 subjects did not report any change in their activities.

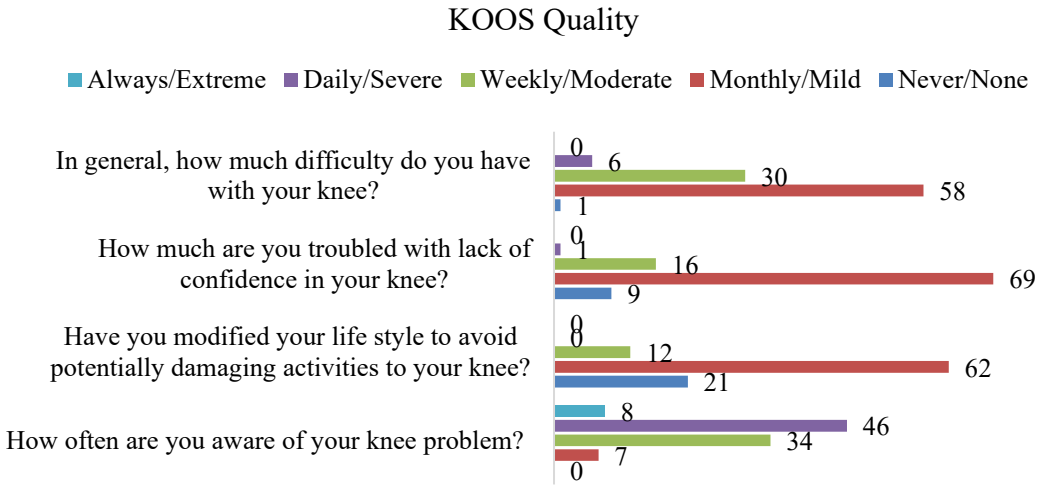


Figure 4. 9 KOOS quality of life score among the subjects

Spatiotemporal Parameters

The spatiotemporal parameters of gait were acquired using WinTrack platform. The data from the individual reports of each patient was extracted and analyzed. A sample report of walk analysis and postural analysis is given below in Figures 4.10 and 4.11, respectively.

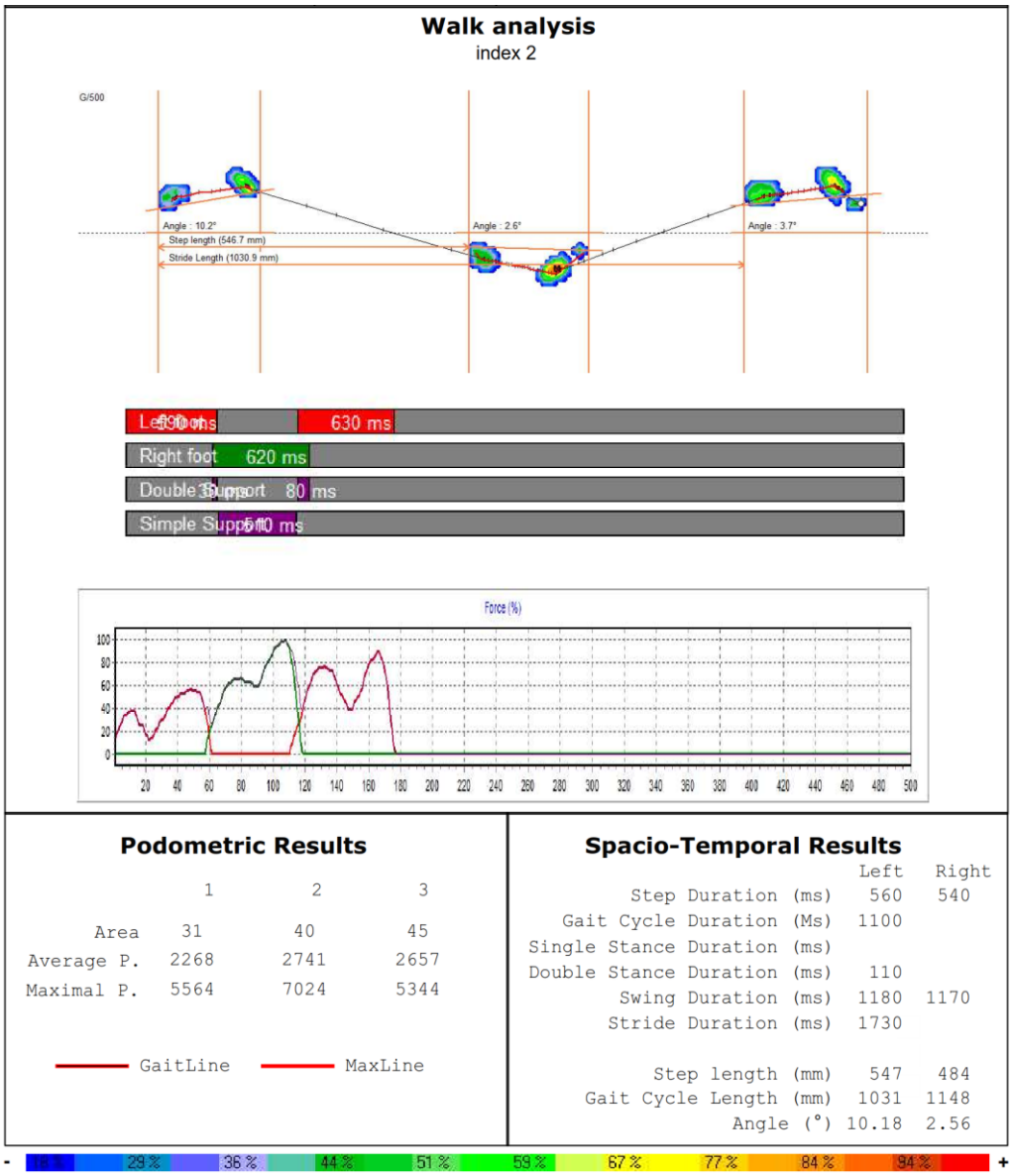


Figure 4. 10 Sample report for walking analysis generated by the WinTrack system

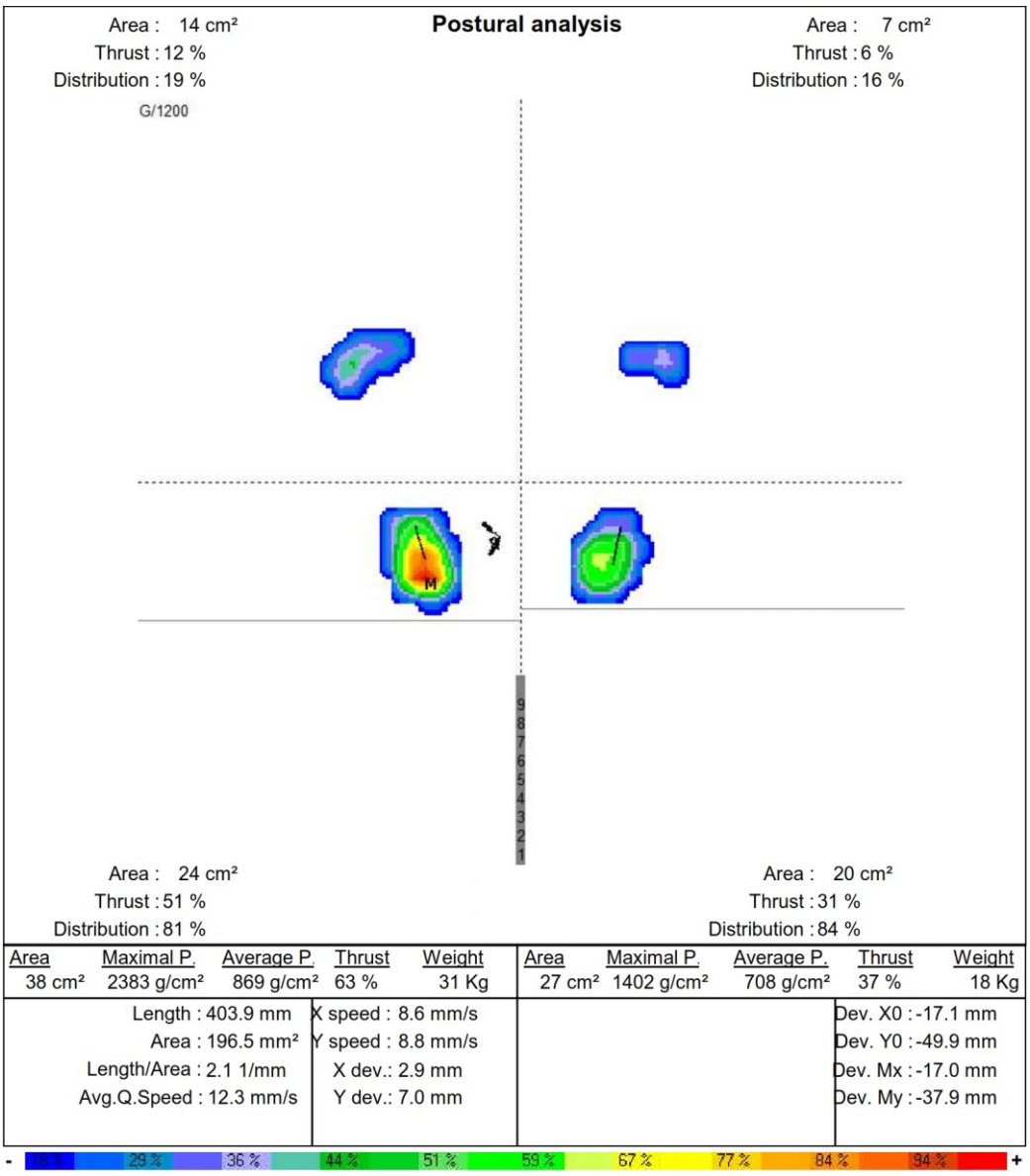


Figure 4. 11 Sample report for postural analysis generated by the WinTrack system

The spatial and temporal parameters of gait were further compared between the participants based on their limb involvement. The finding suggests that the mean value of stride duration, swing phase duration left and right, step duration left, and maximum pressure left and right, was relatively higher among participants with bilateral limb involvement. Whereas the mean value of stance phase duration, step duration right, step length left and right, and stride length were relatively higher among participants with unilateral limb involvement. (Table 4.3)

Table 4. 3 Comparison of descriptive analysis for stance phase duration, stride duration, swing phase duration left, swing phase duration right, step duration left, step duration right, step length left, step length right, stride length, max pressure left, and max pressure right.

n= 95	Unilateral (n=25)				Bilateral (n= 70)			
	Mean	**SD**	**SEM**	**Range**	**Mean**	**SD**	**SEM**	**Range**
Stance Phase Duration (ms)	599.60	128.17	25.63	640.00	597.14	136.96	16.37	860.00
Stride Duration (ms)	1997.20	340.82	68.16	1470.00	2115.20	370.83	44.32	1540.00
Swing Phase Duration Left (ms)	1227.20	157.37	31.47	620.00	1294.40	205.27	24.53	1080.00
Swing Phase Duration Right (ms)	1362.40	271.47	54.29	1250.00	1456.80	363.29	43.42	1590.00
Step Duration Left (ms)	576.00	170.04	34.01	890.00	649.60	134.77	16.11	800.00
Step Duration Right (ms)	658.80	169.60	33.92	770.00	652.80	130.37	15.58	810.00
Step Length Left (mm)	493.96	76.76	15.35	328.00	476.36	62.95	7.52	382.00
Step Length Right (mm)	507.04	65.33	13.07	242.00	489.84	68.94	8.24	331.00
Stride Length (mm)	100.09	11.41	2.28	44.51	95.72	9.75	1.17	55.45
Max Pressure Left (kPa)	5125.60	1159.63	231.93	4650.00	5204.60	1212.54	144.93	6132.00
Max Pressure Right (kPa)	5166.32	1075.27	215.05	4493.00	5514.84	1432.95	171.27	6054.00

Note: SD: standard deviation, SEM- standard error of mean

Based on the individual report generated by the WinTrack system, some additional parameters were also calculated, namely dynamic interlimb max. pressure difference, interlimb swing phase duration difference, interlimb step duration difference, interlimb step length difference, static limb load asymmetry, step length asymmetry, step duration asymmetry, and plantar pressure asymmetry. These parameters were then compared between the participants with unilateral and bilateral limb involvement to understand the impact of these asymmetries on limb involvement (Table 4.4).

Table 4. 4 Descriptive analysis for dynamic interlimb max. pressure difference, interlimb swing phase duration difference, interlimb step duration difference, interlimb step length difference, step duration asymmetry, step length asymmetry, static limb load asymmetry, and plantar pressure asymmetry.

N=95	Unilateral (n= 25)				Bilateral (n= 70)			
	Mean	**SD**	**SEM**	**Range**	**Mean**	**SD**	**SEM**	**Range**
DIMPD (kPa)	1306.40	829.72	165.94	2754.00	1417.97	897.02	107.21	4250
ISPDD (ms)	164.80	200.50	40.10	750.00	155.43	201.99	24.14	1000
ISDD (ms)	182.00	268.33	53.67	970.00	108.14	100.31	11.99	470
ISLD (mm)	60.12	63.47	12.69	312.00	50.83	44.59	5.33	195
SLLA (%)	12.24	10.27	2.05	38.00	14.63	10.31	1.23	42
SLA (%)	11.39	11.38	2.28	54.74	9.57	8.24	0.98	31.46
SDA (%)	20.73	25.30	5.06	86.61	15.02	11.85	1.42	48.44
SPA (%)	10.66	10.88	2.18	36.86	9.80	10.26	1.23	50.50
PPA (%)	22.30	13.11	2.62	45.88	22.82	12.32	1.47	54.13

Note: SD: standard deviation, SEM- standard error of mean, DIMPD- Dynamic Interlimb Max. Pressure Difference, ISPDD- Interlimb Swing Phase Duration Difference, ISDD- Interlimb Step Duration Difference, ISLD- Interlimb Step Length Difference, SLLA- Static Limb Load Asymmetry, SLA- Step Length Asymmetry, SDA- Step Duration Asymmetry, SPA- Swing Phase Asymmetry, PPA- Plantar Pressure Asymmetry.

The comparative data shows a significant difference between the mean of various outcome variables among the subjects with unilateral and bilateral limb involvement. The mean dynamic interlimb max. pressure difference and static limb load asymmetry were higher among the subjects with bilateral limb involvement than those with unilateral limb involvement. The mean (SD) dynamic interlimb max. pressure difference among the subjects with unilateral and bilateral limb involvement was 1306.40 kPa (± 829.72), and 1417.97 kPa (± 897.02), respectively, suggesting that subjects with bilateral limb involvement have a risk of having dynamic plantar pressure

asymmetry. The mean (SD) static limb load asymmetry among the subjects with unilateral and bilateral limb involvement was 12.24 % (± 10.27), and 14.63 % (± 10.31), respectively, which suggests that subjects with bilateral limb involvement have a higher prevalence of static limb load asymmetry.

On the other hand, the mean interlimb swing phase duration difference, interlimb step duration difference, interlimb step length difference, step duration asymmetry, step length asymmetry, and plantar pressure asymmetry were higher among the subjects with unilateral limb involvement compared to those with unilateral limb involvement. The mean (SD) interlimb swing phase duration difference among the subjects with unilateral and bilateral limb involvement was 164.80 ms (± 200.5), and 155.43 ms (± 201.99), respectively, which suggests that subjects with unilateral limb involvement have a risk of having step duration asymmetry. The mean (SD) interlimb step duration difference among the subjects with unilateral and bilateral limb involvement was 182.00 ms (± 268.33), and 108.14 ms (± 100.31), respectively, which suggests that subjects with unilateral limb involvement have a risk of having step duration asymmetry. The mean (SD) interlimb step length difference among the subjects with unilateral and bilateral limb involvement was 60.12 mm (± 63.47), and 50.83 mm (± 44.59), respectively, which suggests that subjects with unilateral limb involvement have a risk of having step length asymmetry. The mean (SD) swing phase duration asymmetry among the subjects with unilateral and bilateral limb involvement was 10.66% (± 10.88) and 9.80% (± 10.26), respectively, which suggests that step length asymmetry does not get influenced by whether single or both knee is involved. The mean (SD) step length asymmetry among the subjects with unilateral and bilateral limb involvement was 11.39% (± 11.38) and 9.57 % (± 8.24), respectively, which suggests that step length asymmetry does not get influenced by whether single or both knee is involved. Whereas the mean (SD) step duration asymmetry among the subjects with unilateral and bilateral limb involvement was 20.73% (± 25.73), and 15.02% (± 11.85), respectively, which suggests that subjects with unilateral limb involvement have a higher prevalence and risk of developing step duration asymmetry. The mean (SD) plantar pressure asymmetry among the subjects with unilateral and bilateral limb involvement was nearly same 22.30% (± 13.11) and 22.82% (± 12.32), respectively,

which suggests that plantar pressure asymmetry does not get influenced by whether single or both knee is involved, and has similar distribution among the subjects with bilateral, and unilateral limb involvement.

Prevalence of Asymmetries

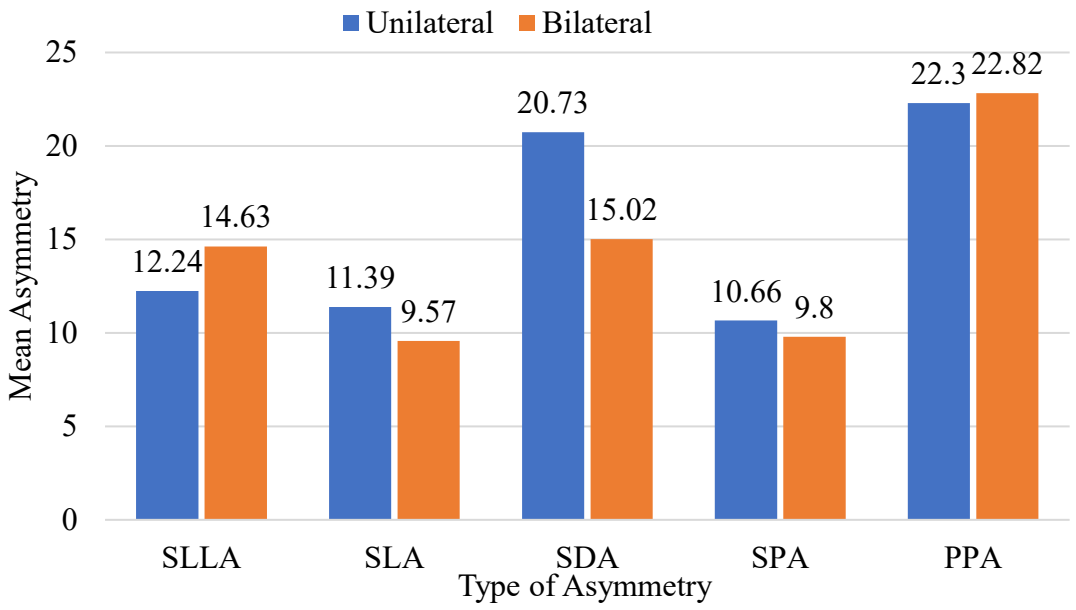
The overall prevalence of asymmetries in limb loading, plantar pressure, and spatiotemporal parameter of gait was calculated and further analyzed for correlation (Table 4.5). The prevalence of static limb load asymmetry was 53%, out of which 32 (34%) participants had static limb load asymmetry between 10 – 20%, and 18 (19%) participants had asymmetry above 20 %. Whereas, the prevalence of step length asymmetry was slightly less, and it was evaluated to be 44%, out of which 28 participants (29.5%) had step length asymmetry between 10 – 20%, and only 13 (13.7%) participants had asymmetry of above 20 %. The prevalence of step duration asymmetry was evaluated to be 56%, out of which 20 (21%) participants had step duration asymmetry between 10 – 20%, and 33 (34.75%) participants had asymmetry of above 20 %. The prevalence of swing phase asymmetry was evaluated to be 33%, out of which 14 (14.75%) participants had swing phase asymmetry between 10 – 20%, and 18 (19%) participants had asymmetry of above 20 %. However, the prevalence of plantar pressure asymmetry was significantly higher as compared to other asymmetries. The prevalence of plantar pressure asymmetry was evaluated to be 86%, out of which 25 (25.3%) participants had plantar pressure asymmetry between 10 – 20%, and 57 (60%) participants had asymmetry of above 20%.

Table 4. 5 Overall prevalence of asymmetries in knee osteoarthritis

Asymmetry type	Asymmetry (%)	Unilateral (n= 25)		Bilateral (n= 70)		Overall (n= 95)	
		Subjects (n)	Precent (%)	Subjects (n)	Precent (%)	Subjects (n)	Precent (%)
Static Limb Load Asymmetry (%)	<10	14	56	31	44.29	45	47.37
	10-20	8	32	24	34.29	32	33.68
	>20	3	12	15	21.43	18	18.95
Step Length Asymmetry (%)	<10	13	52	43	61.43	54	56.84
	10-20	9	36	19	27.14	28	29.47
	>20	3	12	8	11.43	13	13.68
Step Duration Asymmetry (%)	<10	13	52	30	42.86	42	44.21
	10-20	4	16	21	30	20	21.05
	>20	8	32	19	27.14	33	34.75
Swing Phase Asymmetry (%)	<10	17	68	47	67.14	63	66.32
	10-20	3	12	11	15.71	14	14.74
	>20	5	20	12	17.14	18	18.95
Plantar Pressure Asymmetry (%)	<10	2	8	11	15.71	13	13.68
	10-20	11	44	22	31.43	25	25.32
	>20	12	48	37	52.86	57	60

The mean of asymmetries in limb loading step length, step duration, and plantar pressure were compared between participants with unilateral and bilateral limb involvement among the study population. The result suggests that the participants with unilateral limb involvement have a significant level of asymmetries in static limb loading (12.24%), step duration (14.37%), and plantar pressure (13.16%), except step length asymmetry (6.47%). Whereas the participants with bilateral limb involvement have a significant level of asymmetries in static limb loading (17.84%) and plantar pressure (13.22%), except step length asymmetry (8.45%) and step duration (5.78%). The mean asymmetry (%) of different types of asymmetries among unilateral and bilateral limb involvement subjects is shown in Figure 4.12. It was also observed that

the step length asymmetry does not get affected due to knee pain in general and in osteoarthritis of both unilateral and bilateral KOA. In addition to this, the static limb load asymmetry was higher among participants with bilateral limb involvement, whereas step duration asymmetry was higher among participants with unilateral limb involvement. The result of this study is further reported based on the subject's limb involvement in the following section.



Note: SLLA- Static limb load asymmetry, SLA- step length asymmetry, SDA- Step duration asymmetry, SPA- Swing phase asymmetry, PPA- Plantar pressure asymmetry.

Figure 4. 12 Comparison of mean asymmetry (%) of different types of asymmetries among unilateral and bilateral limb involvement subjects.

4.3.1 Unilateral KOA

Among the subjects with unilateral KOA, 19 were female, and 6 were males, with most subjects being moderately active (88%) with an active lifestyle (88%). Out of 25 subjects, only 1 had a history of injury to the lower limb. In terms of BMI, the majority of 72 % of the samples were either overweight (64%) or obese (8%). (Table 4.6)

Table 4. 6 Frequency distribution of age, BMI, lifestyle, physical activity, injury history, and limb involvement based on gender.

n=95		Male (n=6)		Female (n=19)		Total	
		Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
Age (years)	< 40	0	0	3	12	3	12
	41–50	4	16	12	48	16	64
	> 50	2	8	4	16	6	24
BMI	< 18.5	0	0	0	0	0	0
	18.5-24.9	3	12	4	16	7	28
	25 - 30	3	12	13	52	16	64
	> 30	0	3.2	2	8	2	8
Lifestyle	Active	3	12	19	76	22	88
	Sedentary	3	12	0	0	3	12
Physical Activity	Moderate	3	12	19	76	22	88
	Low	3	12	0	0	3	12
Injury History	Yes	1	4	0	0	1	4
	No	5	20	19	76	24	96

Note: BMI- body mass index

The mean (SD) of age, BMI, KOOS- pain, function, quality of life, and global among patients with unilateral knee pain were 47.16 (± 7.98), 26.93 (± 3.63), 66.25 (± 13.86), 76.25 (± 14.66), 62.75 (± 16.48), and 68.42 (± 14.14) respectively. (Table 4.7) The overall KOOS-12 score suggests that, on average, all the subjects experienced pain about 34 % of the time in the past week, difficulty in performing their activities of daily living about 24% of the time, and difficulty in having a good quality life around 37 % of the time.

Table 4. 7 Descriptive statistics for age, BMI, and KOOS score in terms of pain, function, and quality of life.

	Mean	SD	SEM	Range
Age (years)	47.16	7.98	1.596	40.00
BMI	26.93	3.63	0.726	20.01
KOOS Global	67.35	9.70	1.16	54.17
KOOS Pain	65.80	11.04	1.32	56.25
KOOS Function	73.84	10.44	1.25	56.25
KOOS QOL	62.41	11.13	1.33	56.25

Note: SD: standard deviation, SEM- standard error of mean, BMI- body mass index, KOOS- Knee Injury and Osteoarthritis Outcome Score, QOL- quality of life

KOOS Score

The overall response to the KOOS questionnaire of all the subjects is summarized in Figure 4.13. Out of 25 subjects, 22 reported pains in the knee at least once in the past week while walking, stair climbing, and descending. In terms of activities of daily living, 14 subjects reported having experienced mild to severe difficulty in twisting or pivoting on their injured knee and getting in or out of a car or public transport, and 19 subjects had trouble due to their knee while standing. Interestingly, almost all the subjects (n=24) reported some degree of difficulty in getting up from the sitting position. In terms of KOOS quality of life, two subjects reported that they are aware of their knee pain at least once a month. Furthermore, 22 subjects mildly lacked confidence in their daily activities due to their knee, and 17 subjects reported having made a modification in their lifestyle to avoid potentially damaging activities to their knee. However, the intensity of pain, functional impairment, and quality of life varied among the subjects for different activities.

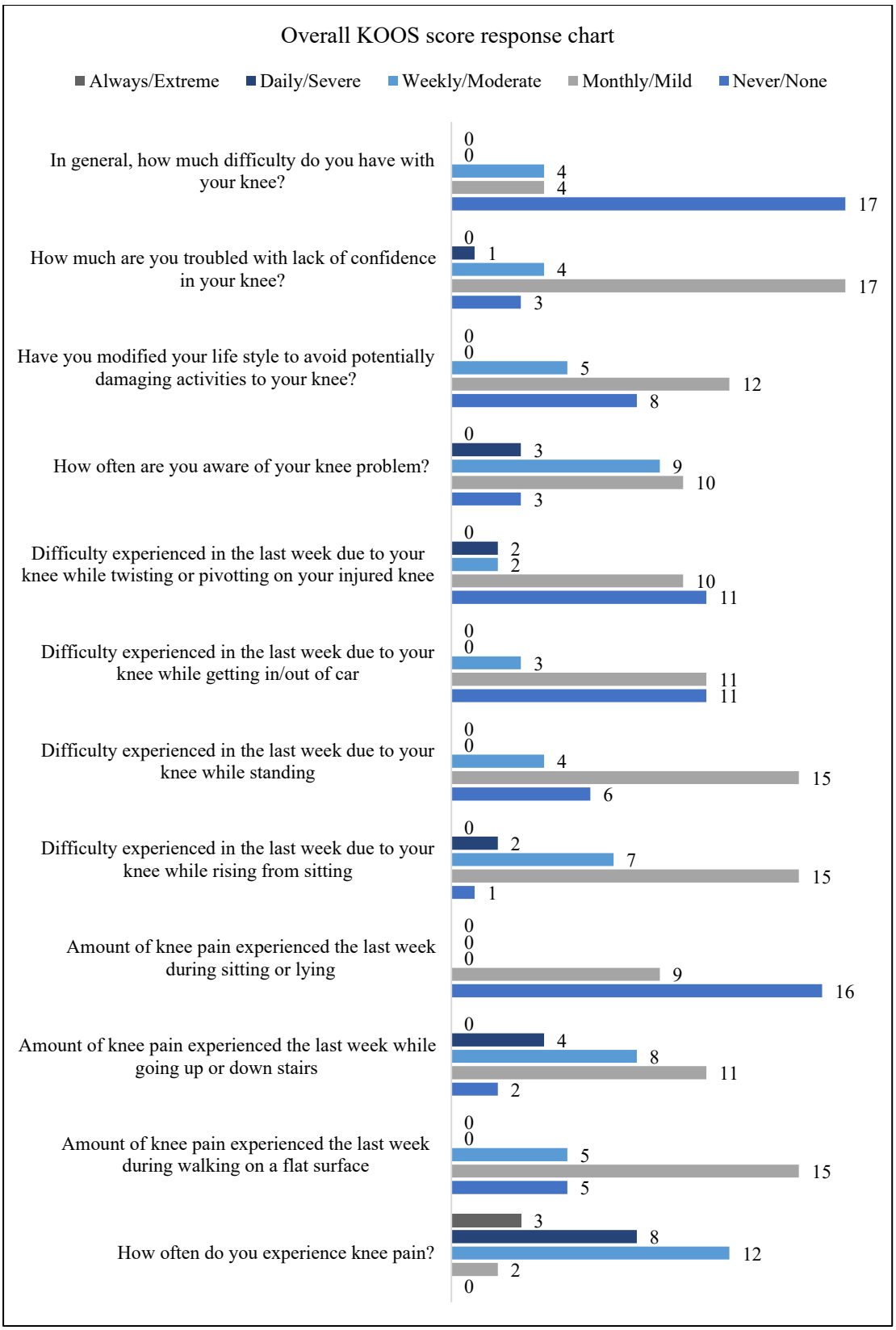


Figure 4. 13 Overall KOOS score response chart of the study participants.

Spatial and Temporal Gait Parameters

The spatial and temporal parameters of gait were acquired using the WinTrack platform. The data from the individual reports of each patient was extracted and analyzed. In terms of spatiotemporal gait parameters, the mean (SD) of stance phase duration, stride duration, swing phase duration left, swing phase duration right, step duration left, step duration right, step length left, step length right, stride length, max pressure left, and max pressure right among the subjects are 599.60 ms (± 130.81), 1997.20 ms (± 347.84), 1227.20 ms (± 160.61), 1362.40 ms (± 277.07), 576.00 ms (± 173.54), 658.80 ms (± 173.09), 493.96 mm (± 78.34), 507.04 mm (± 66.68), 100.09 mm (± 11.65), 5125.60 kPa (± 1183.54), and 5166.32 kPa (± 1097.45), respectively (Table 3). The additional parameters were calculated from the data extracted by the WinTrack system. The mean (SD) of DIMPD, ISPDD, ISDD, ISLD, SLLA, SLA, SDA, SPA, and PPA were calculated to be 1306.40 kPa (± 829.72), 164.80 ms (± 200.50), 182.00 ms (± 268.33), 60.12 mm (± 63.47), 12.24% (± 10.27), 11.39% (± 11.38), 20.73% (± 25.30), 10.66% (± 10.88), and 22.30% (± 13.11) respectively. (Table 4.8)

Prevalence of Asymmetries in Unilateral KOA

The overall prevalence of asymmetries in limb loading, plantar pressure, and spatiotemporal parameter of gait was calculated by division of the total number of subjects with asymmetry by the total number of subjects included in the study and multiplied by 100 (Table 4.9). The prevalence of SLLA was evaluated to be 44%, out of which 32% of participants had static limb load asymmetry between 10-20%, and 12% of participants had asymmetry greater than 20%. Whereas the prevalence of SLA was 48%, out of which 36% of subjects had asymmetry between 10-20%, and only 12% of the participant had asymmetry greater than 20 %. The prevalence of SDA was evaluated to be 48%, out of which 12% had asymmetry between 10-20%, and 36% of participants had asymmetry greater than 20%. The prevalence of SPA was evaluated to be 32%, out of which 12% had asymmetry between 10–20%, and 20% of participants had asymmetry greater than 20%. As compared to other all types of asymmetries assessed in this study, the prevalence of PPA was significantly high, the prevalence of

plantar pressure asymmetry was evaluated to be 92%, out of which 44% of participants asymmetry between 10–20%, and 48% participants had asymmetry greater than 20%.

Table 4. 8 Descriptive analysis of the spatial, and temporal gait parameters acquired using WinTrack platform.

	Mean	SD	SEM	Range
Stance phase duration (ms)	599.60	130.81	26.16	640.00
Stride time (ms)	1997.20	347.84	69.57	1470.00
Swing phase duration Left (ms)	1227.20	160.61	32.12	620.00
Swing phase duration Right (ms)	1362.40	277.07	55.41	1250.00
Step Duration Left (ms)	576.00	173.54	34.71	890.00
Step Duration Right (ms)	658.80	173.09	34.62	770.00
Step Length Left (mm)	493.96	78.34	15.67	328.00
Step length Right (mm)	507.04	66.68	13.34	242.00
Stride length (cm)	100.09	11.65	2.33	44.51
Max. Pressure Left (kPa)	5125.60	1183.54	236.71	4650.00
Max. Pressure Right (kPa)	5166.32	1097.45	219.49	4493.00
DIMPD (kPa)	1306.40	829.72	165.94	2754.00
ISPDD (ms)	164.80	200.50	40.10	750.00
ISDD (ms)	182.00	268.33	53.67	970.00
ISLD (mm)	60.12	63.47	12.69	312.00
SLLA (%)	12.24	10.27	2.05	38.00
SLA (%)	11.39	11.38	2.28	54.74
SDA (%)	20.73	25.30	5.06	86.61
SPA (%)	10.66	10.88	2.18	36.86
PPA (%)	22.30	13.11	2.62	45.88

Note: SD: standard deviation, SEM- standard error of mean, DIMPD- Dynamic Interlimb Max. Pressure Difference, ISPDD- Swing Phase Duration Difference, ISDD- Interlimb Step Duration Difference, ISLD- Interlimb Step Length Difference, SLLA- Static Limb Load Asymmetry, SLA- Step Length Asymmetry, SDA- Step Duration Asymmetry, SPA- Swing Phase Asymmetry, PPA- Plantar Pressure Asymmetry.

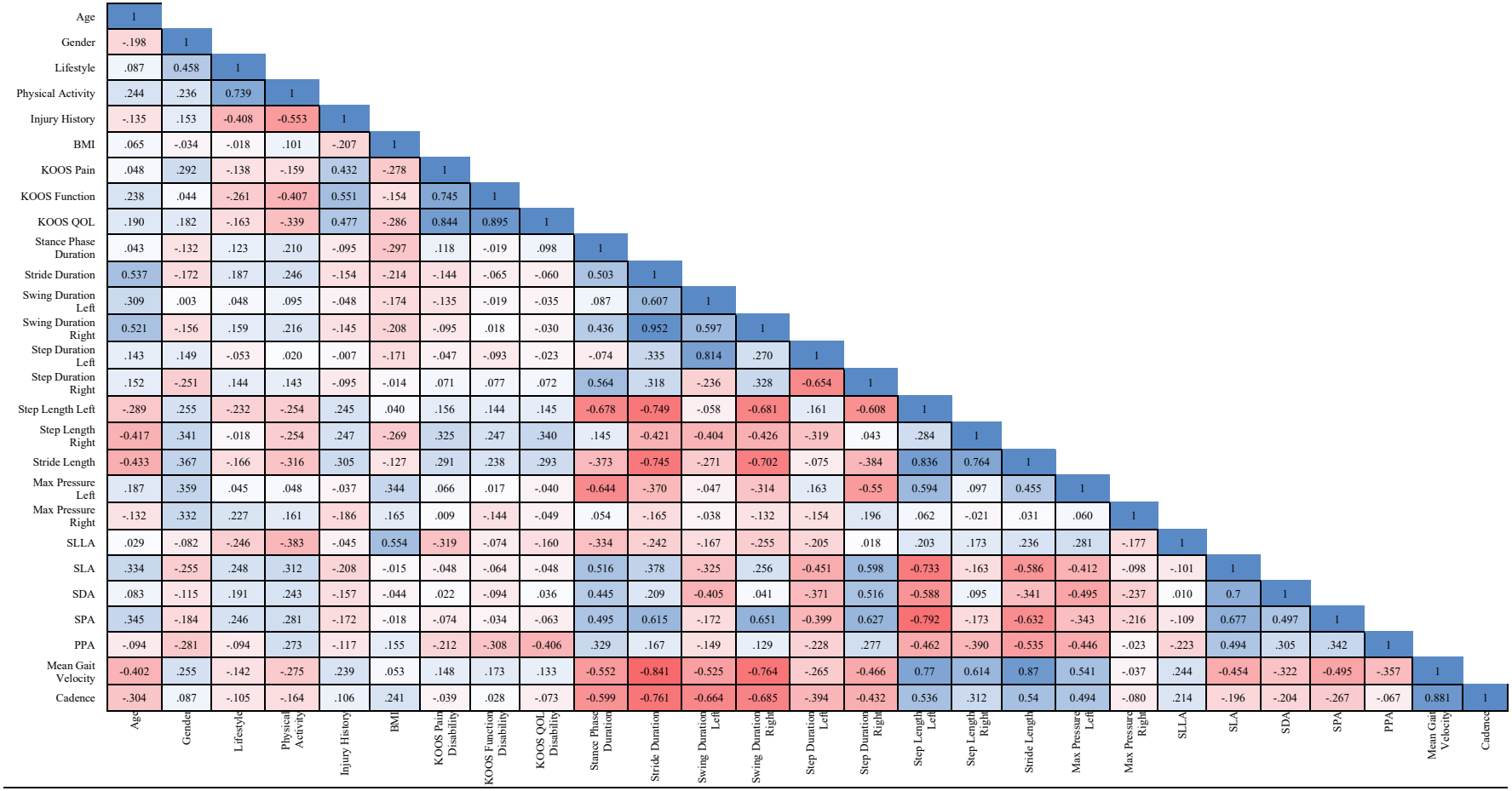
Table 4. 9 Prevalence of asymmetries in static limb loading, step length, step duration, swing phase, and plantar pressure in KOA

Asymmetry type	Asymmetry (%)	Subjects (n)	Percent (%)
Static Limb Load Asymmetry (%)	<10	14	56
	10-20	8	32
	>20	3	12
Step Length Asymmetry (%)	<10	13	52
	10-20	9	36
	>20	3	12
Step Duration Asymmetry (%)	<10	13	52
	10-20	4	16
	>20	8	32
Swing Phase Asymmetry (%)	<10	17	68
	10-20	3	12
	>20	5	20
Plantar Pressure Asymmetry (%)	<10	2	8
	10-20	11	44
	>20	12	48

Correlation between spatiotemporal gait variables and asymmetries

The data was further analyzed statistically to check for a correlation between the outcome variables and the participant's demographic profile. The Pearson coefficient of correlation was used to test the correlation among the continuous variables that included SLLA, SLA, SDA, SPA, PPA, age, BMI, KOOS- pain, function, and quality of life score. A heat-map correlation graph was also generated for easier visualization of the correlation between the tested variables (Figure 4.14), which suggests a significant correlation exists among these variables. The age of the subject does not correlate significantly with any of the outcome variables. The SLLA and BMI have shown a strong positive correlation of 0.623 ($p = 0.004$), which suggests that asymmetry in limb loading while standing increases with the increase in BMI. Whereas the SLA has shown a strong positive correlation with SDA ($r = 0.700$, $p = .000$), SPA ($r = 0.677$, $p = .000$), and medium positive correlation with PPA ($r = 0.494$, $p = .012$), which suggests that the asymmetry in step length increases with the increase of asymmetry in step duration, swing phase duration, and plantar pressure distribution while walking, and vice-versa. Similarly, SDA shows a medium positive correlation with SPA ($r = 0.497$, $p = .012$), which implies that the asymmetry in step duration increases and decreases with the increase and decrease of asymmetry in swing phase duration. The PPA shows a medium positive correlation with KOOS score for quality of life ($r =$

0.406, p = .044), suggesting that the PPA decreases with the increase in the KOOS quality of life score. The higher KOOS quality of life score suggests better quality of life. Therefore, it is imperative to say that the PPA increases with improvement in quality of life which is practically impossible. On the other hand, all the KOOS parameters- pain (KP), function (KF), and quality of life (KQ) show a significantly strong positive correlation with each other at the 0.05 level, which is obvious as they are interdependent.



**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Figure 4. 14 Heat map correlation between demographic characteristics, outcome variables, and different types of asymmetries using Pearson Correlation Coefficient.

4.3.2 Bilateral KOA

Among the subjects with bilateral KOA, 53 were female (75.72%), and 17 were male (24.28%), with most subjects being moderately active (95.71%) with an active lifestyle (91.43%). Out of 70 subjects, only 3 (4.28%) had a history of injury to the lower limb. In terms of BMI, around 51.42% of the samples were either overweight (27.14%) or obese (24.28%). (Table 4.10)

Table 4. 10 Frequency distribution of age, BMI, lifestyle, physical activity, injury history, and limb involvement based on gender.

n=95		**Male (n=17)**		**Female (n=53)**		**Total**	
		Frequency	**Percent (%)**	**Frequency**	**Percent (%)**	**Frequency**	**Percent (%)**
Age (years)	41–50	7	10	41	58.57	48	68.57
	> 50	10	14.30	12	17.14	22	31.43
BMI	< 18.5	1	1.43	2	2.85	3	4.28
	18.5-24.9	9	12.85	22	31.42	31	44.28
	25 - 30	4	5.71	15	21.42	19	27.14
	> 30	3	4.28	14	20	17	24.28
Lifestyle	Active	12	17.14	52	74.28	64	91.43
	Sedentary	5	7.14	1	1.43	6	8.57
Physical Activity	Moderate	15	21.42	51	76	67	95.71
	Low	2	2.85	2	2.85	3	4.28
Injury History	Yes	1	1.43	2	2.85	67	95.71
	No	16	22.85	51	72.85	3	4.28
Note: BMI- body mass index							

The mean (SD) of age, BMI, KOOS- pain, function, quality of life, and global among patients with bilateral KOA were 48.31 (6.01), 26.02 (4.82), 65.80 (11.04), 73.84 (10.44), 62.41 (11.13), and 67.35 (9.70) respectively. (Table 4.11) The overall KOOS-12 score suggests that, on average, all the subjects experienced pain 34.20% of the time in the past week, difficulty in performing their activities of daily living 27.16% of the time, and difficulty in having a good quality of life 26.16% of the time.

Table 4. 11 Descriptive statistics for age, BMI, and KOOS score in terms of pain, function, and quality of life.

	Mean	SD	SEM	Range
Age (years)	48.31	6.01	0.72	27
BMI	26.02	4.82	0.58	22.46
KOOS Global	67.35	9.70	1.16	54.17
KOOS Pain	65.80	11.04	1.32	56.25
KOOS Function	73.84	10.44	1.25	56.25
KOOS QOL	62.41	11.13	1.33	56.25

Note: SD: standard deviation, SEM- standard error of mean, BMI- body mass index, KOOS- Knee Injury and Osteoarthritis Outcome Score, QOL- quality of life

KOOS Score

The overall response to the KOOS questionnaire of all the subjects is summarized in Figure 4.15. Out of 70 subjects, 65 reported pains in the knee at least once in the past week. While walking on a flat surface, 45 subjects reported mild knee pain, and 9 reported moderate knee pain. In the case of stair climbing and descending, 23 subjects reported mild knee pain, 42 subjects reported moderate knee pain, and 3 reported severe knee pain. Whereas, while sitting, only 15 and 3 subjects reported mild and moderate knee pain, respectively. In terms of activities of daily living, 41 and 4 subjects reported to have experienced mild and moderate difficulty in twisting or pivoting, respectively, on their involved knee. While getting in or out of a car or public transport, 41, 5, and 1 subject reported to have experienced mild, moderate, and severe difficulty, respectively, due to their knee. On being asked about the amount of difficulty experienced due to their knee while standing for a shorter/longer period, 44, 14, and 1 subject reported having experienced mild, moderate, and severe difficulty, respectively. On the other hand, all subjects reported some degree of difficulty in rising from a sitting position due to their knee. The number of subjects who reported mild, moderate, and severe difficulty in rising from a sitting position due to their knee are 29, 37, and 4, respectively. In terms of KOOS quality of life, all subjects reported that they are aware of their knee pain to some extent, as 42 subjects reported they were aware of their problem daily or always, 24 reported that they were about their knee problem at least once a week. Furthermore, 64 subjects mildly lacked confidence in their daily activities

due to their knee, and 57 subjects reported having made a modification in their lifestyle and daily activities to avoid potentially damaging activities to their knee. The amount of overall difficulty experienced by the subjects due to their knee ranges from severe (n=2), moderate (n=25), mild (n=42), and no difficulty (n=1). However, the intensity of pain, functional impairment, and quality of life varied among the subjects for different activities.

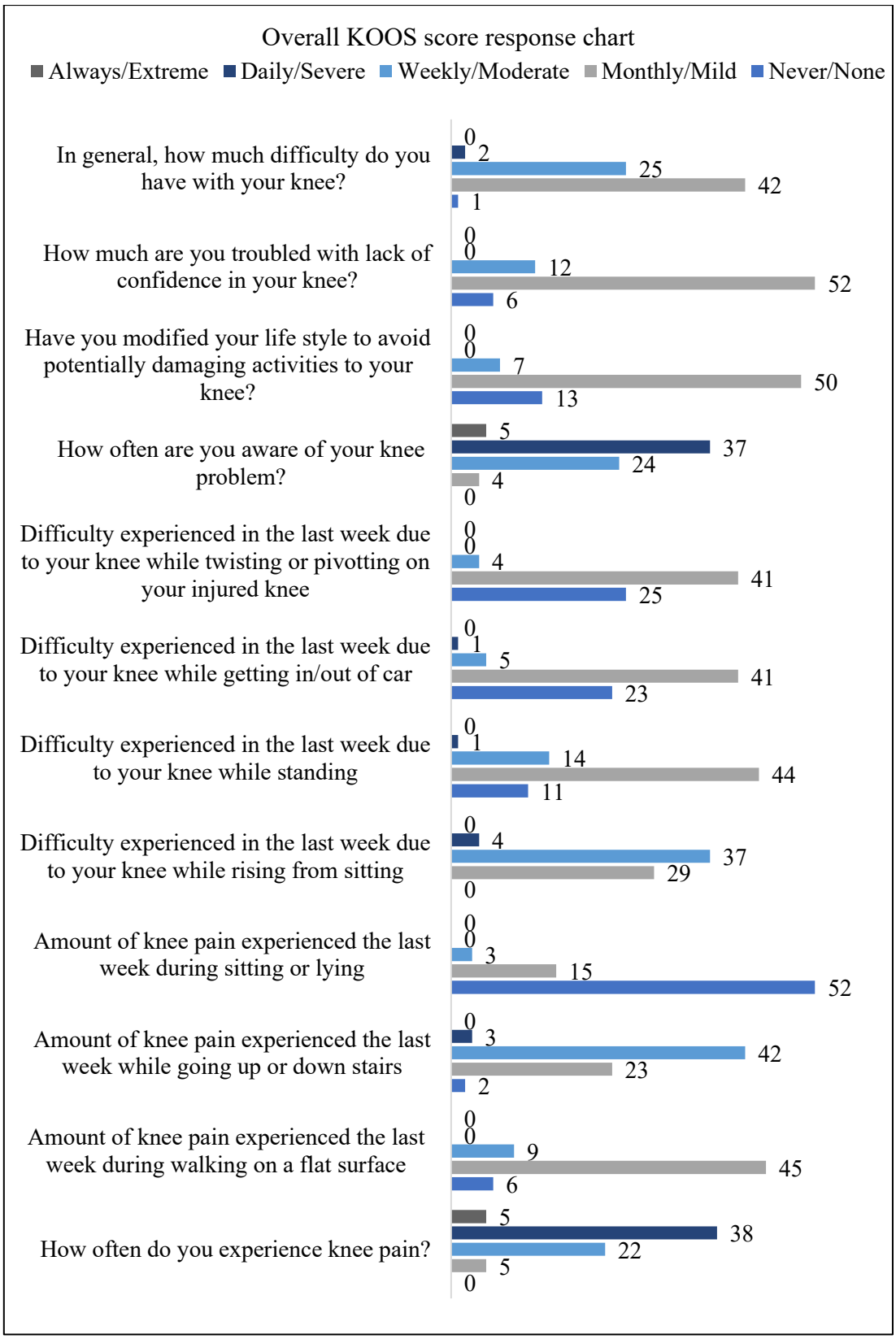


Figure 4. 15 Overall KOOS score response chart.

Spatial and Temporal Gait Parameters

The spatial and temporal parameters of gait were acquired using the WinTrack platform. Data from the individual reports of each patient was extracted and analyzed. In terms of spatiotemporal gait parameters, the mean (SD) of stance phase duration, stride duration, swing phase duration left, swing phase duration right, step duration left, step duration right, step length left, step length right, stride length, max pressure left, and max pressure right among the subjects are 597.140 ms (± 137.95), 1967.71 ms (± 319.82), 1266.00 ms (± 184.58), 1337.71 ms (± 290.88), 632.57 ms (± 130.47), 618.14 ms (± 123.04), 501.07 mm (± 76.76), 507.99 mm (± 65.63), 100.38 mm (± 11.98), 5224.01 kPa (± 1201.12), and 5469.40 kPa (± 1416.68), respectively (Table 4.12). The additional parameters were calculated from the data extracted by the WinTrack system. The mean (SD) of dynamic interlimb max. pressure difference, interlimb swing phase duration difference, interlimb step duration difference, interlimb step length difference, SLLA, SLA, SDA, SPA, and PPA were calculated to be 1417.97 kPa (± 897.02), 155.43 ms (± 201.99), 108.14 ms (± 100.31), 50.83 mm (± 44.59), 14.63% (± 10.31), 9.57% (± 8.24), 15.02% (± 11.85), 9.80% (± 10.26), and 22.82% (± 12.32) respectively.

Prevalence of Asymmetries in Bilateral KOA

The overall prevalence of limb loading asymmetry, plantar pressure asymmetry, and asymmetry of spatiotemporal parameter of gait was calculated (Table 4.13). The prevalence of SLLA was evaluated to be 55.71%, out of which 34.29% of participants had static limb load asymmetry between 10-20%, and 21.43% of participants had asymmetry greater than 20%. Whereas the prevalence of SLA was 38.57%, out of which 27.14% of subjects had asymmetry between 10-20%, and only 11.43% of the participant had asymmetry greater than 20 %. The prevalence of SDA was evaluated to be 57.14%, out of which 30% had asymmetry between 10-20%, and 27.14% of participants had asymmetry greater than 20%. The prevalence of SPA was evaluated to be 32.86%, out of which 15.71% had asymmetry between 10–20%, and 17.14% of participants had asymmetry greater than 20%. As compared to other all types of asymmetries assessed in this study, the prevalence of PPA was significantly high, and the prevalence of plantar pressure asymmetry was evaluated to be 84.29%, out of which

31.43% of participants had asymmetry between 10–20%, and 52.86% participants had asymmetry greater than 20%.

Table 4. 12 Descriptive analysis of the spatial and temporal gait parameters acquired using the WinTrack platform.

	Mean	**SD**	**SEM**	**Range**
Stance phase duration (ms)	597.14	137.95	16.49	860
Stride time (ms)	1967.71	319.82	38.23	1540
Swing phase duration Left (ms)	1266.00	184.58	22.06	1080
Swing phase duration Right (ms)	1337.71	290.88	34.77	1590
Step Duration Left (ms)	632.57	130.47	15.59	800
Step Duration Right (ms)	618.14	123.04	14.71	810
Step Length Left (mm)	501.07	76.76	9.17	382
Step length Right (mm)	507.99	65.63	7.84	331
Stride length (cm)	100.38	11.98	1.43	55.45
Max. Pressure Left (kPa)	5224.01	1201.12	143.56	6132
Max. Pressure Right (kPa)	5469.40	1416.68	169.33	6054
DIMPD (kPa)	1417.97	897.02	107.21	4250
ISPDD (ms)	155.43	201.99	24.14	1000
ISDD (ms)	108.14	100.31	11.99	470
ISLD (mm)	50.83	44.59	5.33	195
SLLA (%)	14.63	10.31	1.23	42
SLA (%)	9.57	8.24	0.98	31.46
SDA (%)	15.02	11.85	1.42	48.44
SPA (%)	9.80	10.26	1.23	50.50
PPA (%)	22.82	12.32	1.47	54.13

Note: SD: standard deviation, SEM- standard error of mean, DIMPD- Dynamic Interlimb Max. Pressure Difference, ISPDD- Swing Phase Duration Difference, ISDD- Interlimb Step Duration Difference, ISLD- Interlimb Step Length Difference, SLLA- Static Limb Load Asymmetry, SLA- Step Length Asymmetry, SDA- Step Duration Asymmetry, SPA- Swing Phase Asymmetry, PPA- Plantar Pressure Asymmetry.

Table 4. 13 Prevalence of asymmetries in static limb loading, step length, step duration, swing phase, and plantar pressure.

Asymmetry type	Asymmetry (%)	Subjects (n)	Percent (%)
Static Limb Load Asymmetry (%)	<10	31	44.29
	10-20	24	34.29
	>20	15	21.43
Step Length Asymmetry (%)	<10	43	61.43
	10-20	19	27.14
	>20	8	11.43
Step Duration Asymmetry (%)	<10	30	42.86
	10-20	21	30.00
	>20	19	27.14
Swing Phase Asymmetry (%)	<10	47	67.14
	10-20	11	15.71
	>20	12	17.14
Plantar Pressure Asymmetry (%)	<10	11	15.71
	10-20	22	31.43
	>20	37	52.86

Correlation between spatiotemporal gait variables and asymmetries

The data was further analyzed statistically to check for a correlation between the outcome variables and the participant's demographic profile. The demographic data were coded in numeric variables as follows: gender (male=1, female=2), lifestyle (active=1, sedentary=2), physical activity (moderate=1, low=2), and injury history (none=0, yes=1). The Pearson coefficient of correlation was used to test the correlation among the following variables stance phase duration, stride duration, swing phase duration left and right, step duration left and right, step length left and right, stride length, maximum pressure left and right, mean gait velocity, cadence, SLLA, SLA, SDA, SPA, PPA, age, gender, lifestyle, physical activity, injury history, BMI, and KOOS scores for pain, function, and quality of life score. A heat-map correlation graph was generated for easier visualization of the correlation between the tested variables (Figure 4.16), which suggests a significant correlation exists among these variables. All the variables showed a significant correlation with at least one of the test variables.

The age of the subject negatively correlated with the gender of the subject (r= -.350, p= .003), suggesting that females developed KOA at a younger age than males

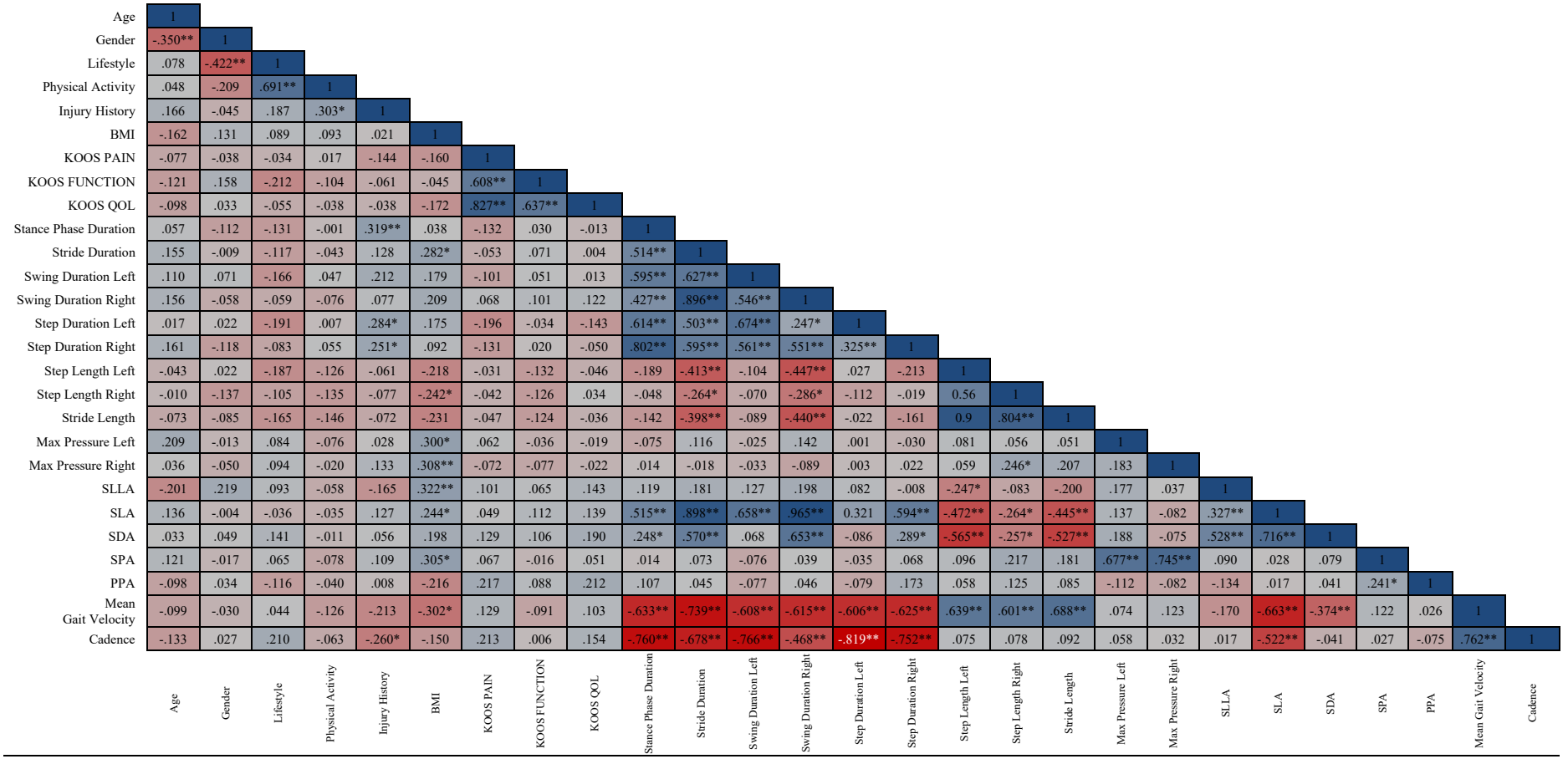
in our study. The physical activity level of the subjects has shown a medium negative correlation with gender (r= -.422, p= .000), a strong positive correlation with the lifestyle (r= 0.691, p= .000) and medium strong positive correlation with injury history (r= 0.303, p= .011) of the subjects which suggests that the female in our study were more active, and the subjects with a sedentary lifestyle and injury history had low physical activity. The injury history showed weak positive correlation with the stance phase duration (r= 0.319, p= .007), step duration left (r= 0.284, p= .017), step duration right (r= 0.251, p= .036), and weak negative correlation with the cadence (r= -.260, p= .030). It suggests that subjects with an injury history spend more time in the stance phase, and the time is taken for both left and right steps, which results in slow-paced walking. Furthermore, BMI showed weak positive correlation with stride duration (r= 0.282, p= .018), maximum pressure left (r= 0.300, p= .012), maximum pressure right (r= 0.308, p= .010), SLLA (r= 0.322, p= .007), SLA (r= 0.244, p= .042), and SPA (r= 0.305, p= .010), and showed weak negative correlation with step length right (r= -.242, p= .044), and mean gait velocity (r= -.302, p= .011). This implies that stride duration, maximum plantar pressure left and right, SLLA, SLA, and SPA increases with the increase in BMI, whereas the step length right and mean gait velocity decrease with an increase in BMI, and vice-versa. Interestingly, the KOOS pain, activities of daily living, and quality of life score did not correlate with any of the outcome variables other than among themselves. The KOOS pain score showed strong positive correlation with KOOS score for activities of daily living (r= 0.608, p= .000) and very strong positive correlation with KOOS quality of life score (r= 0.827, p= .000), whereas the KOOS activities of daily living score showed strong positive correlation with KOOS quality of life score (r= 0.637, p= .000). This implies that KOOS pain, activities of daily living and quality of life are interlinked, if one increase other also increases.

In terms of the spatiotemporal variables and different types of asymmetries, significant correlations were found among them. The SLLA showed medium correlation with injury history (r= 0.322, p= .007), SLA (r= -.327, p= .006), and strong positive correlation with SDA (r= 0.528, p= .000), and weak negative correlation with step length left (r= -.247, p= .039). It suggests that the chances of SLLA are higher among individuals with an injury history, SLA, and SDA, and vice-versa. The SLA showed weak positive correlation with an injury history (r= 0.244, p= .042), step

duration left (r= 0.321, p= .007), SLLA (r= 0.327, p= .006); strong positive correlation with stance phase duration (r= 0.515, p= .000), swing duration left (r= 0.658, p= .000), and step duration right (r= 0.594, p= .000); and SDA (r= 0.716, p= .000), and very strong positive correlation with stride duration (r= 0.898, p= .000), and swing duration right (r= 0.965, p= .000), The SLA showed weak negative correlation with step length right (r= -.264, p= .027), and medium negative correlation step length left (r= -.472, p= .000), stride length (r= -.445, p= .000), mean gait velocity (r= -.663, p= .000), and cadence (r= -.522, p= .000). This implies that the asymmetry in step length increases, and decreases with the increase, and decrease in injury history, stance phase duration, stride duration, swing duration left and right, step duration left, and right, SLLA, and SDA. On the other hand, asymmetry in step length increases with the decrease in step length left and right, stride length, mean gait velocity, and cadence, and vice-versa.

The SDA showed weak positive correlation with stance phase duration (r= 0.248, p= .038) and step duration right (r= 0.289, p= .015); a strong positive correlation with stride duration (r= 0.570, p= .000), swing duration right (r= 0.653, p= .000), , SLLA (r= 0.528, p= .000), and SLA (r= 0.716, p= .000), weak negative correlation with step length right (r= -.257, p= .032), and mean gait velocity (r= -.374, p= .001) and strong negative correlation with step length left (r= -.565, p= .000), and stride length (r= -.527, p= .000). This signifies that the asymmetry in step duration increases with the increase in stance phase duration, stride duration, swing, and step duration of right leg, SLLA, and SDA, and vice-versa. Further, asymmetry in step duration increases with the decrease in step length left and right, stride length, and mean gait velocity, and vice-versa.

The SPA showed weak positive correlation with an injury history (r= 0.305, p= .010), and strong positive correlation with maximum plantar pressure left (r= 0.677, p= .000), and maximum plantar pressure right (r= 0.745, p= .000), which suggests that the asymmetry in the swing phase duration increases, and decreases with the increase, and decrease in injury history, and maximum plantar pressure exerted on left and right foot during walking. On the other hand, PPA showed weak positive correlation only with SPA (r= -.241, p= .045), which suggests that there is an inverse relation between PPA and SPA, i.e., asymmetry in plantar pressure distribution increases with the decrease in the asymmetry of swing phase duration.



**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

SLLA- Static limb load asymmetry, SLA- step length asymmetry, SDA- Step duration asymmetry, SPA- Swing Phase Asymmetry, PPA- Plantar pressure asymmetry, BMI- body mass index, KOOS- Knee Injury, and Osteoarthritis Outcome Score, QOL- quality of life.

Figure 4. 16 Heat map correlation between demographic characteristics, outcome variables, and different types of asymmetries using Pearson Correlation Coefficient

4.4 Development of DT-Walk (Phase III)

After months of struggle starting from December 2020, we finally completed the development of our prototype device in October 2022. It took another two months (December 2022) to build the beta version of DT-walk which we used for validation. The developed wearable device would offers great competition to highly accurate, expensive, and bulkier force platform-based systems and less accurate insole-based systems. The DT-walk is based on a custom-made pressure-sensitive matrix made up of one layer of velostat sheet sandwiched between two layers of copper strips. One layer of copper strips is placed in the horizontal direction, and the other layer in the vertical direction. Each cross-sectional area formed by the velostat and copper layers act as a pressure-sensing unit. This results in a lightweight, flexible, and high-resolution insole that can be worn and carried easily. Additionally, a separate layer consisting of five force-sensitive resistors was placed at key locations on the plantar surface of the foot for accurate gait phase identification. For spatiotemporal gait parameters, two inertial motion sensors with attitude and heading reference system (AHRS) were also incorporated into our device for accurate spatial and temporal gait detection.

Fabrication of the force-sensitive resistor unit

The force-sensitive resistor unit consists of five force-sensitive resistors (FSR) embedded on a thin layer of Ethylene-vinyl acetate sheet. FSRs are sensors that allow you to detect physical pressure, squeezing, and weight. The FSR is made of 2 layers separated by a spacer. The more one presses, the more of those active element dots touch the semiconductor, and that makes the resistance go down. FSRs are basically a resistor that changes their resistive value (in ohms Ω) depending on how much it is pressed. Each force-sensitive resistor unit is composed of five square-shaped FSRs of 1.5” X 1.5”. The square shaped FSR is placed on the main plantar pressure area that receives the maximum amount of pressure (Figure 4.17). The FSRs placed in each force-sensitive resistor unit assists in precise gait phase identification as well as pressure on each of them.

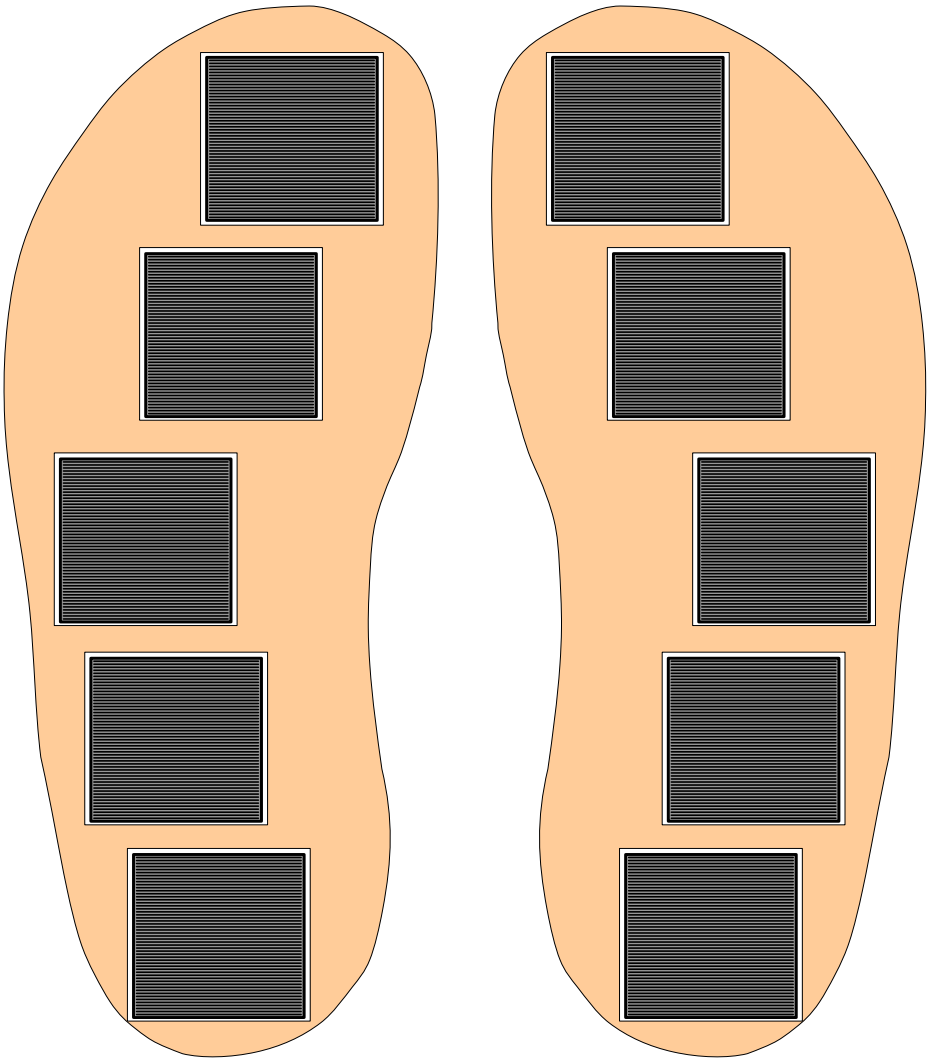
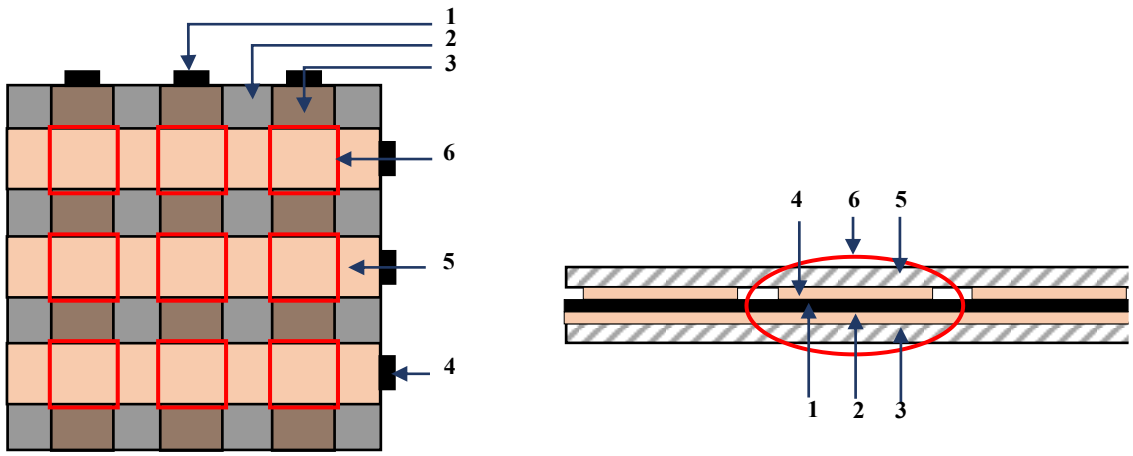


Figure 4. 17 Left and right force-sensitive resistor unit

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 4.18 and 4.19). Velostat is a commercially available conductive material that is sensitive to pressure that reduces resistance when force is applied to it. The copper strips are also commercially available in the form of copper tape, which has adhesive on one side. The pressure-sensitive matrix is formed by pasting copper strips on the top and bottom insulating layers in vertical and horizontal directions, respectively. A velostat sheet is placed between the two layers of copper strip. All the copper strips are then attached to the microcontroller via a 16-channel multiplexer

which gives the reading when current is passed through the circuit and pressure is applied to it.



(a) (b)

Figure 4. 18 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

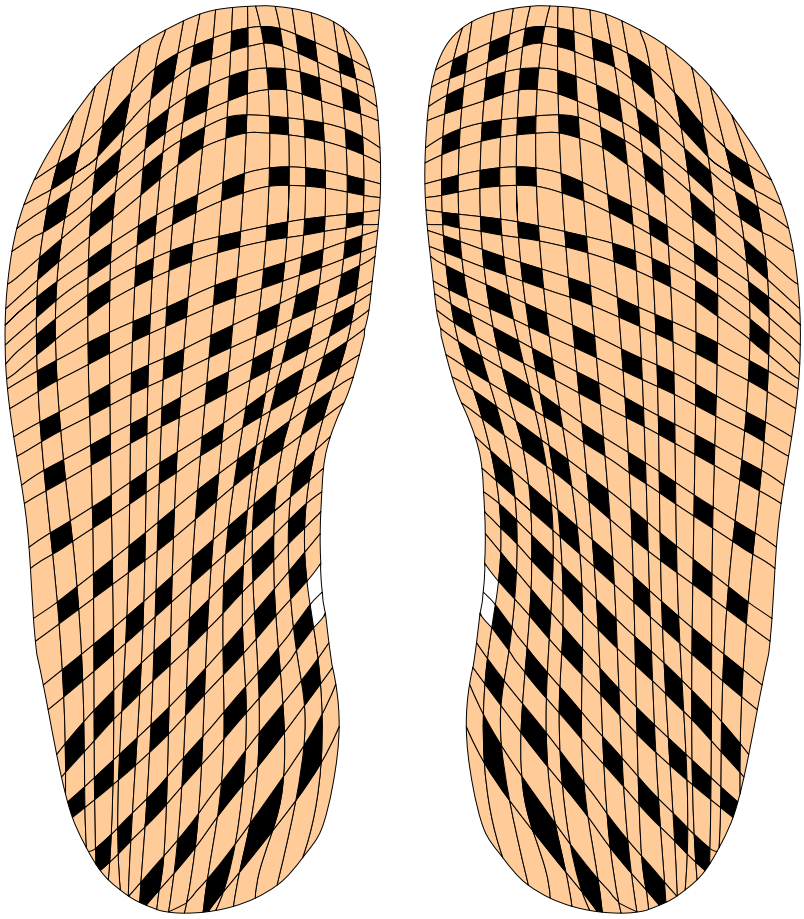


Figure 4. 19 Custom-made pressure-sensitive matrix made developed using copper and velostat.

Data Acquisition system

The inputs from the custom-made pressure-sensitive matrix were acquired using a pair of 16-channel multiplexers/demultiplexers. 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 by the microcontroller (Arduino Mega 2560) that allows to connect sequentially to voltage through each column via M_{top} and to 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}. And the bottom layer with horizontal copper strips was attached to the ground through resistance via 16-channel multiplexer, M_{bottom}. The inputs from all the FSRs in each insole is collected directly by the same microcontroller. The voltage is passed through one of the two pins of FRS, and the output is 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 wireless private network.

Fabrication of prototype of DT-walk

The prototype device of DT-walk consists of three components- an insole component, a motion component, and computation and storage systems. The insole unit consists of two separate pressure detection systems; the first uses the FSRs to identify pressure on the plantar pressure areas of the foot. There are 5 FSRs in each insole placed under the key plantar pressure areas. The other component of the insole was a custom-made pressure-sensitive matrix developed using copper strips and conductive material layering. A custom-made pressure-sensitive matrix was designed in the shape of a shoe insole in which conductive material called velostat is placed between two layers of copper strip, out of which one layer of copper is placed in the horizontal direction and the other in the vertical direction. Each intersection point of the copper strip and the velostat forms the 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 casing superimposed over each other, where the FSR component lies at the bottom, and the matrix lies on the top surface. Both components' connecting wires were taken out from the lateral side where there would be less interference during standing and walking. The connecting wires are attached to the computation, power, and storage system that also incorporates the motion unit. The MPU-9250 sensor is attached directly to the microcontroller (Arduino Mega 328) to assess the spatiotemporal parameters of gait. The motion unit and the computation, power, and storage unit may be called the external unit, which is enclosed in a fiber case that can be attached to the shoe (Figure 4.20, 4.21 and 4.22).

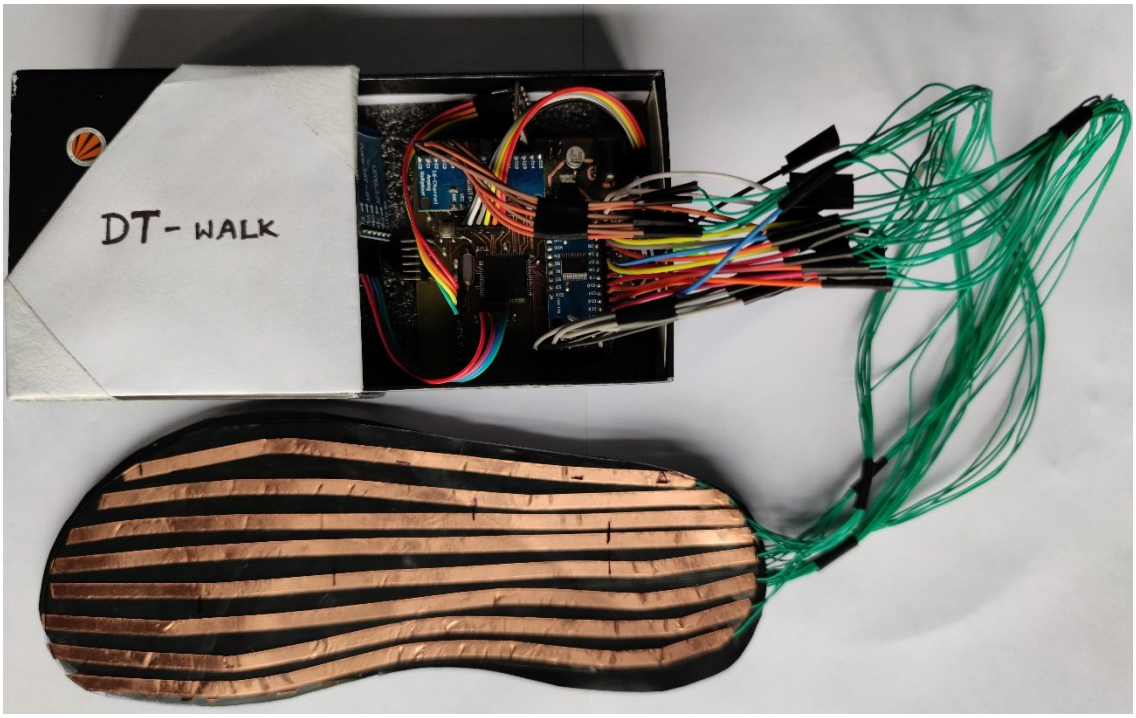


Figure 4. 20 Prototype device with all the components attached to it.

Figure 4. 21 Working prototype of DT-walk.

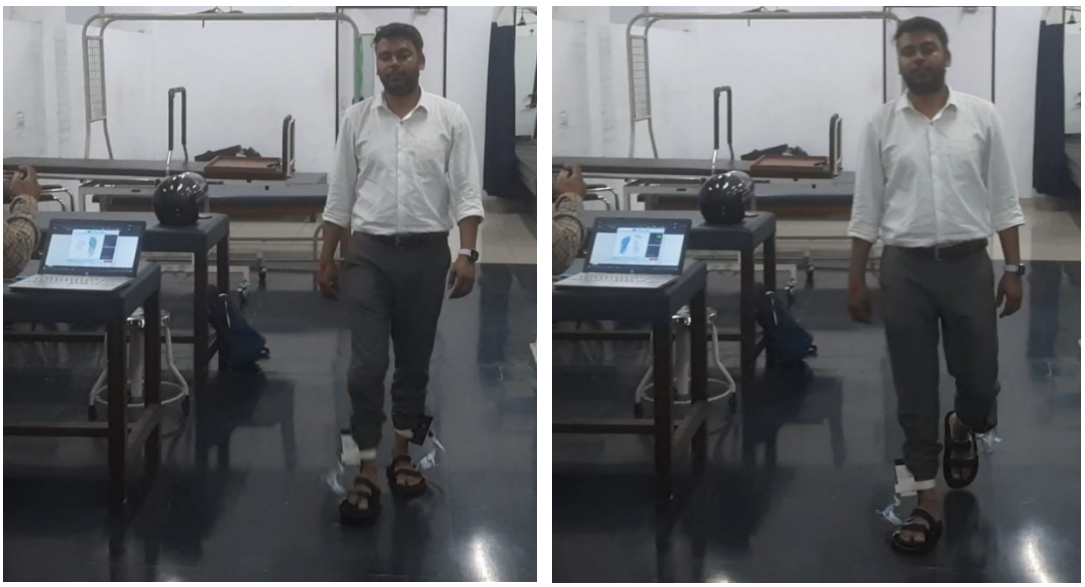


Figure 4. 22 Pre-validation testing for private network communication between DT-walk device and DT-walk application.

Barriers in Prototype Development

There were a few challenges which I faced during prototype development of DT-walk which I would like to mention:

1. Finding the right team for prototype development- I took help from some computer science engineering students who were very initially but later they left the project. So, I had to start again from the beginning with the new team. But thanks to the team headed by Dr. Rajesh Singh, then Head- Division of Research and Innovation, LPU who connected me with Mr. Prabin Kumar Das who worked with me on the project throughout.
2. Lack of advanced technical knowledge- As a physiotherapist I have limited knowledge of prototype development. But thanks to my prior knowledge of C++ programming, I was able to understand and write Arduino codes for our device.
3. Getting good quality sensors online- We had a hard time finding good quality sensors online as the local markets were closed due to government order. We ordered sample sensors from different sellers before finalizing the final list of components we used.
4. COVID pandemic significantly affected our operating capability as only a limited number of resources were available.
5. Getting the fund and settling the bill from the university was another challenge.

4.5 Validation and Reliability Testing of DT-walk (Phase IV)

In this study, a total of 9 subjects (seven female, two male) with bilateral KOA were included, with most subjects being moderately active with an active lifestyle. The mean ± SD of their age and BMI were 53.22±6.63 years, and 28.00±3.78, respectively. The demographic details of the participants included in the validity and reliability of DT-walk is summarized in Table 4.14. The collected using DT-walk and WinTrack device was analyzed to establish the validity and reliability of DT-walk. The raw data is available in Appendix XIX - XXIV.

Table 4. 14 Demographic details of the study participants included in the validity and reliability of DT-walk.

		Male (n=2)		**Female (n=7)**		**Total**	
		Frequency	**Percent (%)**	**Frequency**	**Percent (%)**	**Frequency**	**Percent (%)**
Age (years)	41–50	0	0	5	55.55	5	55.56
	> 50	2	22.22	2	22.22	4	44.44
BMI	18.5–24.9	0	0.00	2	22.22	2	22.22
	25 – 30	1	11.11	4	44.44	5	55.56
	> 30	1	11.11	1	11	2	22.22
Lifestyle	Active	1	11.11	7	77.77	8	88.89
	Sedentary	1	11.11	0	0.00	1	11.11
Physical Activity	Moderate	1	11.11	7	78	8	88.89
	Low	1	11.11	0	0.00	1	11.11
Injury History	Yes	0	0.00	1	22.22	1	11.11
	No	2	22.22	6	66.66	8	88.89

Note: BMI- body mass index

ICCs, and 95% confidence intervals in patients with KOA, as well as the results of the statistical analysis of the comparison of the two assessments sets, for validity, and reliability of DT-walk for assessment of LLA and PPA, are shown in Table 4.15, and Table 4.16.

Table 4. 15 Test-retest reliability and validity of DT-walk for limb load asymmetry in bilateral KOA for limb load asymmetry.

	Mean (SD)	ICC	95% of Class 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 4. 16 Test-retest reliability and validity of DT-walk for dynamic plantar pressure asymmetry in bilateral KOA for plantar pressure asymmetry

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

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 two readings for the same rater in intra-rater reliability and the mean of three readings by different raters in inter-rater reliability, respectively. The mean (SD) of the SLLA among the participants in reading 1 and reading 2 for intra-rater reliability were 17.93 (13.00) and 17.81 (13.04), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the two readings were 0.808603697 and -0.562487625, respectively. At a 95% of the confidence interval, DT-walk showed excellent intra-rater reliability with ICC > 0.9 (SEM=0.00668, MDC= 0.01852, CV=5.43%), for LLA in KOA. The Bland-Altman plots, with the bias between the repeated assessments and the limits of agreement for each measure, are reported in Figure 4.23. Table 4. 17 shows the statistical analysis findings of intra-rater reliability testing using DT-walk for assessment of limb load asymmetry.

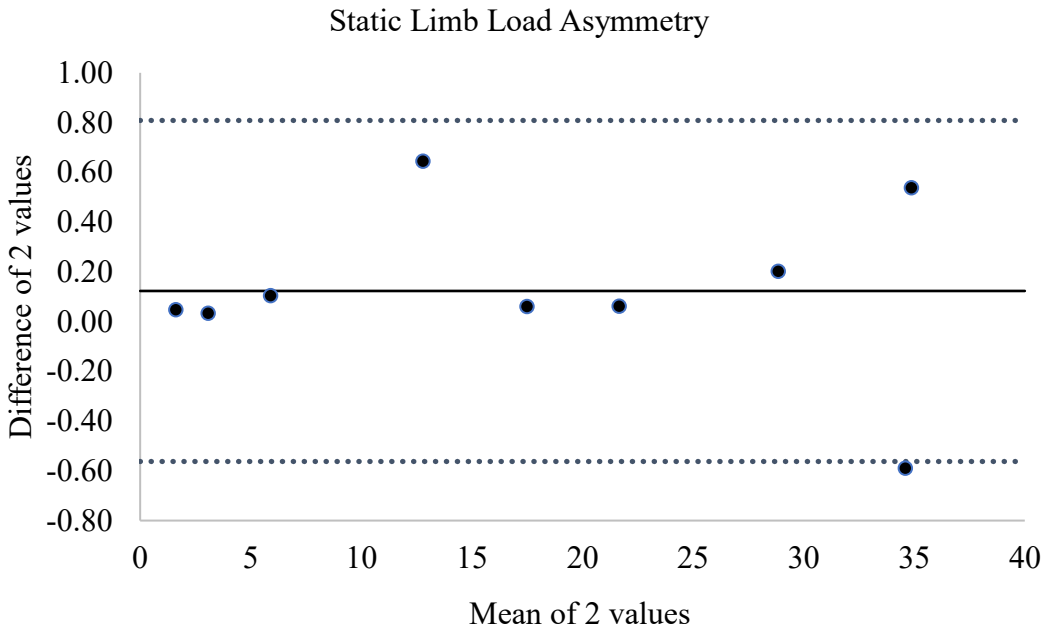


Figure 4. 23 Bland Altman plot for intra-rater reliability of DT-walk for limb load asymmetry.

Table 4. 17 Statistical analysis of intra-rater reliability testing using DT-walk for assessment of limb load asymmetry.

Sample No.	Reading 1	Reading 2	Difference	Mean
1	5.95	5.85	0.10	5.90
2	13.11	12.47	0.65	12.79
3	3.09	3.06	0.03	3.08
4	28.96	28.76	0.20	28.86
5	1.63	1.59	0.05	1.61
6	35.14	34.60	0.54	34.87
7	34.31	34.90	-0.59	34.60
8	17.52	17.46	0.06	17.49
9	21.69	21.63	0.06	21.66
Mean	17.93	17.81	0.12	17.87
Standard Deviation	13.00	13.04	0.35	13.02
		Standard Error of Measurement	0.006684076	
		Minimal Detectable Change	0.018527312	
		Coefficient of Variance	5.431644892	
		Upper Limit of Agreement	0.808603697	
		Lower Limit of Agreement	-0.562487625	
		Intraclass Correlation Coefficient	0.99963	

The mean (SD) of the SLLA among the participants by rater 1 and rater 2 for inter-rater reliability were 17.88 (12.98) and 17.90 (12.97), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the readings of the two raters were 0.371440926 and -0.40196386, respectively. At a 95% of the confidence interval, DT-walk showed excellent inter-rater reliability with ICC > 0.9 (SEM=0.002, MDC= 0.00556, CV= 13.15%) for LLA in KOA. The Bland-Altman plots, with the bias between the repeated assessments and the limits of agreement for each measure, are reported in Figure 4.24. Table 4. 18 shows the statistical analysis findings of inter-rater reliability testing using DT-walk for assessment of limb load asymmetry.

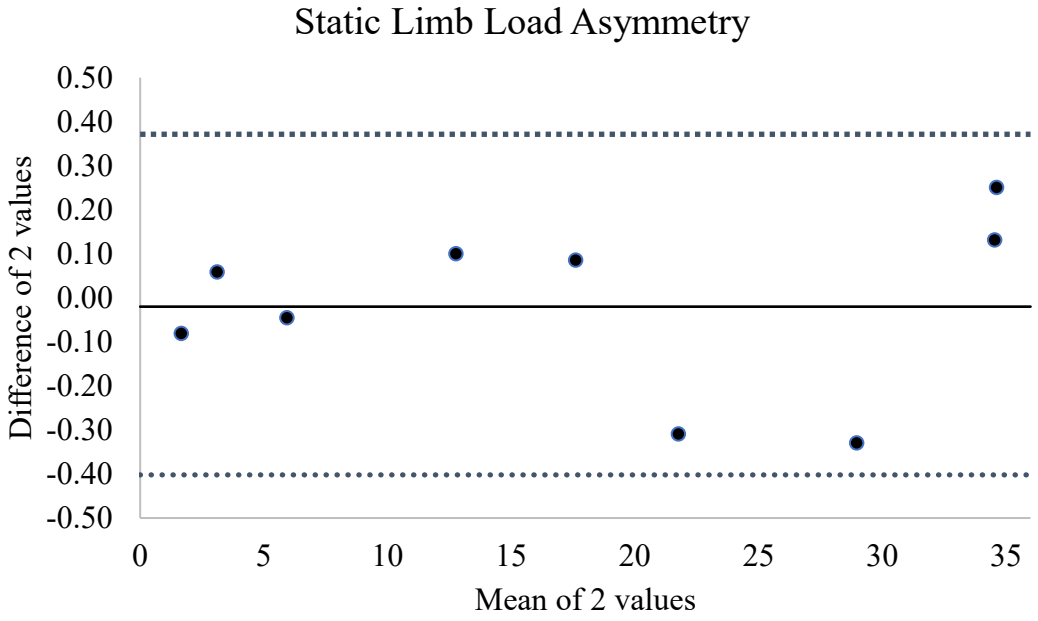


Figure 4. 24 Bland-Altman plot for inter-rater reliability of DT-walk for limb load asymmetry.

Table 4. 18 Statistical analysis of inter-rater reliability testing using DT-walk for assessment of limb load asymmetry.

Sample No.	Rater 1	Rater 2	Difference	Mean
1	5.91	5.96	-0.05	5.94
2	12.82	12.71	0.10	12.77
3	3.15	3.09	0.06	3.12
4	28.81	29.14	-0.33	28.97
5	1.62	1.70	-0.08	1.66
6	34.75	34.50	0.25	34.63
7	34.62	34.49	0.13	34.55
8	17.64	17.56	0.09	17.60
9	21.61	21.91	-0.31	21.76
Mean	17.88	17.90	-0.02	17.89
Standard Deviation	12.98	12.97	0.20	12.97
		Standard Error of Measurement	0.002006834	
		Minimal Detectable Change	0.00556266	
		Coefficient of Variance	13.14967982	
		Upper Limit of Agreement	0.371440926	
		Lower Limit of Agreement	-0.40196386	
		Intraclass Correlation Coefficient	0.99990	

The mean (SD) of the PPA among the participants in reading 1 and reading 2 for intra-rater reliability were 16.06 (6.82) and 15.40 (5.82), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the two readings were 6.466170035 and -5.141566025, respectively. At a 95% of the confidence interval, DT-walk showed good reliability with ICC = 0.884 (SEM=1.18491, MDC= 3.28441, CV=143.55%), for PPA in KOA. The Bland Altman plot for intra-rater reliability of DT-walk for plantar pressure asymmetry is reported in Figure 4.25. Table 4. 19 shows the statistical analysis findings of intra-rater reliability testing using DT-walk for assessment of PPA.

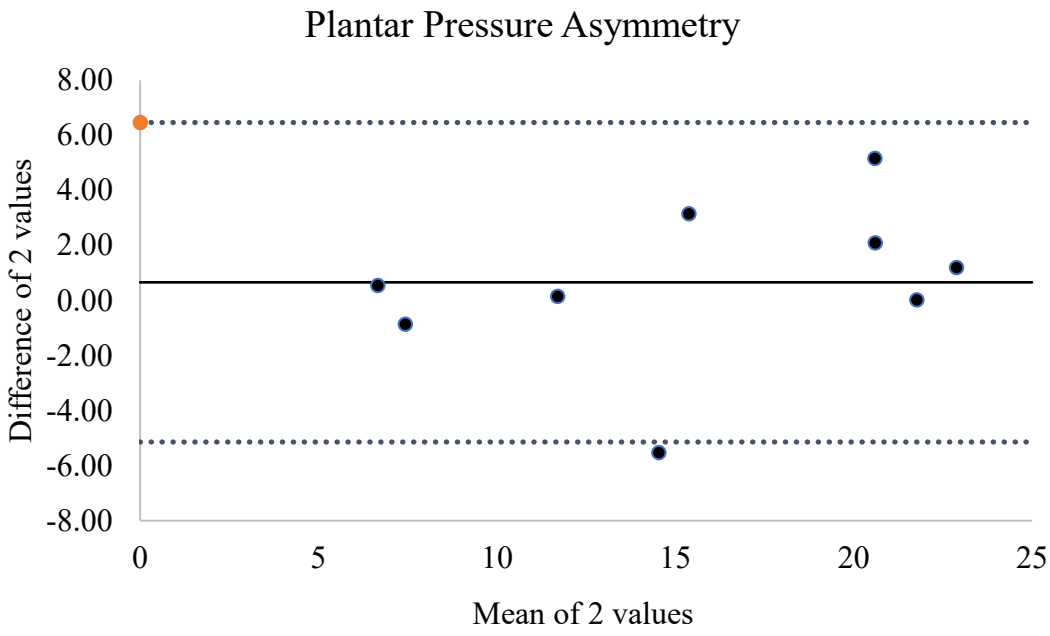


Figure 4. 25 Bland Altman plot for intra-rater reliability of DT-walk for plantar pressure asymmetry.

Table 4. 19 Statistical analysis of intra-rater reliability testing using DT-walk for assessment of plantar pressure asymmetry.

Sample No.	Reading 1	Reading 2	Difference	Mean
1	23.18	18.01	5.17	20.60
2	21.79	21.76	0.02	21.77
3	23.49	22.29	1.20	22.89
4	6.94	6.39	0.55	6.66
5	11.78	17.30	-5.53	14.54
6	11.78	11.63	0.15	11.70
7	7.00	7.86	-0.86	7.43
8	16.96	13.80	3.16	15.38
9	21.65	19.56	2.09	20.60
Mean	16.06	15.40	0.66	15.73
Standard Deviation	6.82	5.82	2.96	6.16

Standard Error of Measurement	0.950745596
Minimal Detectable Change	2.635332341
Coefficient of Variance	143.5516712
Upper Limit of Agreement	6.466170035
Lower Limit of Agreement	-5.141566025
Intraclass Correlation Coefficient	0.88472

The mean (SD) of the PPA among the participants by rater 1 and rater 2 for inter-rater reliability were 16.35 (6.22) and 16.22 (5.88), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the two readings of the two raters were 2.759278941 and -2.512507792, respectively. At a 95% of the confidence interval, DT-walk showed an excellent reliability inter-rater reliability with ICC = 0.977 (SEM= 0.20032, MDC= 0.55527, CV= 162%) for PPA in KOA. The Bland Altman plot for inter-rater reliability of DT-walk for PPA is reported in Figure 4.26. Table 4. 20 shows the statistical analysis findings of inter-rater reliability testing using DT-walk for assessment of PPA.

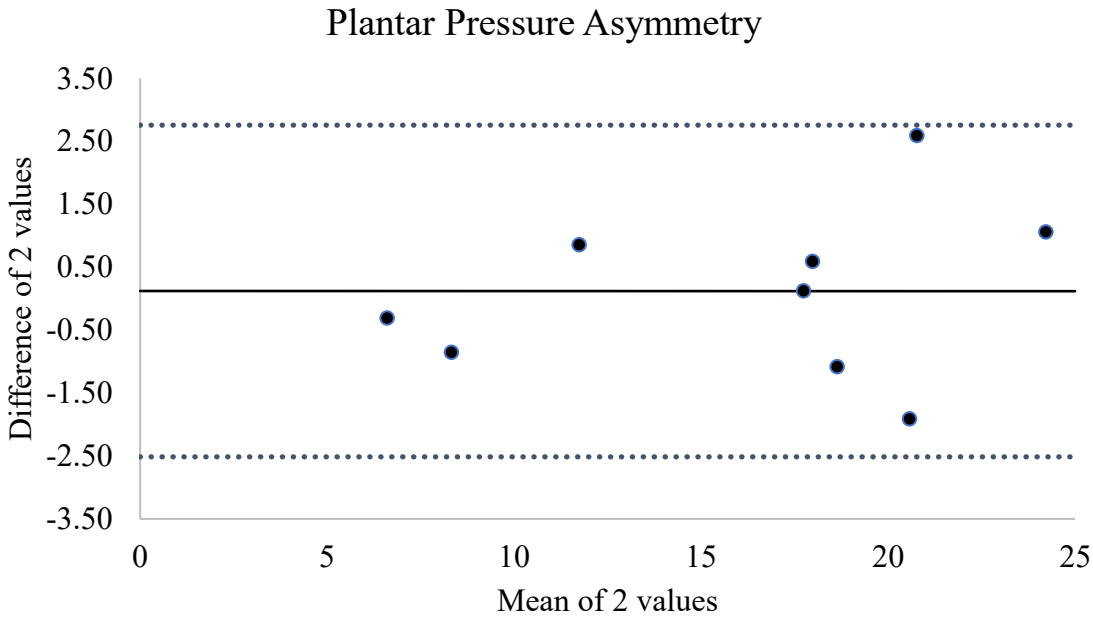


Figure 4. 26 Bland Altman plot for inter-rater reliability of DT-walk for plantar pressure asymmetry.

Table 4. 20 Statistical analysis of inter-rater reliability testing using DT-walk for assessment of plantar pressure asymmetry.

Sample No.	Rater 1	Rater 2	Difference	Mean
1	18.10	19.17	-1.08	18.64
2	22.07	19.47	2.60	20.77
3	24.75	23.68	1.07	24.21
4	6.45	6.76	-0.30	6.61
5	17.81	17.68	0.13	17.74
6	12.17	11.31	0.86	11.74
7	7.90	8.74	-0.85	8.32
8	18.27	17.68	0.59	17.97
9	19.61	21.52	-1.91	20.57
Mean	16.35	16.22	0.12	16.29
Standard Deviation	6.22	5.88	1.34	6.02
		Standard Error of Measurement	0.200325187	
		Minimal Detectable Change	0.55527309	
		Coefficient of Variance	162.357057	
		Upper Limit of Agreement	2.759278941	
		Lower Limit of Agreement	-2.512507792	
		Intraclass Correlation Coefficient	0.97781	

Concurrent Validity

The concurrent validity was tested using the mean of three readings (3-best captured gait cycle out of six) taken for SLLA and PPA by the same rater on the same subjects using DT-walk and WinTrack. The mean (SD) of the SLLA among the participants recorded using WinTrack and DT-walk were 17.58 (12.84) and 17.88 (12.98), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the two readings were 0.29033222 and -0.4927006, respectively. The DT-walk showed excellent validity against the WinTrack platform with ICC > 0.9 at 95% of the confidence interval, SEM=0.00234, MDC= 0.00648, and CV= 2.31% for static LLA. The Bland Altman plot for validity of DT-walk for SLLA is reported in Figure 4.27. Table 4. 21 shows the statistical analysis findings of validity testing using WinTrack and DT-walk for assessment of SLLA.

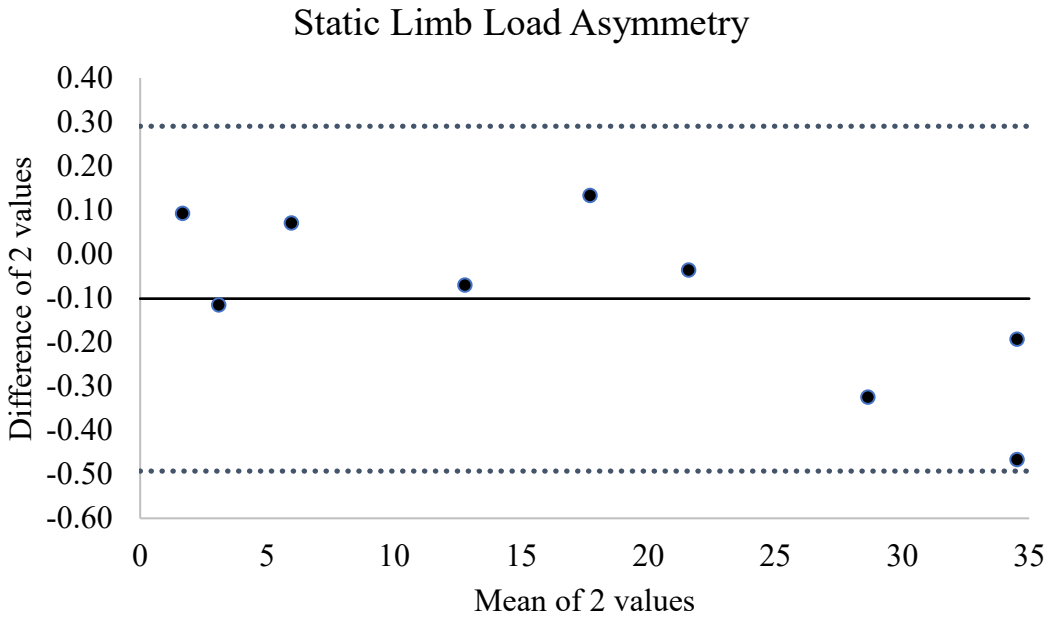


Figure 4. 27 Bland Altman plot for the validity of DT-walk for limb load asymmetry.

Table 4. 21 Statistical analysis for the validity testing of DT-walk against WinTrack platform for assessment of limb load asymmetry.

Sample No.	WT_SLLA	DT_SLLA	Difference	Mean
1	5.98	5.91	0.07	5.95
2	12.75	12.82	-0.07	12.78
3	3.03	3.15	-0.12	3.09
4	28.48	28.81	-0.32	28.65
5	1.71	1.62	0.09	1.66
6	34.29	34.75	-0.47	34.52
7	34.43	34.62	-0.19	34.52
8	17.78	17.64	0.13	17.71
9	21.57	21.61	-0.04	21.59
Mean	17.78	17.88	-0.10	17.83
Standard Deviation	12.84	12.98	0.20	12.91
		Standard Error of Measurement	0.00233865	
		Minimal Detectable Change	0.00648242	
		Coefficient of Variance	-2.3112831	
		Upper Limit of Agreement	0.29033222	
		Lower Limit of Agreement	-0.4927006	
		Intraclass Correlation Coefficient	0.99986	

The mean (SD) of the PPA among the participants recorded using WinTrack and DT-walk were 17.54 (5.47) and 16.35 (6.22), respectively. The upper and lower limit of agreement for the Bland-Altman plot between the two readings were 6.71419961 and -4.3289429, respectively. Similarly, DT-walk showed good to excellent validity against the WinTrack platform with ICC = 0.877 at a 95% of the confidence interval, SEM=0.98608, MDC= 2.73327, and CV= 82.68% for dynamic PPA. The Bland Altman plot for validity of DT-walk for PPA is reported in Figure 4. 28. Table 4. 22 shows the statistical analysis findings of validity testing using WinTrack and DT-walk for assessment of PPA.

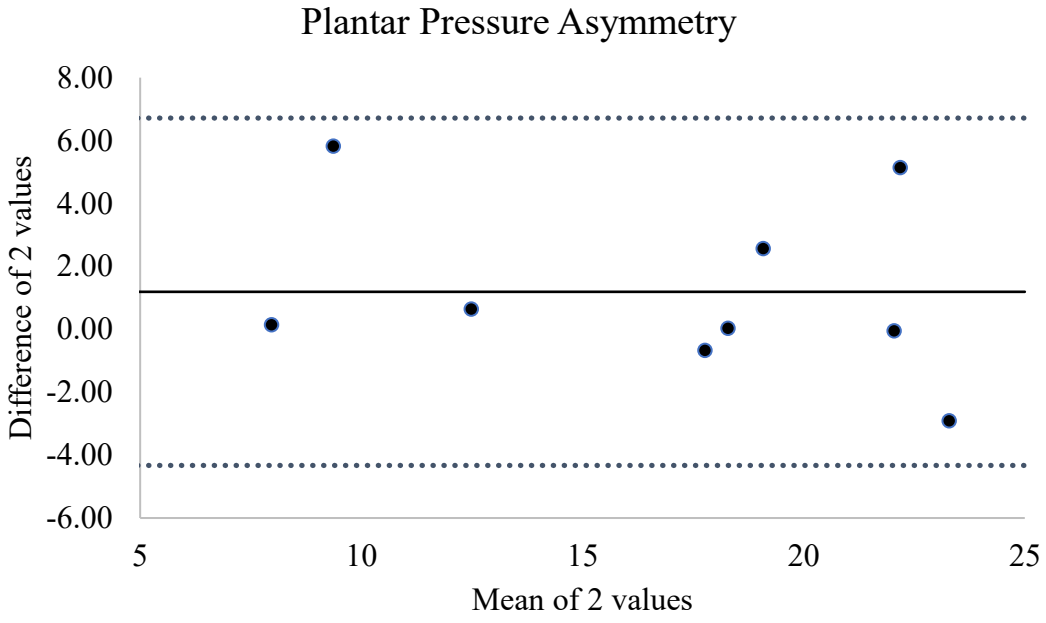


Figure 4. 28 Bland Altman plot for the validity of DT-walk for plantar pressure asymmetry.

Table 4. 22 Statistical analysis for validity testing of DT-walk against WinTrack platform for assessment of plantar pressure asymmetry.

Sample No.	WT_PPA	DT_PPA	Difference	Mean
1	17.43	18.10	-0.66	17.77
2	22.02	22.07	-0.05	22.04
3	21.84	24.75	-2.91	23.29
4	12.28	6.45	5.82	9.37
5	20.37	17.81	2.56	19.09
6	12.81	12.17	0.64	12.49
7	8.04	7.90	0.15	7.97
8	18.30	18.27	0.03	18.29
9	24.76	19.61	5.14	22.19
Mean	17.54	16.35	1.19	16.94
Standard Deviation	5.47	6.22	2.82	5.69
		Standard Error of Measurement	0.98608108	
		Minimal Detectable Change	2.73327731	
		Coefficient of Variance	82.6813384	
		Upper Limit of Agreement	6.71419961	
		Lower Limit of Agreement	-4.3289429	
		Intraclass Correlation Coefficient	0.87747	

Correlation and Hypothesis Testing

The Pearson correlation coefficients and level of significance was used to evaluate the correlation between the readings by same rater in intra-rater, different raters in inter-rater using DT-walk, and readings from DT-walk and WinTrack by same rater for assessing SLLA and PPA in KOA. The Pearson correlation showed excellent correlation between the two readings for all the variables. The Pearson correlation coefficient for SLLA by same rater, between raters and readings of DT-walk and WinTrack was 0.999 (p= 0.000, CI= 95%) for each variable. The Pearson correlation coefficient for PPA by same rater, between raters and readings of DT-walk and WinTrack was 0.902 (p= 0.000), 0.976 (p= 0.000) and 0.891 (p= 0.001) respectively at 95% confidence interval. The Pearson correlation suggests that the pair of readings have strong positive association with each other which implies that the readings of DT-walk are consistent with the readings of WinTrack system. The test statistics are summarized in table 4.23.

Table 4. 23 Pearson correlation coefficients and level of significance for correlation between the readings of static limb load and plantar pressure asymmetry in knee osteoarthritis by same rater and different raters using DT-walk, and readings from DT-walk and WinTrack by same rater.

	Pearson correlation	Sig. (2-tailed)
Intra-rater (Reading 1 vs Reading 2)		
Static Limb Load Asymmetry	0.999	0.000
Plantar Pressure Asymmetry	0.902	0.000
Inter-rater (Rater 1 vs Rater 2)		
Static Limb Load Asymmetry	0.999	0.000
Plantar Pressure Asymmetry	0.976	0.000
Validity (DT-walk vs WinTrack)		
Static Limb Load Asymmetry	0.999	0.000
Plantar Pressure Asymmetry	0.891	0.001

The paired samples t-test was used to test the hypothesis whether DT-walk is a valid and reliable tool for assessing SLLA and PPA in KOA. The paired samples t-test data of the difference in the measurements of static limb load and plantar pressure asymmetry using DT-walk and WinTrack System show insignificant difference between the measurement ($p > 0.05$) at 95% confidence interval. The paired t-test suggests that there is not a significant difference between the pair of readings whether recorded by the same or different rater using DT-walk or between the reading of DT-walk and WinTrack system. This implies that the readings of DT-walk are consistent with the readings of WinTrack system. Therefore, null hypothesis is accepted, and alternate hypothesis is rejected. Thus, DT-walk is a valid and reliable tool for assessing SLLA and PPA in KOA. The paired samples t-test data of the difference in the measurements of SLLA and PPA in KOA using DT-walk and WinTrack System is summarized in table 4.24.

Table 4. 24 Paired samples T-test data of the difference in the measurements of static limb load and plantar pressure asymmetry using DT-walk and WinTrack System.

				95% Confidence Interval				
	Mean	SD	SEM	Lower Limit	Upper Limit	t	dt	Sig. (2-tailed)
Intra-rater								
SLLA	0.12	0.349	0.116	-0.145	0.391	1.055	8	0.322
PPA	0.66	2.961	0.987	-1.613	2.938	0.671	8	0.521
Inter-rater								
SLLA	-0.02	0.197	0.065	-0.167	0.136	-0.232	8	0.822
PPA	0.12	1.344	0.448	-0.91	1.157	0.275	8	0.798
Validity								
SLLA	-0.1	0.199	0.066	-0.254	0.052	-1.519	8	0.167
PPA	1.19	2.817	0.939	-0.972	3.358	1.27	8	0.239

SLLA- static limb load asymmetry, PPA- plantar pressure asymmetry, SD- standard deviation, SEM standard error mean.

CHAPTER V

DISCUSSION

5.1 Focused Group Discussion for Need Assessment (Phase I)

Limb load asymmetry, and gait can be assessed both objectively, and subjectively. Gait is mostly assessed subjectively in clinical practice based on examiner's observations due to unavailability of gait analysis labs in most clinical practices; hence, it lacks accuracy, and cannot analyze most of the gait parameters. However, it can be assessed objectively by various commercially available gait lab systems which are very expensive but is considered as gold standards in terms of analysis. Various gait analysis systems are available in the market, and in research laboratories vary only in their sensor configuration to meet various application demands. The configuration of these systems can be the combination of one of the these three: pressure distribution platform, imaging system with advanced motion analysis software, and insole-based system [174]. A standard gait analysis system requires a multi camera motion capture system, and a pressure or force sensing platform along with the motion analysis software. [175] These kinds of systems require special laboratories, expensive equipment, heavy setup, pre, and post processing time, and trained operators. Moreover, these devices have a limited moving area; hence, it can assess limited number of gait cycles for the observed subjects. [174]

Hence, to address these limitations, wearable sensors have emerged as an alternative method of analyzing gait. This method is cost-effective and can be used both inside and outside of the laboratory setting, making it an increasingly popular option. Inertial motion units and pressure sensors are applied on various body parts to analyze gait using wearable technology. The sensors used in wearable devices are gyroscope, magnetometer, eTextile, accelerometer, pressure sensor, inclinometer, and many others for assessing different parameters of gait [47]. The wearable devices exist in different forms- sensor units, sensor embedded clothing, and in-shoe systems.

The factors that influenced the acceptance of wearable technology among the participants were its looks, how comfortable it felt, and how easy it was to operate. In addition, the cost of the device and the user interface's simplicity, along with the ability to store data both locally and in the cloud, were also contributing factors. The clinicians suggested that these wearable devices should be small, lightweight, portable, discrete, and cosmetically sound such that it does not reveal the user identity and allow them to use it with their usual outfit. In terms of duration of usage, the clinicians agreed to usage of clinician variant of wearable device for assessment, and training purpose whereas patient's variant can be used by the patients throughout the day for activity tracking, while exercising or consulting with their clinician remotely. It aligns with clinicians' as well as patients' perspective on real-time, and real-life scenario data for assessment, and the need of quantifiable data for rehabilitation, and ongoing optimization of patient outcomes. Depending on who, when, and how the device is used, the assessment parameters may vary.

The participants showed a preference for utilizing a wearable device for purposes such as evaluation, remote monitoring, providing feedback, tracking physical activity, maintaining exercise adherence, and accomplishing rehabilitation objectives, as these were the key drivers for accepting wearable technology. The device should evaluate and offer immediate feedback to the user for any asymmetry in limb loading, plantar pressure, and gait parameters pertaining to space and time. However, the parameters to be assessed may vary with the intended use of technology (e.g., clinician may assess all parameters during an activity, whereas the patient may require only a few parameters).

The usage of wearable technology as recommended by the participants would allow them to improve their clinical practice by supporting their rehabilitation goals. They suggested that the technology would be useful in assessment, training, and telemonitoring of their patients during different phases of their rehabilitation in both their clinical setting, and patients' living environment. In addition, they suggested that real-time assessment, and feedback would be useful in telemonitoring their patients' movement pattern, daily activity, adherence to exercise, active participation, prognosis, and guiding them virtually in real-time. These factors encourage the patients to actively participate in their rehabilitation and adhere to the rehabilitation program as prescribed

by their clinician in reaching desired goals. The inclusion of telemonitoring has added benefits of saving time, and money involved with frequent visits to the clinics. Also, the information derived from the system can be utilized for designing, and modifying the rehabilitation plan, patient prognosis, identifying challenges or problems being faced by the patients, research, and evidence-based practice by the clinicians; and for tracking daily performance, and improvement overtime by the patients.

The recommendation from this study has clearly identified the need for wearable technology for clinical practice in terms of real-time assessment, training, and telemonitoring of patients. The design, content, structure, and features of such wearable technology depends on perceived usefulness of the technology, stage of the clinical condition being treated, and clinical outcome measures to be considered; hence it should be considered while developing the technology. The transmission, and storage of data on local device, and cloud server should be addressed adequately to provide accurate real-time feedback, and track user performance overtime based on parameters assessed. In addition, few physiotherapists suggested that incorporating electromyography would be very useful for assessing the muscle activation pattern during the activity; however, it may add challenges for the developers to incorporate all features in a single device. Electromyography has been shown to be effective for assessing muscle activity, and providing muscle retraining, and biofeedback to the user in the rehabilitation phase in various condition [176, 177]. Hence, the use of wearable technology has a great potential not only in enhancing patient performance, and clinical outcomes in KOA, but also for improving clinical practices in terms of assessment, exercise prescription, rehabilitation, and patient prognosis overtime.

The adaptation of wearable technology in clinical rehabilitation has been suggested to develop a patient-centric healthcare model in which the data related to patient performance not only encourage their active participation, but it also impacts the delivery of treatment in the clinician practice, and development of new guidelines, and recommendations based on the information generated through the technology. The design of wearable technology as proposed in this study by the clinician lies in line with the patients' perspective as identified in previous studies [178]. This study further addresses the need of literature for identifying the clinician's perspective towards the

wearable technology in clinical rehabilitation in terms of design, structure, features, and applicability. The previous studies have reported use of wearable, and portable sensors for acquiring patient health-related data in different health conditions without considering clinicians, and patients' perspective to understand the clinical issues with the existing technologies. Based on the patient's preferences as proposed by Papi et al. (2015), this focus group-based study further identified the clinical issues with the existing assessment technology as well as the clinician's preference for wearable technology in terms of features, functions, application, perceived usefulness, and cost of the proposed technology [178]. Considering the economical background, the cost of device was identified as major factor for non-adaptation of technology by clinicians as most of the clinician's work in independent clinical practice, and they cannot afford it. The same stands true for the patients as well as majority of Indians live in rural areas and have poor economic status. The commercially available wearable technology has failed to consider these issues despite having a well-structured product in addressing the challenges faced by the clinical in terms of assessment, rehabilitation, and telemonitoring, and bridging the gap between patient's, and clinician's need.

The proposed technology would not only allow the clinicians to assess their patient, and plan, and carry out their rehabilitation with real-time feedback but also to diagnose the limb loading, and gait changes at an early stage thereby preventing the development, and further progression of the condition. Further, the same technology can be used by the patients while performing their rehabilitation program based on real-time feedback provided via mobile computing application for, correction, and during daily activity for tracking purposes as performed by most of the commercially available devices. It would also allow the patient to be actively involved in their rehabilitation, adhere to their rehabilitation program, and track their performance overtime. Telemonitoring function would have additional advantage over the commercially available technologies in situations like COVID pandemic, remote locations, etc. where travelling is not possible as it allows clinicians to monitor and provide feedback to their patient's rehabilitation in real-time remotely via cloud computing.

This study primarily focused on clinician's perspective of wearable technology towards KOA. However, this findings are applicable to any other conditions in which

gait, and balance is affected for improving clinical rehabilitation including both assessment, and training. Studies involving osteoarthritis population have reported a similar finding. Although the concepts are similar, the clinical outcomes may change; therefore, the technology should be developed based on the clinical presentation of each condition and follow the clinical guidelines for assessment of patient performance.

Limitations

Unlike any other study, this study also had some limitations like focus group discussions were conducted via video conferencing which brings additional challenges of active participation, technical issues, communication difficulty. The discussion could have been better if they had been conducted physically. No restriction was made for recruitment of participants based on their clinical specialization. The participants in this study only represents the perspective of physiotherapists working in clinical setup in India except one from Malaysia with 3 or more years of experience with majority of them being male. Although the recommendations from the discussion were relevant to the objective of the study, the future research should include physiotherapist as well as orthopedics, and physical medicine rehabilitation specialist working across the globe.

5.2. Prevalence of Asymmetries in Knee Osteoarthritis (Phase II)

This study investigated the prevalence of asymmetries in limb loading, plantar pressure distribution, step length, and step duration using a baropodometry system. The prevalence of asymmetry greater than 10% was found in all the assessment parameters. However, the prevalence rate varied among the parameters; for instance, SLLA, and PPA had a significantly higher prevalence rate of 53%, and 60%, respectively. Whereas, SLA, and SDA had a significantly lower prevalence rate of 15%, and 35%, respectively.

Unilateral KOA

This study investigated the prevalence of asymmetries in limb loading, plantar pressure distribution, step length, and step duration using a baropodometry system among individuals with unilateral knee pain. The prevalence of asymmetry greater than 10% was found in nearly half of subjects among all the assessment parameters. Comparison of these asymmetries among the study participants suggests that individuals with unilateral knee pain had mean asymmetry of greater than 10% in their static limb loading, stance phase duration, step length, step duration, and plantar pressure distribution. This suggests that a significant proportion of population with knee pain exhibit asymmetries in their gait pattern and standing posture.

Strong positive correlation between SLLA and BMI suggests that asymmetry in limb loading while standing increases with the increase in BMI. Silverwood et al., has identified obesity as one the predisposing factor for development of OA of knee and hip joint [179]. The BMI has shown a strong, and significant correlation with the static limb loading suggesting that individuals with BMI higher than 25kg/m2 have higher risk of developing KOA. In weight-bearing positions, the whole-body weight is transferred to foot through hip, knee, and ankle joints. The relationship between obesity, and KOA is very complex to understand [180]; however, it is evident from the study that a large number of population having BMI higher than 25kg/m2 have higher chances of developing KOA [16, 87, 181] which can be contributed to excessive pressure on the knee joint cartilage that results in early cartilage degeneration, and altered gait

mechanics. Further, occupation-related physical activities that involves frequent sitting, and standing, prolonged standing or walking, and vigorous physical activity like in sports, and athletic events predisposes the individual for developing KOA at an early age [87]. It might be the reason for higher prevalence of these asymmetries in our study as majority of subjects works in house-keeping division that require prolonged standing, and frequent ascending, and descending on stairs which continuously compresses the knee, and results in faster degeneration of joint cartilage of the knee. In addition, lifting weight during these activities may put additional load on the knee joints which further compresses the meniscus, and may potentially damage ACL and MCL that may predispose the knee joint to adapt to altered biomechanics, and limb loading pattern [17, 179] leading to the development of KOA [71].

Knee is the most commonly affected joint in osteoarthritis of lower limb followed by hip [94]. Various potential biomechanical deviations have been identified that may occur due to the joint articular changes leading to altered weight bearing pattern, and may contribute to development, and further progression of osteoarthritis in the lower limb joints especially knee [26]. The subjects with knee pain in our study compensated for their functional, and physical limitations due to pain by altering their limb loading, and movement pattern both between the limbs, and within the limb resulting in asymmetrical limb loading, and asymmetry in spatiotemporal variable. Riskowski et al., (2005) suggested that repetitive stress, and associated complications can be experienced by the body at the initial contact of the foot with the ground due to cyclic nature of walking, and the ROL. The ROL may be increased by an individual's gait kinematics at initial contact, and a repetitively high ROL can contribute to the development of a variety of disorders, including osteoarthritis. Proprioceptive feedback signals related to limb position, and movement, plays an important role in understanding how the foot strikes the ground, and thus, effects the ROL [128]. Further, the tightness in calf muscle has also been suggested to lead to asymmetry in loading response, and single limb support duration [182].

Altered knee joint loading, and pressure location during gait has been identified in early KOA, in form of elevated knee contact forces, and shift in center of pressure.

As the structural degeneration of the knee joint progresses, biomechanics alterations of gait lead to an overall increased joint loading, impacting both medial, and lateral compartments of knee [30]. A highly significant correlation between different types of asymmetries observed in this study suggests that depending on the severity of the knee pain the individual compensates their walking pattern to the avoid pain. Compensatory movement, and overloading of other joints of the lower limb have been identified as potential predisposing factor for development of KOA [183]. In our study, the prevalence of asymmetry of limb loading, step length, step duration, swing phase duration, and plantar pressure was very high with mean asymmetry greater than 10.66%. The finding also suggests that these asymmetries may act as predisposing factor or early signs of development of KOA. In KOA, altered joint loading exists in the contralateral conjugate joint [71]. Asymmetrical limb loading leads to altered gait mechanics which further enhances joint degeneration [71]. Furthermore, increased tibiofemoral rotation, and peak knee abduction moment during the weight bearing positions [184], along with limb load asymmetry, and spatiotemporal gait parameters have been identified as important factors in the assessment of KOA.

Bilateral KOA

This study investigated the prevalence of asymmetries in limb loading, plantar pressure distribution, step length, and step duration using a baropodometry system among individuals with bilateral KOA. The prevalence of asymmetry greater than 10% was found in nearly half of the subjects in all the assessment parameters. However, the prevalence rate varied among the parameters. Comparison of these asymmetries among the study participants suggests that individuals with bilateral KOA had mean asymmetry of greater than 10% in their static limb loading, step duration, and plantar pressure distribution, whereas less than 10% asymmetry in their swing phase, duration, and step length. This suggests that a significant proportion of the population with bilateral KOA exhibit asymmetries in their gait pattern and standing posture. The prior studies have primarily focused on the kinematic, and kinetic manifestations in KOA. However, the prevalence, and correlation of limb loading, and spatiotemporal gait parameters have not been assessed.

In our study, the strong positive correlation between SLLA and BMI showed that asymmetry in limb loading while standing increases with the increase in BMI. Silverwood et al., has identified obesity as one of the predisposing factors for the development of KOA [179]. The BMI has shown a strong, and significant correlation with static limb loading suggesting that individuals with BMI higher than 25kg/m2 have a higher risk of developing KOA. In weight-bearing positions, the whole-body weight is transferred to the foot through the hip, knee, and ankle joints. The relationship between obesity, and KOA is very complex to understand [180]; however, it is evident from the study that a large number of the population having a BMI higher than 25kg/m2 have higher chances of developing KOA [16, 181, 185] which can be contributed to excessive pressure on the knee joint cartilage that results in early cartilage degeneration, and altered gait mechanics. Further, occupation-related physical activities that involve frequent sitting, and standing, prolonged standing or walking, and vigorous physical activity like in sports, and athletic events predispose the individual to developing KOA at an early age [87]. It might be the reason for the higher prevalence of these asymmetries in our study as most subjects worked in the house-keeping division that requires prolonged standing, and frequent ascending, and descending stairs which continuously compresses the knee, and results in faster degeneration of joint cartilage of the knee. In addition, lifting weight during these activities may put additional load on the knee joints, which further compresses the meniscus, and may potentially damage the anterior cruciate ligament, and medial collateral ligament that, may predispose the knee joint to adapt to altered biomechanics, and limb loading pattern [17, 179] leading to the development of KOA.[71]

Many possible biomechanical deviations may develop because of articular changes in joint structure which leads to abnormal weight-bearing patterns, and further contribute to progression of KOA [26]. The subjects with bilateral KOA in our study compensated for their functional, and physical limitations due to pain by altering their limb loading, and movement pattern both between the limbs, and within the limb resulting in asymmetrical limb loading, and asymmetry in the spatiotemporal variables. Changes in the way the knee joint bears weight and where pressure is placed during walking have been detected in the early stages of KOA. This is manifested by increased

forces on the knee during contact and a displacement of the center of pressure. Dynamic loads on the joints and limbs during physical activity primarily contributes to biomechanical pathophysiology and progression of KOA [29]. As joint degeneration progresses, deviations in biomechanics of gait lead to increased overall joint loading, affecting both medial and compartments of the knee joint [30]. Compensatory movement and overloading other joints have been identified as potential predisposing factors for developing KOA [31–34]. Riskowski et al., (2005) suggested that repetitive stress, and associated complications can be experienced by the body at the initial contact of the foot with the ground due to cyclic nature of walking, and the ROL. Further, the tightness in the calf muscle has also been suggested to lead to asymmetry in loading response, and single limb support duration [182].

A moderately significant correlation between different types of asymmetries observed in this study suggests that depending on the severity of the knee pain, the individual compensate for their walking pattern to avoid pain. Compensatory movement and overloading of other joints of the lower limb have been identified as a potential predisposing factor for the development of KOA [183]. In our study, the prevalence of asymmetry of limb loading, step length, step duration, swing phase duration, and plantar pressure was significant with mean asymmetry of greater than 9.5%. The finding also suggests that these asymmetries may act as a predisposing factors or early signs of the development, and progression of KOA. In KOA, altered joint loading exists in the contralateral conjugate joint.[71] Asymmetrical limb loading leads to altered gait mechanics, which further enhances joint degeneration.[71, 184] Furthermore, increased tibiofemoral rotation, and peak knee abduction moment during the weight-bearing positions, along with limb load asymmetry, and spatiotemporal gait parameters, have been identified as important factors in the assessment of KOA. However, the assessment of asymmetries in limb loading, and spatiotemporal gait parameters has been given less importance in clinical practice. The finding of our study suggests that the assessment of these parameters should be given utmost importance in clinical practice for early detection of asymmetries, and thereby preventing the development, and progression of osteoarthritis of lower limb joints by implementing

corrective measures in the form of exercises, gait training, orthotics, and self-awareness of their problem.

Limitations

The study included subjects only with bilateral knee involvement with different levels of severity between the limbs. The subjects were included in the study based on the fulfilment of the American College of Rheumatology's clinical diagnostic criteria for KOA without considering the radiological examination. However, that does not influence the result significantly, as this study was targeted to understand the biomechanical alterations that take place in KOA. Further as per the recommendations of National Institute for Health, and Care Excellence, osteoarthritis can be diagnosed clinically without any investigations if a person is 45 years or old, has activity-related joint pain, and has either no morning joint-related stiffness or morning stiffness that does not last longer than 30 minutes. The limb dominance was not evaluated, hence should be reported as a limitation, as it is impossible to compare the impact of limb involvement on the assessment parameters.

5.3. Validation and Reliability Testing of DT-walk (Phase IV)

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 interval of 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 $\geq$ 0.9996. On the other hand, DT-walk showed good 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. [148, 186–199] However, the differences in the type of 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 measuring plantar pressure in a controlled environment. [190] Similarly, Khandakar et al. (2022) also developed an insole-based device for monitoring plantar pressure and foot temperature in real-time using FSRs, piezoelectric sensors, and velostat for early detection of diabetic foot complications [187]. In 2020, Zhao et al. developed a flexible sensor matrix film using 16 piezoresistive cell sensors for detecting plantar pressure and found it effective in assessing average pressure, maximum pressure, pressure distributions, and variations over time. [196] However, these devices have not been validated for use in clinical 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. [198] Antti et al. (2021) correlated the highest GRF recorded using MoveSole ® with the Kistler force plate and found a strong correlation (.875). [188] 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). [192] Peebles et al. in 2018 studied the validity and repeatability of the single-sensor Loadsol insoles during single-hop and stop-jump landing. They found moderate to excellent repeatability ICC between 0.616 and 0.928. [199] 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). [194] During the same period, Lin et al. (2016) used the eTextile fabric sensor technique to obtain a high-resolution pressure foot map with 48 sensing points. They could interpret clinically significant data, but clinical studies were recommended to establish its validity. [191]

In 2014, Godi et al. examined gait using a plantar pressure system along linear and curved pathways and found excellent reliability (ICC > 0.90) for peak pressure. [197] 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. [148] Crea et al. (2014) developed a wireless flexible sensorized insole (PSP2.0) using the optoelectronic transduction principle and validated it with a force platform and found a Pearson's correlation ≥ 0.88 between the reading. [189] Low and Dixon (2010) found good reliability of Footscan pressure insoles (ICC > 0.75) with poor accuracy when compared with AMTI force plate ($p > 0.05$). [193] 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. [186]

The type of technology and sensors used in these devices for plantar pressure and limb loading are velostat [187], FSR [187], piezoelectric sensor [148, 186, 187, 193, 196], pressure sensing pad [189], capacitive force sensor [190, 192, 194, 198, 199], and eTextile sensor [191]. In addition, 3D printed flexible insole with plantar pressure sensing capability are also being developed [200]. The present study's finding 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 pressure values 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 progress over time. The study has tested the validity and reliability of DT-walk for assessing static limb loading and plantar pressure asymmetry but not the spatiotemporal variables of gait. However, all this can be achieved at the later stage.

CHAPTER VI

CONCLUSION

This study was conducted in four phases. The study was delayed by one year due to the COVID-19 pandemic as most of the institutions were shut down by the Government of India. The pandemic resulted in modification of the mode of conduct of focus group discussion from physical to videoconferencing. Whereas the preliminary got delayed by more than an year as the flow of patients in the Physiotherapy OPD was reduced post pandemic. The data collection for preliminary study started in March 2021 and was completed in December 2021. The development of DT-walk was also affected due to limited availability of resources and funding. However, the issues were resolved and development of windows-based application software for DT-walk was given to an external agency. The validity and reliability of DT-walk was tested in January 2023 as per the protocol after registering the study in the Clinical Trial Registry of India.

6.1 Conclusion

The prevalence study suggests that a significant proportion of population with KOA exhibit asymmetries in their gait pattern and standing posture. Whereas the focus group discussion helped us in understanding the clinicians' perspective towards the design, content, structure, features, and clinical application of wearable device for KOA. Lastly, the validity and reliability study suggest that DT-walk was equally effective in assessing asymmetries in limb loading and plantar pressure compared to the platform-based device. The DT-walk showed excellent validity and reliability for the assessment of SLLA with ICC > 0.9. The DT-walk showed good to excellent validity and reliability for the assessment of PPA with ICC > 0.87. The Pearson correlation showed strong positive correlation for reliability and validity of DT-walk (r > 0.891, CI=95%). The paired samples t-test showed insignificant difference between the reading of SLLA and PPA taken by same or different rater using DT-walk and between reading taken from DT-walk and WinTrack on same subject (p > 0.05, CI= 95%). Therefore, null hypothesis is accepted, and alternate hypothesis is rejected. Hence, it can be concluded that DT-walk is effective in the real-time assessment of LLA and PPA in standing and walking in KOA.

6.2 Future Recommendations

The DT-walk should be upgraded by integrating telemonitoring feature and motion sensing units for the assessment of kinematic parameters of gait as recommended by the clinicians in focus group discussion. The device, when used by clinicians, will help in assessment, training, and prognosis. Additionally, 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 with cloud storage, 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. The future study using DT-walk should focus on dynamic limb loading, gait pattern and asymmetries in different target populations to evaluate its efficacy. Therefore, this study recommends that clinicians may use the proposed device or other similar devices for the assessment of foot mapping, plantar pressure distribution, gait, and limb loading pattern identification in their clinical practice for early identification of gait and balance disturbances

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Appendices

Appendix I Information Sheet for Focus Group Discussion (Phase I)

Research Title

Development, and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis.

Purpose

The purpose of this focus group discussion to gain an understanding of design and development of a new wearable device for real-time assessment of limb load asymmetry and spatiotemporal gait parameters in patients with KOA. The aim of this focus group discussion is to understand clinician's needs and perceived usefulness of new device resulting in conceptualization of structure, content, features and required system design of the prototype for assessing limb load asymmetry in KOA.

What would this involve?

If you agree to take part in the study, you will be part of a focus group discussion. During this session, you will be requested to discuss or answer, questions related to existing assessment technologies and approaches used in clinical practice for limb load asymmetry and biomechanical deviations of lower limb and the current need of clinical assessment and treatment.

The benefits

The participants will be benefited by acquiring latest knowledge and understanding on the assessment using wearable technology with the help of a simple mobile application for knee osteoarthritis. However, this technology can be used for various other conditions that involves alteration in biomechanics of lower limb; but only for the clinical testing purpose we are considering knee osteoarthritis. The information shared during the focus group discussion will educate the participants about the usage of wearable technology for assessment and management in healthcare.

The risks

There are no known risks to this research.

Confidentiality

The results of the discussion data obtained will be reported in a collected manner with no reference to a specific individual. Hence, the data from each individual will remain confidential.

Do I have to take part?

The participation in this study is voluntary, if you prefer not to take part, you do not have to give a reason and your decision will not affect the data collection.

The right to withdraw.

The participants have the right to withdraw from the study at any time without affecting the future discussion.

Payment and compensation

You do not have to pay for the participating in this study. Similarly, no payment is available to you for participating in this study. However, an E-Certificate of Participation will be provided to the participants upon completion of the discussion.

Ethical Considerations

This research has been reviewed and approved by the Institutional Ethical Committee of Lovely Professional University, Phagwara, Punjab.

If you have any further questions or concerns about this study, please contact:

Mr. Amber Anand	Dr. Suresh Mani
PhD Scholar (Physiotherapy)	Associate Professor,
School of Physiotherapy	School of Physiotherapy
Faculty of Applied Medical Science	Faculty of Applied Medical Science
Lovely Professional University	Lovely Professional University
Mobile: 7837708195	Mobile: 9878331006

Google form link: https://forms.gle/PJSE1cAmhjPHy1tB8

Appendix II Consent Form for Participation in Focus Group Discussion

Declaration:

I agree to participate in the focus group discussion "Clinician's perspective about wearable device for assessment, monitoring and training in Knee Osteoarthritis", carried out by Amber Anand, Dr. Suresh Mani and Dr. Senthil N S Kumar of the Lovely Professional University, to aid with the research titled "Development, and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis."

- I have read the information sheet related to the Development, and testing of concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis, and understand the aims of the project.
- I am aware of the topics to be discussed in the focus group.
- I am fully aware that I will remain anonymous throughout data reported and that I have the right to leave the focus group at any point.
- I am fully aware that data collected will be stored securely, safely and in accordance with the Personal Data Protection Bill, (2018).
- I am fully aware that I am not obliged to answer any question, but that I do so at my own free will.
- I agree to have the focus group recorded (video or audio), so it can be transcribed after the focus group is held. I am aware that I have the right to edit the transcript of the Focus Group once it has been completed.
- I am aware that I can make any reasonable changes to this consent form.

Date:

Participant's Signature

_____

Participant's Name

_____

Researcher's Signature

_____

Appendix III Semi-structured guide for Focused Group Discussion

1. **Introduction**

- Moderators and participants introduce themselves.
- Clarification on the format of the focus group and aim.
- Assurance of confidentiality

2. **Knee Osteoarthritis**

- Definition of knee osteoarthritis
- What is their opinion about of knee osteoarthritis and its prevalence in our society?
- What is the most common complaint of patients with KOA in their perspective?
- Do they think assessment of limb load asymmetry important in KOA?
- How do they assess limb load asymmetry?
- What are the challenges with the current technologies?

3. **Wearable technology**

- Definition of wearable technology
- Ask if they know of any wearable devices and demonstration of prototype developed?
- Ask if they like this kind of technology and if so why:
  - Would you use it?
  - How often will you be willing to wear it? Daily?
- Ask what they do not like about this kind of technology and if so, why:
  - What would put you off in using such technologies?
- Ask if they know of any alternative to wearable sensor technology?

4. **Feelings about wearable medical technology**

- How are they doing in general in dealing with KOA?
- Do they think wearable technology would help their patient's situation? If so, how?
- How do they view this technology in comparison to conventional forms of treatment? And why?
- Do they see themself using this kind of technology? If so, how?

- Would they use this technology for monitoring their patient's rehabilitation practice from their home rather than going to a clinical practice?

5. Features & Functionality

- What features they would like to include in such a device for knee osteoarthritis?

– Portable
– Wearable
– Easy to use
– Storage
– Light weight
– Cloud access and telemonitoring
– Real-time assessment
– Real-time feedback

- What parameters would you like to include in such a device for knee osteoarthritis?

– Limb loading Pattern
– Limb load asymmetry
– Foot Mapping
– Foot arch index
– Arch type
– Spatial parameters of gait
– Temporal parameters of gait

6. Impact on relationships

- If they did decide to use this technology, how do they think it would impact their clinical practice?
- Do they think it would change how they interact with patients?
- What are their views on data privacy?

7. Closing

- Is there anything else they would like to say about what we have discussed?
- What are their expectations from the new technology and its cost?
- Summarize the discussion and thank everyone for their time and useful participation

Appendix IV Information Sheet for Patients- English (Phase II)

Research Title

Development, and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis.

Introduction

To address the growing disability among the patients with knee osteoarthritis in the society, this study will develop a new wearable device for real-time assessment of limb load asymmetry. This new device will assist the clinicians as well as patients in early assessment of altered biomechanics of lower limb in knee osteoarthritis. Hence, the aim of this study is to evaluate the clinical limb loading pattern in standing and walking in patients with knee osteoarthritis using gold standard device.

What would this involve?

In this study, therapist will take the assessment of your limb loading pattern that is how weight is being transferred from one leg to another and identify various spatiotemporal gait parameters.

The benefits

This study will help us identify the prevalence and cause of limb load asymmetry and between limb spatiotemporal gait deviation that occurs commonly in patients with knee osteoarthritis.

The risks

There are no known risks to this research.

Confidentiality

The results of the data obtained will be reported in a collected manner with no reference to a specific individual. Hence, the data from each individual will remain confidential.

Do I have to take part?

The participation in this study is voluntary, if you prefer not to take part, you do not have to give a reason and your decision will not affect the data collection.

The right to withdraw

The participants have the right to withdraw from the study at any time without affecting the study.

Payment and compensation

You do not have to pay for the participating in this study. Similarly, no payment is available to you for participating in this study.

If I have any questions, whom can I ask at any time point of the study?

Mr. Amber Anand	Dr. Suresh Mani
PhD Student, Physiotherapy Program	Associate Professor,
School of Physiotherapy	School of Physiotherapy
Faculty of Applied Medical Science	Faculty of Applied Medical Science
Lovely Professional University	Lovely Professional University
Mobile: 7837708195	Mobile: 9878331006

Appendix V Information Sheet for Patients- Punjabi (Phase II)

ਖੋਜ ਸਿਰਲੇਖ

ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਵਿੱਚ ਵਜ਼ਨ ਵੰਡ ਦੇ ਅੰਤਰਾਂ ਦੇ ਮੁਲਾਂਕਣ ਲਈ ਇੱਕ ਨਵੇਂ ਪਹਿਨਣਯੋਗ ਯੰਤਰ ਦਾ ਵਿਕਾਸ ਅਤੇ ਪ੍ਰਮਾਣਿਕਤਾ।

ਜਾਣ ਪਛਾਣ

ਸਮਾਜ ਵਿਚ ਗੋਡੇ ਗਠੀਏ ਦੇ ਰੋਗੀਆਂ ਵਿਚ ਵੱਧ ਰਹੀ ਅਪਾਹਜਤਾ ਨੂੰ ਦੂਰ ਕਰਨ ਲਈ, ਇਹ ਅਧਿਐਨ ਅੰਗਾਂ ਦੇ ਭਾਰ ਦੀ ਅਸਮਾਨਤਾ ਦੇ ਅਸਲ-ਸਮੇਂ ਮੁਲਾਂਕਣ ਲਈ ਇਕ ਨਵਾਂ ਪਹਿਨਣ ਯੋਗ ਉਪਕਰਣ ਵਿਕਸਤ ਕਰੇਗਾ. ਇਹ ਨਵਾਂ ਉਪਕਰਣ ਕਲੀਨਿਸਟਾਂ ਦੇ ਨਾਲ ਨਾਲ ਮਰੀਜ਼ਾਂ ਨੂੰ ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਦੇ ਹੇਠਲੇ ਅੰਗਾਂ ਦੇ ਬਦਲਦੇ ਬਾਇਓਮੇਕਨਿਕਸ ਦੇ ਮੁ ਮੁਲਾਂਕਣ ਲੇ ਮੁਲਾਂਕਣ ਵਿਚ ਸਹਾਇਤਾ ਕਰੇਗਾ. ਇਸ ਲਈ, ਇਸ ਅਧਿਐਨ ਦਾ ਉਦੇਸ਼ ਸੋਨੇ ਦੇ ਸਟੈਂਡਰਡ ਉਪਕਰਣ ਦੀ ਵਰਤੋਂ ਨਾਲ ਗੋਡੇ ਗਠੀਏ ਦੇ ਮਰੀਜ਼ਾਂ ਵਿਚ ਖੜ੍ਹੇ ਅਤੇ ਤੁਰਨ ਵਿਚ ਕਲੀਨਿਕਲ ਅੰਗ ਲੋਡਿੰਗ ਦੇ ਪੈਟਰਨੰਗ ਦਾ ਮੁਲਾਂਕਣ ਕਰਨਾ ਹੈ.

ਇਸ ਵਿੱਚ ਕੀ ਸ਼ਾਮਲ ਹੋਵੇਗਾ?

ਇਸ ਅਧਿਐਨ ਵਿੱਚ, ਥੈਰੇਪਿਸਟ ਤੁਹਾਡੇ ਅੰਗ ਲੋਡ ਕਰਨ ਦੇ ਪੈਟਰਨ ਚੇ ਦਾ ਮੁਲਾਂਕਣ ਕਰੇਗਾ ਜੋ ਇਸ ਤਰ੍ਹਾਂ ਹੈ ਕਿ ਭਾਰ ਇੱਕ ਪੈਰ ਤੋਂ ਦੂਜੇ ਪੈਰ ਵਿੱਚ ਤਬਦੀਲ ਕੀਤਾ ਜਾ ਰਿਹਾ ਹੈ ਅਤੇ ਵੱਖੋ ਵੱਖਰੇ ਸਪੋਟਿਓਟੋਮੋਰਲ ਚਾਲ ਪੈਰਾਮੀਟਰਾਂ ਦੀ ਪਛਾਣ ਕਰੇਗਾ.

ਲਾਭ

ਇਹ ਅਧਿਐਨ, ਅੰਗਾਂ ਦੇ ਚਾਲ ਅਸਮੈਟਰੀ ਦੇ ਪ੍ਰਚਲਣ ਅਤੇ ਕਾਰਣ ਅਤੇ ਅੰਗ ਸਪੋਟੀਓਮਪੋਰਲ ਗੇਅਟ ਭਟਕਣਾ ਦੇ ਵਿਚਕਾਰ ਦੀ ਪਛਾਣ ਕਰਨ ਵਿੱਚ ਸਹਾਇਤਾ ਕਰੇਗਾ ਜੋ ਆਮ ਤੌਰ ਤੇ ਗੋਡੇ ਦੇ ਗਠੀਏ ਦੇ ਰੋਗੀਆਂ ਵਿੱਚ ਵਾਪਰਦਾ ਹੈ.

ਜੋਖਮ

ਇਸ ਖੋਜ ਲਈ ਕੋਈ ਜਾਣਿਆ ਜੋਖਮ ਨਹੀਂ ਹੈ.

ਗੁਪਤਤਾ

ਪ੍ਰਾਪਤ ਕੀਤੇ ਗਏ ਡੇਟਾ ਦੇ ਨਤੀਜਿਆਂ ਦੀ ਜਾਣਕਾਰੀ ਇਕੱਠੇ ਕੀਤੇ mannerੰਗ ਨਾਲ ਕੀਤੀ ਜਾਏਗੀ ਜਿਸਦਾ ਕੋਈ ਖਾਸ ਵਿਅਕਤੀ ਦਾ ਹਵਾਲਾ ਨਹੀਂ ਹੁੰਦਾ. ਇਸ ਲਈ, ਹਰੇਕ ਵਿਅਕਤੀ ਤੋਂ ਡਾਟਾ ਗੁਪਤ ਰਹੇਗਾ.

ਕੀ ਮੈਨੂੰ ਹਿੱਸਾ ਲੈਣਾ ਪਏਗਾ?

ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣਾ ਸਵੈਇੱਛੁਕ ਹੈ, ਜੇ ਤੁਸੀਂ ਹਿੱਸਾ ਲੈਣਾ ਨਹੀਂ ਚਾਹੁੰਦੇ ਹੋ, ਤਾਂ ਤੁਹਾਨੂੰ ਕੋਈ ਕਾਰਨ ਦੱਸਣ ਦੀ ਜ਼ਰੂਰਤ ਨਹੀਂ ਹੈ ਅਤੇ ਤੁਹਾਡੇ ਫੈਸਲੇ ਨਾਲ ਡਾਟਾ ਇਕੱਠਾ ਕਰਨ 'ਤੇ ਕੋਈ ਅਸਰ ਨਹੀਂ ਪਵੇਗਾ.

ਵਾਪਸ ਲੈਣ ਦਾ ਅਧਿਕਾਰ

ਹਿੱਸਾ ਲੈਣ ਵਾਲਿਆਂ ਨੂੰ ਅਧਿਐਨ ਨੂੰ ਪ੍ਰਭਾਵਿਤ ਕੀਤੇ ਬਿਨਾਂ ਕਿਸੇ ਵੀ ਸਮੇਂ ਅਧਿਐਨ ਤੋਂ ਪਿੱਛੇ ਹਟਣ ਦਾ ਅਧਿਕਾਰ ਹੈ.

ਭੁਗਤਾਨ ਅਤੇ ਮੁਆਵਜ਼ਾ

ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਤੁਹਾਨੂੰ ਭੁਗਤਾਨ ਕਰਨ ਦੀ ਜ਼ਰੂਰਤ ਨਹੀਂ ਹੈ. ਇਸੇ ਤਰ੍ਹਾਂ, ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਤੁਹਾਡੇ ਲਈ ਕੋਈ ਭੁਗਤਾਨ ਉਪਲਬਧ ਨਹੀਂ ਹੈ

ਜੇ ਮੇਰੇ ਕੋਈ ਪ੍ਰਸ਼ਨ ਹਨ, ਤਾਂ ਮੈਂ ਅਧਿਐਨ ਦੇ ਕਿਸੇ ਵੀ ਸਮੇਂ ਕਿਸ ਨੂੰ ਪੁੱਛ ਸਕਦਾ ਹਾਂ?

ਸ੍ਰੀ ਅੰਬਰ ਅਨੰਦ

ਪੀਐਚਡੀ ਵਿਦਿਆਰਥੀ, ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਪ੍ਰੋਗਰਾਮ

ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਦਾ ਸਕੂਲ

ਅਪਲਾਈਡ ਮੈਡੀਕਲ ਸਾਇੰਸ ਦੀ ਫੈਕਲਟੀ

ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ

ਮੋਬਾਈਲ: 7837708195

ਡਾ ਸੁਰੇਸ਼ ਮਨੀ

ਦੇ ਐਸੋਸੀਏਟ ਪ੍ਰੋਫੈਸਰ,

ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਦਾ ਸਕੂਲ

ਅਪਲਾਈਡ ਮੈਡੀਕਲ ਸਾਇੰਸ ਦੀ ਫੈਕਲਟੀ

ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ

ਮੋਬਾਈਲ: 9878331006

Appendix VI मरीजों के लिए सूचना पत्रक - हिंदी (द्वितीय चरण)

अनुसंधान शीर्षक

घुटने के गठिया में वजन वितरण के अंतर के आकलन के लिए एक नए पहनने योग्य उपकरण का विकास और सत्यापन।

परिचय

समाज में घुटने के पुराने ऑस्टियोआर्थराइटिस के रोगियों के बीच बढ़ती विकलांगता को संबोधित करने के लिए, इस अध्ययन से अंग भार विषमता के वास्तविक समय के आकलन के लिए एक नया पहनने योग्य उपकरण विकसित होगा। यह नया उपकरण चिकित्सकों के साथ-साथ रोगियों को घुटने के पुराने ऑस्टियोआर्थराइटिस में निचले अंग के परिवर्तित बायोमैकेनिक्स के प्रारंभिक मूल्यांकन में सहायता करेगा। इसलिए, इस अध्ययन का उद्देश्य स्वर्ण मानक डिवाइस का उपयोग करके घुटने के पुराने ऑस्टियोआर्थराइटिस के रोगियों में खड़े और चलने में नैदानिक अंग लोडिंग पैटर्न का मूल्यांकन करना है।

इसमें क्या शामिल होगा?

इस अध्ययन में, चिकित्सक आपके अंग के लोडिंग पैटर्न का आकलन करेगा कि कैसे वजन को एक पैर से दूसरे में स्थानांतरित किया जा रहा है और विभिन्न स्पोटीओपोर्मल गैट मापदंडों की पहचान की जाती है।

लाभ

यह अध्ययन हमें अंग भार विषमता के बीच के प्रसार और कारण की पहचान करने में मदद करेगा और अंग स्पैटिओटेम्पोरल गेट विचलन के बीच जो आमतौर पर घुटने के पुराने ऑस्टियोआर्थराइटिस के रोगियों में होता है।

जोखिम

इस शोध के लिए कोई ज्ञात जोखिम नहीं हैं।

गोपनीयता

प्राप्त आंकड़ों के परिणामों को एक विशिष्ट व्यक्ति के संदर्भ में एकत्र किए गए तरीके से रिपोर्ट किया जाएगा। इसलिए, प्रत्येक व्यक्ति का डेटा गोपनीय रहेगा।

क्या मुझे भाग लेना है?

इस अध्ययन में भागीदारी स्वैच्छिक है, यदि आप भाग नहीं लेना पसंद करते हैं, तो आपको कोई कारण नहीं देना होगा और आपका निर्णय डेटा संग्रह को प्रभावित नहीं करेगा।

वापस लेने का अधिकार

प्रतिभागियों को अध्ययन को प्रभावित किए बिना किसी भी समय अध्ययन से वापस लेने का अधिकार है।

भुगतान और मुआवजा

आपको इस अध्ययन में भाग लेने के लिए भुगतान करने की आवश्यकता नहीं है। इसी तरह, इस अध्ययन में भाग लेने के लिए आपको कोई भुगतान उपलब्ध नहीं है

यदि मेरे कोई प्रश्न हैं, तो मैं अध्ययन के किसी भी समय किससे पूछ सकता हूं?

श्री अंबर आनंद
पीएचडी छात्र, फिजियोथेरेपी प्रोग्राम
फिजियोथेरेपी विभाग
स्कूल ऑफ एलाइड मेडिकल साइंस
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Appendix VII Information Sheet for Patients- English (Phase III)

Research Title

Development, and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis.

Introduction

To address the growing disability among the patients with knee osteoarthritis in the society, this study has developed a new wearable device for real-time assessment of limb load asymmetry. This new device will assist the clinicians as well as patients in assessment of altered biomechanics of lower limb in knee osteoarthritis. Hence, the aim of this study is to determine the validity and reliability of this new wearable device in real-time assessment of limb load asymmetry.

What would this involve?

In this study, therapist will assess the limb load asymmetry and plantar pressure asymmetry using newly developed wearable device. During the initial consultation, the therapist will collect your consent. Then, the assessment will be taken for limb loading and plantar pressure distribution using the new device. The duration of the study is approximately 1 hours with appropriate rest period in between assessment.

The benefits

This model will help you to extent the physical assessment service at your own living environment. The cost and the time involved to access the treatment and consultation with physiotherapists in a hospital or institutional based setup could be saved.

The risks

There are no known risks to this research.

Confidentiality

The results of the data obtained will be reported in a collected manner with no reference to a specific individual. Hence, the data from each individual will remain confidential.

Do I have to take part?

The participation in this study is voluntary, if you prefer not to take part, you do not have to give a reason and your decision will not affect the data collection.

The right to withdraw

The participants have the right to withdraw from the study at any time without affecting the study.

Payment and compensation

You do not have to pay for the participating in this study. Similarly, no payment is available to you for participating in this study

If I have any questions, whom can I ask at any time point of the study?

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School of Physiotherapy

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Appendix VIII Information Sheet for Patients- Punjabi (Phase III)

ਖੋਜ ਸਿਰਲੇਖ

ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਵਿੱਚ ਵਜ਼ਨ ਵੰਡ ਦੇ ਅੰਤਰਾਂ ਦੇ ਮੁਲਾਂਕਣ ਲਈ ਇੱਕ ਨਵੇਂ ਪਹਿਨਣਯੋਗ ਯੰਤਰ ਦਾ ਵਿਕਾਸ ਅਤੇ ਪ੍ਰਮਾਣਿਕਤਾ।

ਜਾਣ ਪਛਾਣ

ਸਮਾਜ ਵਿਚ ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਦੇ ਰੋਗੀਆਂ ਵਿਚ ਵੱਧ ਰਹੀ ਅਪਾਹਜਤਾ ਨੂੰ ਦੂਰ ਕਰਨ ਲਈ, ਇਸ ਅਧਿਐਨ ਨੇ ਅੰਗਾਂ ਦੇ ਭਾਰ ਦੇ ਅਸਮਾਨਤਾ ਦੇ ਅਸਲ ਸਮੇਂ ਦੇ ਮੁਲਾਂਕਣ ਲਈ ਇਕ ਨਵਾਂ ਪਹਿਨਣ ਯੋਗ ਯੰਤਰ ਵਿਕਸਤ ਕੀਤਾ ਹੈ. ਇਹ ਨਵਾਂ ਉਪਕਰਣ ਕਲੀਨਿਸਟਾਂ ਦੇ ਨਾਲ ਨਾਲ ਮਰੀਜ਼ਾਂ ਨੂੰ ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਦੇ ਹੇਠਲੇ ਅੰਗਾਂ ਦੇ ਬਦਲਦੇ ਬਾਇਓਮੈਕਨਿਕਸ ਦੇ ਮੁਲਾਂਕਣ ਵਿਚ ਸਹਾਇਤਾ ਕਰੇਗਾ. ਇਸ ਲਈ, ਇਸ ਅਧਿਐਨ ਦਾ ਉਦੇਸ਼ ਅੰਗਾਂ ਦੇ ਲੋਡ ਅਸਮੈਟਰੀ ਦੇ ਅਸਲ ਸਮੇਂ ਦੇ ਮੁਲਾਂਕਣ ਵਿੱਚ ਇਸ ਨਵੇਂ ਪਹਿਨਣ ਯੋਗ ਉਪਕਰਣ ਦੀ ਯੋਗਤਾ ਅਤੇ ਭਰੋਸੇਯੋਗਤਾ ਨੂੰ ਨਿਰਧਾਰਤ ਕਰਨਾ ਹੈ.

ਇਸ ਵਿੱਚ ਕੀ ਸ਼ਾਮਲ ਹੋਵੇਗਾ?

ਇਸ ਅਧਿਐਨ ਵਿੱਚ, ਕਲੀਨੀਸ਼ੀਅਨ ਇੱਕ ਨਵੇਂ ਵਿਕਸਤ ਪਹਿਨਣਯੋਗ ਯੰਤਰ ਦੀ ਵਰਤੋਂ ਕਰਦੇ ਹੋਏ ਲੱਤ 'ਤੇ ਹਰ ਇੱਕ ਦੇ ਭਾਰ ਅਤੇ ਪੈਂਦਿਆਂ ਦੇ ਦਬਾਅ ਦੀ ਸਮਰੂਪਤਾ ਦਾ ਮੁਲਾਂਕਣ ਕਰੇਗਾ। ਸ਼ੁਰੂਆਤੀ ਸਲਾਹ-ਮਸ਼ਵਰੇ ਦੌਰਾਨ, ਡਾਕਟਰ ਤੁਹਾਡੀ ਸਹਿਮਤੀ ਪ੍ਰਾਪਤ ਕਰੇਗਾ। ਫਿਰ, ਥੈਰੇਪਿਸਟ ਨਵੇਂ ਯੰਤਰ ਦੀ ਵਰਤੋਂ ਕਰਦੇ ਹੋਏ ਅੰਗ ਦੇ ਭਾਰ ਅਤੇ ਪਲਾਂਟਰ ਪ੍ਰੈਸ਼ਰ ਦੀ ਵੰਡ ਦਾ ਮੁਲਾਂਕਣ ਕਰੇਗਾ। ਅਧਿਐਨ ਦੀ ਮਿਆਦ ਲਗਭਗ 1 ਘੰਟਾ ਹੈ ਅਤੇ ਮੁਲਾਂਕਣਾਂ ਦੇ ਵਿਚਕਾਰ ਕਾਫ਼ੀ ਆਰਾਮ ਦੀ ਮਿਆਦ ਹੈ।

ਲਾਭ

ਇਹ ਮਾਡਲ ਤੁਹਾਡੇ ਆਪਣੇ ਜੀਵਤ ਵਾਤਾਵਰਣ ਤੇ ਸਰੀਰਕ ਮੁਲਾਂਕਣ ਸੇਵਾ ਨੂੰ ਸੀਮਤ ਕਰਨ ਵਿੱਚ ਤੁਹਾਡੀ ਸਹਾਇਤਾ ਕਰੇਗਾ. ਹਸਪਤਾਲ ਜਾਂ ਸੰਸਥਾਗਤ ਅਧਾਰਤ ਸੈੱਟਅਪ ਵਿੱਚ ਫਿਜ਼ੀਓਥੈਰਾਪਿਸਟਾਂ ਨਾਲ ਇਲਾਜ ਅਤੇ ਸਲਾਹ-ਮਸ਼ਵਰੇ ਲਈ ਪਹੁੰਚਣ ਵਿਚ ਆਉਣ ਵਾਲੇ ਖਰਚੇ ਅਤੇ ਸਮੇਂ ਦੀ ਬਚਤ ਕੀਤੀ ਜਾ ਸਕਦੀ ਹੈ.

ਜੋਖਮ

ਇਸ ਖੋਜ ਲਈ ਕੋਈ ਜਾਣਿਆ ਜੋਖਮ ਨਹੀਂ ਹੈ.

ਗੁਪਤਤਾ

ਪ੍ਰਾਪਤ ਕੀਤੇ ਗਏ ਡੇਟਾ ਦੇ ਨਤੀਜਿਆਂ ਦੀ ਜਾਣਕਾਰੀ ਇਕੱਠੇ ਕੀਤੇਂਗ ਨਾਲ ਕੀਤੀ ਜਾਏਗੀ ਜਿਸਦਾ ਕੋਈ ਖਾਸ ਵਿਅਕਤੀ ਦਾ ਹਵਾਲਾ ਨਹੀਂ ਹੁੰਦਾ. ਇਸ ਲਈ, ਹਰੇਕ ਵਿਅਕਤੀ ਤੋਂ ਡਾਟਾ ਗੁਪਤ ਰਹੇਗਾ.

ਕੀ ਮੈਨੂੰ ਹਿੱਸਾ ਲੈਣਾ ਪਏਗਾ?

ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣਾ ਸਵੈਇੱਛੁਕ ਹੈ, ਜੇ ਤੁਸੀਂ ਹਿੱਸਾ ਲੈਣਾ ਨਹੀਂ ਚਾਹੁੰਦੇ ਹੋ, ਤਾਂ ਤੁਹਾਨੂੰ ਕੋਈ ਕਾਰਨ ਦੱਸਣ ਦੀ ਜ਼ਰੂਰਤ ਨਹੀਂ ਹੈ ਅਤੇ ਤੁਹਾਡੇ ਫੈਸਲੇ ਨਾਲ ਡਾਟਾ ਇਕੱਠਾ ਕਰਨ 'ਤੇ ਕੋਈ ਅਸਰ ਨਹੀਂ ਪਵੇਗਾ.

ਵਾਪਸ ਲੈਣ ਦਾ ਅਧਿਕਾਰ

ਹਿੱਸਾ ਲੈਣ ਵਾਲਿਆਂ ਨੂੰ ਅਧਿਐਨ ਨੂੰ ਪ੍ਰਭਾਵਿਤ ਕੀਤੇ ਬਿਨਾਂ ਕਿਸੇ ਵੀ ਸਮੇਂ ਅਧਿਐਨ ਤੋਂ ਪਿੱਛੇ ਹਟਣ ਦਾ ਅਧਿਕਾਰ ਹੈ.

ਭੁਗਤਾਨ ਅਤੇ ਮੁਆਵਜ਼ਾ

ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਤੁਹਾਨੂੰ ਭੁਗਤਾਨ ਕਰਨ ਦੀ ਜ਼ਰੂਰਤ ਨਹੀਂ ਹੈ. ਇਸੇ ਤਰ੍ਹਾਂ, ਇਸ ਅਧਿਐਨ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਤੁਹਾਡੇ ਲਈ ਕੋਈ ਭੁਗਤਾਨ ਉਪਲਬਧ ਨਹੀਂ ਹੈ

ਜੇ ਮੇਰੇ ਕੋਈ ਪ੍ਰਸ਼ਨ ਹਨ, ਤਾਂ ਮੈਂ ਅਧਿਐਨ ਦੇ ਕਿਸੇ ਵੀ ਸਮੇਂ ਕਿਸ ਨੂੰ ਪੁੱਛ ਸਕਦਾ ਹਾਂ?

ਸ੍ਰੀ ਅੰਬਰ ਅਨੰਦ

ਪੀਐਚਡੀ ਵਿਦਿਆਰਥੀ, ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਪ੍ਰੋਗਰਾਮ

ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਦਾ ਸਕੂਲ

ਸਿਹਤ ਵਿਗਿਆਨ ਦੀ ਫੈਕਲਟੀ

ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ

ਮੋਬਾਈਲ: 7837708195

ਡਾ ਸੁਰੇਸ਼ ਮਨੀ

ਦੇ ਐਸੋਸੀਏਟ ਪ੍ਰੋਫੈਸਰ,

ਫਿਜ਼ੀਓਥੈਰੇਪੀ ਦਾ ਸਕੂਲ

ਸਿਹਤ ਵਿਗਿਆਨ ਦੀ ਫੈਕਲਟੀ

ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ

ਮੋਬਾਈਲ: 9878331006

Appendix IX मरीजों के लिए सूचना पत्र- हिंदी (तीसरा चरण)

अनुसंधान शीर्षक

घुटने के गठिया में वजन वितरण के अंतर के आकलन के लिए एक नए पहनने योग्य उपकरण का विकास और सत्यापन।

परिचय

समाज में घुटने के पुराने गठिया के रोगियों के बीच बढ़ती विकलांगता को संबोधित करने के लिए, इस अध्ययन ने अंग भार विषमता के वास्तविक समय के आकलन के लिए एक नया पहनने योग्य उपकरण विकसित किया है। यह नया उपकरण चिकित्सकों के साथ-साथ घुटने के पुराने गठिया में निचले अंग के परिवर्तित बायोमैकेनिक्स के रोगियों की सहायता करेगा। इसलिए, इस अध्ययन का उद्देश्य अंगों के विषमता के वास्तविक समय के आकलन में इस नए पहनने योग्य उपकरण की वैधता और विश्वसनीयता निर्धारित करना है।

इसमें क्या शामिल होगा?

इस अध्ययन में, चिकित्सक नव विकसित पहनने योग्य उपकरण का उपयोग करके अंग भार विषमता और तल के दबाव विषमता का आकलन करेगा। प्रारंभिक परामर्श के दौरान, चिकित्सक आपकी सहमति प्राप्त करेगा। फिर, थेरेपिस्ट नए डिवाइस का उपयोग करके अंग भार और तल दबाव वितरण का आकलन करेगा। मूल्यांकन के बीच उचित आराम की अवधि के साथ अध्ययन की अवधि लगभग 1 घंटे है।

लाभ

यह मॉडल आपको अपने स्वयं के रहने वाले वातावरण में भौतिक मूल्यांकन सेवा को सीमित करने में मदद करेगा। अस्पताल या संस्थागत आधारित सेटअप में फिजियोथेरेपिस्ट के साथ उपचार और परामर्श तक पहुंचने में लगने वाला खर्च और समय बचाया जा सकता है।

जोखिम

इस शोध के लिए कोई ज्ञात जोखिम नहीं हैं।

गोपनीयता

प्राप्त आंकड़ों के परिणामों को एक विशिष्ट व्यक्ति के संदर्भ में एकत्र किए गए तरीके से रिपोर्ट किया जाएगा। इसलिए, प्रत्येक व्यक्ति का डेटा गोपनीय रहेगा।

क्या मुझे भाग लेना है?

इस अध्ययन में भागीदारी स्वैच्छिक है, यदि आप भाग नहीं लेना पसंद करते हैं, तो आपको कोई कारण नहीं देना होगा और आपका निर्णय डेटा संग्रह को प्रभावित नहीं करेगा।

वापस लेने का अधिकार

प्रतिभागियों को अध्ययन को प्रभावित किए बिना किसी भी समय अध्ययन से वापस लेने का अधिकार है।

भुगतान और मुआवजा

आपको इस अध्ययन में भाग लेने के लिए भुगतान करने की आवश्यकता नहीं है। इसी तरह, इस अध्ययन में भाग लेने के लिए आपको कोई भुगतान उपलब्ध नहीं है

यदि मेरे कोई प्रश्न हैं, तो मैं अध्ययन के किसी भी समय किससे पूछ सकता हूं?

श्री अंबर आनंद
पीएचडी छात्र, फिजियोथेरेपी प्रोग्राम
फिजियोथेरेपी विभाग
स्कूल ऑफ एलाइड मेडिकल साइंस
लवली प्रोफेशनल यूनिवर्सिटी
मोबाइल: 7837708195

डॉ. सुरेश मणि
एसोसिएट प्रोफेसर,
फिजियोथेरेपी विभाग
स्कूल ऑफ एलाइड मेडिकल साइंस
लवली प्रोफेशनल यूनिवर्सिटी
मोबाइल: 9878331006

Appendix X Information Consent- English

Research Title: Development, and concurrent validity and reliability of a new wearable device for assessment of limb load asymmetry in knee osteoarthritis.

Researcher ‘s Name: Amber Anand

I, _____, UID No:_____

• have read the information in the Patient Information Sheet including information regarding the risk in this study

• have been given time to think about it and all of my questions have been answered to my satisfaction.

• understand that I may freely choose to withdraw from this study at any time without reason and without repercussion

• understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

Place : _____ **Signature**

Date : _____

Appendix XI Information Consent- Punjabi

ਰਿਸਰਚ ਦਾ ਸਿਰਲੇਖ: ਗੋਡਿਆਂ ਦੇ ਗਠੀਏ ਵਿੱਚ ਵਜ਼ਨ ਵੰਡ ਦੇ ਅੰਤਰਾਂ ਦੇ ਮੁਲਾਂਕਣ ਲਈ ਇੱਕ ਨਵੇਂ ਪਹਿਨਣਯੋਗ ਯੰਤਰ ਦਾ ਵਿਕਾਸ ਅਤੇ ਪ੍ਰਮਾਣਿਕਤਾ।

ਖੋਜਕਰਤਾ ਦਾ ਨਾਮ: ਅੰਬਰ ਅਨੰਦ

ਮੈਂ, _____, ਯੂਆਈਡੀ ਨੰ: _____

- ਅਧਿਐਨ ਇਸ ਅਧਿਐਨ ਵਿਚ ਜੋਖਮ ਸੰਬੰਧੀ ਜਾਣਕਾਰੀ ਸਮੇਤ ਮਰੀਜ਼ ਦੀ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਵਿਚ ਦਿੱਤੀ ਜਾਣਕਾਰੀ ਨੂੰ ਪੜ੍ਹਿਆ ਹੈ
- ਮੈਨੂੰ ਇਸ ਬਾਰੇ ਸੋਚਣ ਲਈ ਸਮਾਂ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੇਰੇ ਸਾਰੇ ਪ੍ਰਸ਼ਨਾਂ ਦੇ ਜਵਾਬ ਮੇਰੀ ਸੰਤੁਸ਼ਟੀ ਲਈ ਦਿੱਤੇ ਗਏ ਹਨ.
- ਇਹ ਸਮਝ ਲਓ ਕਿ ਮੈਂ ਬਿਨਾਂ ਕਿਸੇ ਕਾਰਨ ਅਤੇ ਜਬਰਦਸਤੀ ਕਿਸੇ ਵੀ ਸਮੇਂ ਇਸ ਅਧਿਐਨ ਤੋਂ ਪਿੱਛੇ ਹਟਣਾ ਚੁਣ ਸਕਦਾ ਹਾਂ
- ਸਮਝੋ ਕਿ ਮੇਰੀ ਗੁਮਨਾਮਤਾ ਲਿਖਤੀ ਰੂਪ ਵਿੱਚ ਯਕੀਨੀ ਬਣਾਈ ਜਾਏਗੀ.

ਮੈਂ ਸਵੈ-ਇੱਛਾ ਨਾਲ ਇਸ ਖੋਜ ਅਧਿਐਨ ਦਾ ਹਿੱਸਾ ਬਣਨ ਲਈ, ਅਧਿਐਨ ਪ੍ਰਕਿਰਿਆਵਾਂ ਦੀ ਪਾਲਣਾ ਕਰਨ ਲਈ, ਅਤੇ ਡਾਕਟਰ, ਨਰਸਾਂ, ਜਾਂ ਹੋਰ ਸਟਾਫ ਮੈਂਬਰਾਂ ਨੂੰ ਬੇਨਤੀ ਅਨੁਸਾਰ, ਲੋੜੀਂਦੀ ਜਾਣਕਾਰੀ ਪ੍ਰਦਾਨ ਕਰਨ ਲਈ ਸਹਿਮਤ ਹਾਂ.

ਸਥਾਨ: _____ **ਦਸਤਖਤ**

ਤਾਰੀਖ਼ : _____

Appendix XII सूचना सहमति- हिंदी

अनुसंधान का शीर्षक: घुटने के गठिया में वजन वितरण के अंतर के आकलन के लिए एक नए पहनने योग्य उपकरण का विकास और सत्यापन।

शोधकर्ता का नाम: अंबर आनंद

मैं, _____, UID नंबर: _____

- इस अध्ययन में जोखिम के बारे में जानकारी सहित रोगी सूचना पत्रक में जानकारी को पढ़ा है
- इसके बारे में सोचने के लिए समय दिया गया है और मेरे सभी सवालों का जवाब मेरी संतुष्टि के लिए दिया गया है।
- समझें कि मैं बिना किसी कारण के और बिना किसी नतीजे के इस अध्ययन से स्वतंत्र रूप से वापस लेने का विकल्प चुन सकता हूं
- समझें कि लेखन में मेरी गुमनामी सुनिश्चित की जाएगी।

मैं स्वेच्छा से इस शोध अध्ययन का हिस्सा बनने के लिए सहमत हूं, अध्ययन प्रक्रियाओं का पालन करने के लिए, और डॉक्टर, नर्सों या अन्य स्टाफ सदस्यों को आवश्यक जानकारी प्रदान करने के लिए अनुरोध के रूप में।

स्थान: _____ हस्ताक्षर

दिनांक : _____

Appendix XIII Patient Assessment Form

Name: _____ **Age/Sex:** _____

Address: _____ **Contact No.:** _____

Weight: _____ **Height:** _____ **BMI:** _____

Occupation: _____

Chief Complaint: _____

History of present complaint: _____

Kind of disorder: _____

Onset: _____ **Duration:** _____

Medical and surgical history:

Past medical problem: _____

Present medical problem: _____

Past surgical history: _____

Any current medications: _____

Any previous treatment received for the current problem: _____

_____

Injury History:

Site: _____, When: _____, Activity: _____

Physical Activity: _____

Lifestyle: _____

American College of Rheumatology Knee Osteoarthritis Criteria:

- ☐ Knee Pain

+ at least 3 of 6:

- ☐ Age > 50 years
- ☐ Stiffness < 30 minutes
- ☐ Crepitus
- ☐ Bony Tenderness
- ☐ Bony Enlargement
- ☐ No Palpable Warmt

KOOS-12 KNEE SURVEY

INSTRUCTIONS: This survey asks for your views about your knee. Answer every question by marking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Pain

1. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of knee pain have you experienced the **last week** during the following activities?

2. Walking on a flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

3. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

5. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

6. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

7. Getting in/out of a car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

8. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

9. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

10. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

11. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

12. In general, how much difficulty do you have with your knee?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

Appendix XV Patient Recruitment Flyer

Is knee pain impacting your activities of daily living?

If you are having knee pain, this study may be helpful for you.

Study for adults with knee pain

We are looking for adults 40 years and older who suffer from knee pain to identify the prevalence and cause of asymmetries in limb loading and gait(walking) parameters.

Many individuals with chronic knee pain tend to develop asymmetrical weight bearing pattern between the legs as a result of compensatory mechanism to avoid pain in affected knee.

The participants will be asked to:

- Visit the physiotherapy OPD
- Undergo Knee Osteoarthritis Screening

Participants will receive:

- Physiotherapy Consultation
- Knee Osteoarthritis Screening
- Corrective Advice

Location

Physiotherapy OPD, Block 3A- 105, Uni Hospital
Lovely Professional University

Are you eligible?

- Knee pain
- 40 years or older
- Knee stiffness
- Crackling sound in knee
- Bony enlargement
- Tenderness
- No palpable warmth

If you have any query or you're unsure if you meet the requirements contact a member of the study team

Dr. Suresh Mani (HOD, Physiotherapy)
9878331006
Mr. Amber Anand (PhD Scholar)
7837708195

Lovely Professional University

School of Physiotherapy and Paramedical Sciences
Lovely Faculty of Applied Medical Sciences

Appendix XVI Master Chart- Demographic details of study participants

(Phase II)

S. No.	Age (years)	Gender	Weight (Kg)	Height (m)	BMI	Foot Size (cm)	Lifestyle	Physical Activity	Injury History	Limb Involved
1	63	F	63.00	1.62	24.01	23.00	Sedentary	Low	Yes	Bilateral
2	45	M	71.50	1.60	27.93	27.00	Sedentary	Low	None	Bilateral
3	42	M	69.00	1.72	23.32	24.50	Sedentary	Low	Yes	Unilateral
4	42	F	62.00	1.52	26.84	24.00	Active	Moderate	None	Unilateral
5	44	M	73.00	1.68	25.86	25.00	Sedentary	Low	None	Unilateral
6	33	F	60.00	1.57	24.34	23.00	Active	Moderate	None	Bilateral
7	46	M	55.00	1.62	20.96	24.50	Active	Moderate	None	Bilateral
8	52	F	70.00	1.58	28.04	23.00	Active	Moderate	None	Bilateral
9	50	M	40.00	1.55	16.65	23.50	Active	Moderate	None	Bilateral
10	51	M	55.00	1.55	22.89	23.00	Sedentary	Moderate	None	Bilateral
11	72	M	52.00	1.48	23.74	23.50	Active	Moderate	None	Unilateral
12	52	F	52.00	1.39	26.91	22.00	Active	Moderate	None	Bilateral
13	38	M	82.00	1.59	32.44	24.00	Sedentary	Low	None	Bilateral
14	47	F	75.00	1.51	32.89	23.50	Active	Moderate	None	Bilateral
15	58	M	75.00	1.65	27.55	26.50	Active	Moderate	None	Bilateral
16	58	F	57.00	1.47	26.38	24.00	Active	Moderate	None	Bilateral
17	58	M	70.00	1.66	25.40	27.50	Active	Moderate	None	Unilateral
18	54	M	70.00	1.68	24.80	27.00	Sedentary	Moderate	None	Bilateral
19	49	F	65.00	1.56	26.71	24.00	Active	Moderate	None	Unilateral
20	53	F	53.00	1.55	22.06	25.00	Active	Moderate	None	Bilateral
21	58	F	67.00	1.55	27.89	24.00	Active	Moderate	None	Unilateral
22	48	F	95.00	1.55	39.54	24.00	Active	Moderate	None	Unilateral
23	40	F	46.00	1.42	22.81	22.00	Active	Moderate	None	Bilateral
24	44	F	58.00	1.44	27.97	21.50	Active	Moderate	None	Bilateral
25	45	F	65.00	1.55	27.06	24.50	Active	Moderate	None	Bilateral
26	47	F	60.00	1.52	25.97	24.50	Active	Moderate	None	Bilateral
27	37	F	88.00	1.50	39.11	23.50	Active	Moderate	None	Bilateral
28	51	M	68.00	1.48	31.04	23.50	Active	Moderate	None	Bilateral
29	47	F	70.00	1.56	28.76	24.00	Active	Moderate	None	Bilateral
30	56	M	63.00	1.64	23.42	26.50	Active	Moderate	None	Bilateral
31	42	F	64.00	1.52	27.70	24.00	Active	Moderate	None	Unilateral
32	47	F	60.00	1.62	22.86	25.50	Active	Moderate	None	Bilateral
33	42	F	85.00	1.57	34.48	23.50	Active	Moderate	None	Bilateral
34	41	M	75.00	1.65	27.55	25.50	Sedentary	Low	None	Unilateral
35	51	F	40.00	1.47	18.51	23.50	Active	Moderate	None	Bilateral
36	43	M	52.00	1.61	20.06	26.00	Active	Moderate	None	Bilateral

S. No.	Age (years)	Gender	Weight (Kg)	Height (m)	BMI	Foot Size (cm)	Lifestyle	Physical Activity	Injury History	Limb Involved
37	47	F	81.00	1.57	32.86	24.50	Active	Moderate	None	Bilateral
38	35	F	55.00	1.50	24.44	22.50	Active	Moderate	None	Bilateral
39	45	F	70.00	1.55	29.14	24.50	Active	Moderate	None	Unilateral
40	52	F	48.00	1.50	21.33	24.50	Active	Moderate	None	Bilateral
41	41	F	45.00	1.42	22.32	22.00	Active	Moderate	None	Bilateral
42	46	F	45.00	1.48	20.54	21.50	Active	Moderate	None	Bilateral
43	45	F	43.00	1.59	17.01	22.50	Active	Moderate	None	Bilateral
44	48	F	70.00	1.58	28.04	24.50	Active	Moderate	None	Bilateral
45	49	F	52.00	1.50	23.11	23.00	Active	Moderate	None	Bilateral
46	57	M	60.00	1.59	23.73	24.00	Active	Moderate	None	Bilateral
47	67	M	62.00	1.67	22.23	26.50	Active	Moderate	None	Bilateral
48	46	F	68.00	1.48	31.04	23.00	Active	Moderate	None	Bilateral
49	46	F	60.00	1.52	25.97	23.00	Active	Moderate	None	Bilateral
50	47	F	70.00	1.55	29.14	23.00	Active	Moderate	None	Bilateral
51	46	F	70.00	1.54	29.52	23.00	Active	Moderate	Yes	Bilateral
52	46	F	57.00	1.49	25.67	22.00	Active	Moderate	None	Bilateral
53	40	F	36.00	1.44	17.36	21.00	Active	Moderate	None	Bilateral
54	50	F	60.00	1.48	27.39	22.00	Active	Moderate	None	Unilateral
55	45	F	52.00	1.50	23.11	23.00	Active	Moderate	None	Bilateral
56	48	F	68.00	1.61	26.23	24.00	Active	Moderate	None	Bilateral
57	43	F	45.00	1.49	20.27	23.00	Active	Moderate	None	Bilateral
58	45	F	70.00	1.54	29.52	23.00	Active	Moderate	None	Unilateral
59	40	F	49.00	1.54	20.66	22.00	Active	Moderate	None	Bilateral
60	45	F	54.00	1.45	25.68	21.50	Active	Moderate	None	Unilateral
61	47	F	70.00	1.55	29.14	23.50	Active	Moderate	None	Unilateral
62	49	F	70.00	1.53	29.90	23.50	Active	Moderate	None	Unilateral
63	42	F	52.00	1.50	23.11	22.50	Active	Moderate	None	Bilateral
64	50	M	64.00	1.57	25.96	23.50	Active	Moderate	Yes	Bilateral
65	43	F	75.00	1.53	32.04	24.50	Active	Moderate	None	Bilateral
66	36	F	75.00	1.52	32.46	24.00	Active	Moderate	None	Bilateral
67	50	F	85.00	1.63	31.99	25.00	Active	Moderate	None	Bilateral
68	36	F	50.00	1.60	19.53	22.00	Active	Moderate	None	Unilateral
69	54	M	75.00	1.65	27.55	27.00	Active	Moderate	None	Bilateral
70	51	F	60.00	1.59	23.73	24.50	Active	Moderate	None	Bilateral
71	60	F	45.00	1.50	20.00	22.00	Active	Moderate	None	Bilateral
72	46	F	67.00	1.49	30.18	24.50	Active	Moderate	None	Bilateral
73	48	F	60.00	1.59	23.73	20.00	Active	Moderate	None	Bilateral
74	50	M	65.00	1.65	23.88	24.50	Active	Moderate	None	Unilateral

S. No.	Age (years)	Gender	Weight (Kg)	Height (m)	BMI	Foot Size (cm)	Lifestyle	Physical Activity	Injury History	Limb Involved
75	59	M	60.00	1.68	21.26	26.50	Active	Moderate	None	Bilateral
76	57	M	70.00	1.76	22.60	27.00	Active	Moderate	None	Bilateral
77	32	F	58.00	1.53	24.78	21.50	Active	Moderate	None	Unilateral
78	49	F	80.00	1.53	34.17	23.00	Active	Moderate	None	Bilateral
79	51	F	74.00	1.56	30.41	25.00	Active	Moderate	None	Bilateral
80	48	F	70.00	1.68	24.80	23.50	Active	Moderate	None	Bilateral
81	39	F	55.00	1.46	25.80	22.00	Active	Moderate	None	Unilateral
82	46	F	71.00	1.50	31.56	22.00	Active	Moderate	None	Unilateral
83	51	F	58.00	1.48	26.48	22.50	Active	Moderate	None	Unilateral
84	48	F	65.00	1.56	26.71	24.50	Active	Moderate	None	Bilateral
85	40	F	50.00	1.48	22.83	22.50	Active	Moderate	None	Bilateral
86	53	F	75.00	1.68	26.57	24.00	Active	Moderate	None	Unilateral
87	52	F	78.00	1.55	32.47	22.50	Active	Moderate	None	Bilateral
88	45	F	50.00	1.50	22.22	21.00	Active	Moderate	None	Bilateral
89	43	F	55.00	1.50	24.44	22.00	Active	Moderate	None	Unilateral
90	52	F	62.00	1.58	24.84	23.00	Active	Moderate	None	Unilateral
91	43	F	80.00	1.50	35.56	22.00	Active	Moderate	None	Bilateral
92	62	F	62.00	1.53	26.49	22.50	Active	Moderate	None	Bilateral
93	44	F	79.00	1.60	30.86	23.50	Active	Moderate	None	Bilateral
94	44	F	55.00	1.53	23.50	22.00	Active	Moderate	None	Bilateral
95	45	M	82.00	1.59	32.44	24.00	Sedentary	Moderate	None	Bilateral
Mean	**47.68**	**Male= 23**	**63.34**	**1.55**	**26.26**	**23.63**	**Active= 86**	**Moderate= 89**	**None= 91**	**Bilateral= 70**
Std. dev.	**7.00**	**Female= 72**	**11.80**	**0.07**	**4.54**	**1.53**	**Sedentary= 9**	**Low= 6**	**Yes= 4**	**Unilateral= 25**

Appendix XVII Master Chart- KOOS-12 scores of participants (Phase II)

S. No.	KP 1	KP 2	KP 3	KP 4	KF 5	KF 6	KF 7	KF 8	KQ 9	KQ 10	KQ 11	KQ 12	Pain (%)	ADL (%)	QOL (%)
1	4	1	2	0	2	1	1	1	2	2	1	2	56.25	68.75	56.25
2	2	1	2	0	1	1	2	2	2	1	1	2	68.75	62.5	62.5
3	4	2	3	1	3	2	2	3	4	2	3	3	37.5	37.5	25
4	1	0	0	0	1	0	1	1	1	1	0	1	93.75	81.25	81.25
5	4	2	2	1	2	2	2	3	4	2	2	3	43.75	43.75	31.25
6	3	0	1	0	2	0	1	1	2	1	1	1	75	75	68.75
7	1	0	1	0	2	0	0	1	1	1	1	1	87.5	81.25	75
8	3	1	1	1	3	2	1	1	3	1	1	2	62.5	56.25	56.25
9	4	2	3	1	2	3	3	2	4	2	2	2	37.5	37.5	37.5
10	3	1	1	1	3	1	1	1	3	1	1	2	62.5	62.5	56.25
11	2	1	2	0	2	2	2	1	3	1	2	2	68.75	56.25	50
12	3	2	0	0	1	1	2	2	3	1	2	1	68.75	62.5	56.25
13	2	1	1	0	1	1	1	1	2	1	1	2	75	75	62.5
14	1	1	1	0	1	1	0	1	1	1	1	1	81.25	81.25	75
15	2	1	2	0	2	1	0	1	2	0	1	1	68.75	75	75
16	3	1	2	1	2	1	2	1	3	2	1	2	56.25	62.5	50
17	3	1	1	0	1	1	1	1	3	2	1	2	68.75	75	50
18	2	2	2	1	2	2	1	1	2	1	2	2	56.25	62.5	56.25
19	2	1	1	1	1	1	1	1	2	1	1	2	68.75	75	62.5
20	1	0	1	0	1	0	0	1	1	1	1	1	87.5	87.5	75
21	2	1	2	1	1	1	1	1	2	1	1	1	62.5	75	68.75
22	2	0	1	0	1	0	1	1	2	0	1	1	81.25	81.25	75
23	3	1	2	2	2	1	0	1	3	1	1	2	50	75	56.25
24	3	1	2	1	2	1	1	1	3	1	1	2	56.25	68.75	56.25

S. No.	KP 1	KP 2	KP 3	KP 4	KF 5	KF 6	KF 7	KF 8	KQ 9	KQ 10	KQ 11	KQ 12	Pain (%)	ADL (%)	QOL (%)
25	3	1	2	0	2	2	1	1	3	1	2	1	62.5	62.5	56.25
26	3	1	2	0	2	2	0	1	3	1	1	1	62.5	68.75	62.5
27	3	1	2	0	2	1	0	1	3	1	1	2	62.5	75	56.25
28	2	2	2	1	1	1	1	1	3	1	2	2	56.25	75	50
29	3	2	2	1	1	1	1	1	3	1	1	2	50	75	56.25
30	2	0	2	0	2	0	1	1	3	0	1	1	75	75	68.75
31	3	2	2	1	2	2	1	1	3	2	2	3	50	62.5	37.5
32	3	0	1	1	1	0	1	1	3	1	1	1	68.75	81.25	62.5
33	2	0	1	0	1	1	0	1	2	0	0	1	81.25	81.25	81.25
34	2	1	1	0	1	0	1	0	2	1	1	1	75	87.5	68.75
35	2	1	1	0	1	1	1	1	2	1	1	1	75	75	68.75
36	1	0	1	0	1	1	1	0	2	0	0	1	87.5	81.25	81.25
37	3	1	2	1	2	2	1	1	3	1	1	2	56.25	62.5	56.25
38	3	1	2	0	1	1	1	1	3	0	1	1	62.5	75	68.75
39	2	0	1	0	1	0	1	0	2	0	1	1	81.25	87.5	75
40	3	1	2	0	1	1	1	1	3	1	1	1	62.5	75	62.5
41	2	0	1	0	1	1	1	0	2	1	1	1	81.25	81.25	68.75
42	3	2	1	0	1	2	1	1	3	1	0	1	62.5	68.75	68.75
43	4	2	2	0	2	1	1	1	4	2	2	2	50	68.75	37.5
44	3	1	2	0	2	2	1	1	3	1	2	2	62.5	62.5	50
45	1	0	0	0	1	0	0	0	1	0	0	1	93.75	93.75	87.5
46	3	0	1	0	1	0	1	0	3	0	1	1	75	87.5	68.75
47	3	1	1	0	2	1	1	0	3	1	1	2	68.75	75	56.25
48	2	0	1	0	1	0	1	1	2	1	1	1	81.25	81.25	68.75
49	2	1	1	1	1	1	1	1	2	1	0	1	68.75	75	75
50	2	1	2	0	2	1	1	0	2	1	1	1	68.75	75	68.75

S. No.	KP 1	KP 2	KP 3	KP 4	KF 5	KF 6	KF 7	KF 8	KQ 9	KQ 10	KQ 11	KQ 12	Pain (%)	ADL (%)	QOL (%)
51	3	1	2	0	1	1	0	1	3	1	1	1	62.5	81.25	62.5
52	3	1	1	2	1	2	0	0	3	0	1	1	56.25	81.25	68.75
53	2	0	1	0	1	1	0	0	2	0	1	1	81.25	87.5	75
54	3	1	2	0	1	1	0	1	3	1	1	1	62.5	81.25	62.5
55	3	1	2	0	2	1	1	0	2	1	1	1	62.5	75	68.75
56	3	1	2	0	2	1	1	1	3	1	1	1	62.5	68.75	62.5
57	3	1	2	0	1	1	0	0	3	0	1	1	62.5	87.5	68.75
58	2	1	2	0	0	0	1	1	2	0	1	1	68.75	87.5	75
59	2	1	2	0	2	1	1	0	2	1	1	1	68.75	75	68.75
60	3	1	1	0	1	1	0	0	3	1	1	1	68.75	87.5	62.5
61	2	1	2	0	2	1	0	0	2	0	1	1	68.75	81.25	75
62	3	1	1	0	2	1	0	1	3	1	1	1	68.75	75	62.5
63	2	1	1	0	1	1	1	0	2	1	1	1	75	81.25	68.75
64	3	2	2	0	2	2	1	1	3	1	1	1	56.25	62.5	62.5
65	4	1	2	2	2	2	1	0	4	2	2	2	43.75	68.75	37.5
66	3	1	2	0	2	1	0	0	3	0	1	1	62.5	81.25	68.75
67	2	1	2	0	1	1	1	1	2	1	1	1	68.75	75	68.75
68	3	0	1	0	2	1	0	0	3	0	1	1	75	81.25	68.75
69	3	1	2	0	2	1	0	0	3	1	1	1	62.5	81.25	62.5
70	3	1	2	0	2	1	1	0	3	1	1	2	62.5	75	56.25
71	3	1	2	0	2	2	1	1	3	1	1	0	62.5	62.5	68.75
72	2	1	2	0	2	1	1	0	2	1	1	1	68.75	75	68.75
73	2	0	2	0	1	0	0	0	2	0	0	1	75	93.75	81.25
74	3	1	1	0	1	1	0	0	3	1	1	1	68.75	87.5	62.5
75	3	1	2	1	2	2	1	1	4	1	2	2	56.25	62.5	43.75
76	3	0	2	0	2	1	0	0	3	1	1	1	68.75	81.25	62.5

S. No.	KP 1	KP 2	KP 3	KP 4	KF 5	KF 6	KF 7	KF 8	KQ 9	KQ 10	KQ 11	KQ 12	Pain (%)	ADL (%)	QOL (%)
77	2	1	3	1	1	1	0	0	2	0	1	2	56.25	87.5	68.75
78	3	1	2	1	3	2	2	2	3	1	2	3	56.25	43.75	43.75
79	3	1	2	0	2	0	1	1	3	1	1	2	62.5	75	56.25
80	3	1	3	0	3	1	2	1	3	1	1	2	56.25	56.25	56.25
81	1	0	1	0	1	0	0	0	1	0	0	1	87.5	93.75	87.5
82	2	1	1	0	2	1	0	0	2	0	0	1	75	81.25	81.25
83	2	1	2	1	2	1	1	1	3	1	1	2	62.5	68.75	56.25
84	3	1	2	0	2	1	0	0	3	2	1	2	62.5	81.25	50
85	3	1	2	0	2	1	1	0	3	1	1	2	62.5	75	56.25
86	4	2	3	1	3	2	1	2	4	2	2	3	37.5	50	31.25
87	3	1	2	0	1	0	0	0	3	1	1	1	62.5	93.75	62.5
88	2	0	1	0	1	1	0	1	2	1	1	1	81.25	81.25	68.75
89	2	1	3	1	1	1	0	0	1	1	1	1	56.25	87.5	75
90	2	1	2	0	1	1	0	0	2	1	1	1	68.75	87.5	68.75
91	4	1	3	1	2	2	0	1	4	2	2	3	43.75	68.75	31.25
92	2	1	1	1	1	1	0	0	2	1	1	1	68.75	87.5	68.75
93	3	2	2	0	2	1	1	0	3	1	2	2	56.25	75	50
94	2	0	1	0	2	1	0	0	2	0	1	1	81.25	81.25	75
95	2	1	2	0	2	1	1	1	2	1	1	1	68.75	68.75	68.75
Mean													**67.09**	**71.68**	**61.48**
Standard Deviation													**13.43**	**11.97**	**13.40**

Note: KP- KOOS Pain, KF- KOOS Activities of daily living (ADL), KQ- KOOS Quality of life (QOL)

Appendix XVIII Master Chart- Spatiotemporal and limb load asymmetry result (Phase II)

S. No	Stance phase duration (ms)	Stride time (ms)	Swing phase duration Left (ms)	Swing phase duration Right (ms)	Step Duration Left (ms)	Step Duration Right (ms)	Step Length Left (mm)	Step length Right (mm)	Stride length (cm)	Max. Pressure Left (kPa)	Max. Pressure Right (kPa)	Static Limb Load Asymmetry (%)	Step Length Asymmetry (%)	Step Duration Asymmetry (%)	Swing Phase Asymmetry (%)	Plantar Pressure Asymmetry (%)
1	630	1950	1460	1200	750	650	461	383	84.35	5724	4804	16	27.78	13.33	17.81	16.07
2	560	1650	1020	1100	510	630	578	586	116.37	4114	5581	20	27.78	19.05	7.27	26.29
3	540	1740	1190	1170	570	580	586	586	117.15	4917	4184	22	27.78	8.20	11.71	56.87
4	470	1830	1260	1270	560	580	523	547	107	4983	4318	10	27.78	6.15	2.46	38.32
5	570	1560	1020	1150	410	630	578	617	119.49	5098	4578	4	27.78	10.94	3.01	12.16
6	540	1540	1110	980	560	610	578	610	105.43	5548	2393	6	27.78	5.00	2.52	34.12
7	630	1800	1190	1220	650	610	500	578	107.78	5720	3528	8	27.78	11.76	3.96	5.10
8	550	1900	1290	1330	570	640	476	562	103.87	6682	7607	2	27.78	22.06	9.09	35.68
9	560	1760	1160	1190	570	600	672	594	126.52	5709	3761	4	27.78	2.99	2.78	19.21
10	450	1460	1010	970	510	450	547	547	109.34	5720	5428	14	27.78	48.44	50.51	18.43
11	710	3030	1550	2310	720	820	344	406	74.98	4487	3871	6	27.78	20.00	4.41	16.85
12	540	1780	1100	1210	530	680	422	406	82.79	4357	6774	26	27.78	12.28	3.42	32.15
13	600	2110	1440	1400	650	670	328	430	75.76	4543	5623	18	27.78	16.07	4.59	23.93
14	540	2310	980	1980	330	640	305	445	74.98	6811	5556	22	27.78	4.00	3.70	10.97
15	560	2000	1360	1300	700	560	531	515	104.65	4726	5684	4	27.78	3.28	3.10	15.29
16	440	1740	1170	1130	500	570	547	562	110.9	3527	5198	36	27.78	9.68	3.48	12.16
17	560	2010	1350	1320	600	660	578	531	110.9	6310	7215	28	27.78	32.95	12.10	23.14
18	450	1600	1090	1040	560	470	508	523	103.09	6400	8413	20	27.78	22.37	5.00	31.77
19	1040	2330	930	1490	150	1120	258	570	82.79	2524	5190	4	27.78	40.71	5.63	17.93

S. No	Stance phase duration (ms)	Stride time (ms)	Swing phase duration Left (ms)	Swing phase duration Right (ms)	Step Duration Left (ms)	Step Duration Right (ms)	Step Length Left (mm)	Step length Right (mm)	Stride length (cm)	Max. Pressure Left (kPa)	Max. Pressure Right (kPa)	Static Limb Load Asymmetry (%)	Step Length Asymmetry (%)	Step Duration Asymmetry (%)	Swing Phase Asymmetry (%)	Plantar Pressure Asymmetry (%)
20	480	1560	1080	1040	500	480	562	484	104.65	7407	8320	6	27.78	3.17	3.97	12.54
21	470	2000	1130	1390	610	460	500	383	88.25	6349	3261	24	27.78	0.00	2.59	19.61
22	400	1690	1180	1110	520	510	539	492	103.09	6789	5005	24	27.78	6.94	16.36	31.37
23	540	1880	1250	1290	590	610	476	515	99.19	3534	4172	0	27.78	16.42	5.19	16.09
24	620	1670	1110	1150	620	560	422	453	87.47	3453	3931	0	27.78	39.51	10.42	2.74
25	620	2260	1570	1380	880	590	445	570	101.53	4917	6397	12	27.78	21.21	7.69	14.27
26	630	1990	1400	1330	760	590	547	476	102.31	5194	3544	8	27.78	3.64	1.85	21.57
27	840	2270	1600	1510	1130	670	687	508	119.49	6783	5567	6	27.78	9.38	8.33	19.21
28	580	1840	1260	1210	630	610	531	539	107	6848	5989	10	27.78	33.78	6.06	29.02
29	540	1700	1130	1160	570	570	523	523	104.65	4284	5329	8	27.78	5.00	21.23	9.24
30	660	2320	1380	1650	670	720	461	469	92.94	3967	5780	4	27.78	41.38	21.05	8.25
31	570	1740	1110	1170	570	620	531	523	105.43	5023	5593	10	27.78	5.88	7.76	20.24
32	480	1950	1280	1350	560	670	547	508	105.43	5706	4788	14	27.78	21.13	1.59	26.27
33	490	2100	1440	1290	810	490	500	500	99.97	6637	6824	4	27.78	26.58	20.69	19.62
34	700	1730	1240	1140	750	490	523	531	105.43	5090	3912	18	27.78	20.63	3.28	47.06
35	610	1740	1170	1080	660	520	578	578	115.59	4198	4897	20	27.78	8.45	2.21	14.11
36	510	1610	1060	1080	530	550	687	617	130.43	5490	4306	16	27.78	2.78	3.70	4.40
37	540	2020	1320	1440	580	640	609	625	123.4	6824	8447	14	27.78	8.96	25.58	40.01
38	570	1980	1320	1240	740	490	383	523	90.6	3431	4834	10	27.78	8.20	0.83	20.00
39	470	1970	1140	1330	370	830	453	375	82.79	2925	4969	10	27.78	3.57	0.85	20.79

S. No	Stance phase duration (ms)	Stride time (ms)	Swing phase duration Left (ms)	Swing phase duration Right (ms)	Step Duration Left (ms)	Step Duration Right (ms)	Step Length Left (mm)	Step length Right (mm)	Stride length (cm)	Max. Pressure Left (kPa)	Max. Pressure Right (kPa)	Static Limb Load Asymmetry (%)	Step Length Asymmetry (%)	Step Duration Asymmetry (%)	Swing Phase Asymmetry (%)	Plantar Pressure Asymmetry (%)
40	570	2060	1150	1460	600	570	445	508	95.3	4567	5032	28	27.78	3.28	3.68	26.67
41	550	1480	1140	900	580	340	469	492	96.06	4960	4551	2	27.78	40.87	24.86	28.23
42	450	1670	1160	1070	510	480	476	430	90.6	4337	3459	10	27.78	1.67	3.23	52.16
43	660	1820	1260	1240	710	560	555	562	111.68	5444	4014	18	27.78	20.63	3.28	47.06
44	600	2530	1380	1740	790	580	445	461	90.6	4721	5873	14	27.78	4.55	2.84	17.65
45	550	1810	1180	1220	500	630	562	531	109.34	8121	4299	18	27.78	9.43	5.77	20.79
46	610	2010	1330	1360	650	710	500	476	97.63	4481	5217	26	27.78	3.08	21.43	41.17
47	700	2000	1300	1350	720	700	562	539	110.12	5784	6050	12	27.78	18.31	8.21	27.45
48	610	2330	1280	1720	610	670	469	406	87.47	6184	3710	16	27.78	0.94	15.93	27.06
49	520	1770	1210	1200	610	560	601	547	114.81	4248	5310	18	27.78	12.33	12.33	27.45
50	510	1730	1180	1170	560	540	547	484	103.09	5564	7024	36	27.78	29.17	7.32	20.01
51	480	1950	1360	1310	610	590	578	594	117.15	4753	6482	18	27.78	23.73	13.28	9.01
52	1130	2040	1810	1360	680	1150	453	648	110.12	4701	6550	0	27.78	13.33	28.14	33.33
53	570	1830	1240	1200	600	590	547	515	106.22	2781	5813	8	27.78	5.26	7.28	27.44
54	560	1980	930	1300	220	1050	445	586	103.1	5471	4784	0	27.78	17.39	17.76	12.56
55	710	1810	1180	1220	500	630	562	531	109.34	4299	8121	22	27.78	12.50	4.35	35.69
56	550	2070	1370	1410	660	630	523	484	100.1	6724	5537	10	27.78	14.63	23.30	14.89
57	470	1460	980	1040	530	480	461	476	93.72	5643	4470	38	27.78	3.45	0.88	20.78
58	790	2040	1370	1380	660	810	508	508	101.53	3831	6030	34	27.78	5.71	0.00	27.84
59	630	2310	1320	1680	630	650	531	484	101.53	2776	4719	4	27.78	4.69	5.59	25.89

S. No	Stance phase duration (ms)	Stride time (ms)	Swing phase duration Left (ms)	Swing phase duration Right (ms)	Step Duration Left (ms)	Step Duration Right (ms)	Step Length Left (mm)	Step length Right (mm)	Stride length (cm)	Max. Pressure Left (kPa)	Max. Pressure Right (kPa)	Static Limb Load Asymmetry (%)	Step Length Asymmetry (%)	Step Duration Asymmetry (%)	Swing Phase Asymmetry (%)	Plantar Pressure Asymmetry (%)
60	720	2490	1310	1850	640	680	414	476	89.03	4359	5642	18	27.78	21.43	22.42	27.86
61	580	1930	1230	1310	620	700	453	375	82.79	4652	7754	6	27.78	22.67	5.33	7.46
62	490	1680	1100	1150	530	530	547	515	106.22	7174	6780	4	27.78	18.06	10.08	5.30
63	600	1810	1230	1340	710	580	539	469	100.75	4435	6113	20	27.78	18.46	12.75	5.88
64	1300	2580	1530	1820	1060	1050	398	476	87.47	5670	7773	12	27.78	13.43	2.16	9.03
65	590	2100	730	640	730	640	500	531	103.09	5495	7574	42	27.78	17.74	2.73	39.14
66	640	1740	1230	1140	720	510	469	383	85.13	4366	5458	16	27.78	15.25	2.48	11.38
67	600	1730	1280	1110	590	450	476	469	94.5	4472	4915	10	27.78	19.44	27.87	49.81
68	650	2160	1390	1510	650	640	500	539	103.87	3475	5275	42	27.78	13.70	7.95	4.71
69	660	2640	1430	1990	650	750	406	484	89.03	4482	6723	20	27.78	1.79	4.17	32.15
70	740	2160	1400	1510	720	760	390	359	74.99	4340	3149	14	27.78	48.44	50.51	18.43
71	610	2090	1250	1520	570	690	586	690	104.65	6356	5558	10	27.78	1.72	1.68	14.91
72	500	1710	1150	1100	490	560	555	560	111.68	5226	8126	38	27.78	3.45	0.79	13.35
73	700	2880	1580	2060	820	700	398	484	88.25	5144	4378	8	27.78	34.92	11.30	10.20
74	640	2520	1430	1480	1040	350	422	500	92.16	4644	3916	8	27.78	12.20	32.90	13.73
75	580	1690	1130	1120	580	560	484	508	99.19	4264	3378	14	27.78	9.09	2.22	12.54
76	660	2160	1460	1460	700	660	469	578	104.55	4556	6314	10	27.78	86.61	37.58	51.37
77	680	1860	1190	1320	540	720	476	531	100.7	4523	5884	6	27.78	24.59	18.71	48.64
78	520	2040	1350	1430	610	640	445	445	89.03	6307	4674	38	27.78	1.92	5.93	26.28
79	910	3000	1730	2230	770	980	484	437	92.16	4954	3574	20	27.78	8.06	5.13	10.19

S. No	Stance phase duration (ms)	Stride time (ms)	Swing phase duration Left (ms)	Swing phase duration Right (ms)	Step Duration Left (ms)	Step Duration Right (ms)	Step Length Left (mm)	Step length Right (mm)	Stride length (cm)	Max. Pressure Left (kPa)	Max. Pressure Right (kPa)	Static Limb Load Asymmetry (%)	Step Length Asymmetry (%)	Step Duration Asymmetry (%)	Swing Phase Asymmetry (%)	Plantar Pressure Asymmetry (%)
80	510	2170	1500	1420	750	580	570	469	103.87	6043	5592	16	27.78	34.67	8.06	23.14
81	480	1630	1110	1060	500	520	547	531	107.78	5640	5175	14	27.78	55.42	14.29	41.14
82	590	2480	1430	1790	690	670	453	469	92.16	6372	5523	26	27.78	79.05	28.46	12.56
83	600	2110	1440	1370	740	680	547	453	99.97	5367	3809	12	27.78	18.52	0.72	36.47
84	640	1880	1160	1290	590	720	476	367	84.35	5204	3469	0	27.78	5.88	29.19	22.74
85	560	2020	1300	1490	530	650	492	484	97.63	4692	4416	0	27.78	11.43	6.11	40.01
86	620	1980	1350	1370	610	730	476	531	100.75	5304	6065	10	27.78	0.00	4.35	5.49
87	490	2030	1360	1390	580	670	476	492	96.84	4804	5281	0	27.78	1.54	7.95	34.12
88	510	1610	1070	1100	510	620	508	547	105.43	3811	6262	6	27.78	66.35	3.38	15.68
89	520	1670	1100	1150	520	520	562	586	114.81	6913	4853	6	27.78	25.00	9.85	23.13
90	570	1770	1200	1170	610	570	586	515	110.12	5920	5572	0	27.78	3.85	4.50	15.05
91	450	1770	1210	1180	590	500	523	539	106.22	7182	8104	18	27.78	2.90	20.11	24.45
92	600	2550	1320	1830	720	580	414	469	88.25	8908	4471	12	27.78	8.11	4.86	14.18
93	710	2140	1510	1390	730	630	500	515	101.53	5124	5377	4	27.78	16.44	1.46	12.55
94	550	1760	1150	1200	560	550	515	562	107.78	4693	6917	10	27.78	0.00	4.35	29.80
95	540	2310	980	1980	330	640	305	445	74.98	6811	5556	20	27.78	6.56	2.50	5.88
Mean	**597.79**	**1975.47**	**1255.79**	**1344.21**	**617.68**	**628.84**	**499.20**	**507.74**	**100.31**	**5198.12**	**5389.64**	**14.00**	**27.78**	**16.52**	**10.02**	**22.68**
SD	**135.42**	**325.80**	**178.58**	**286.05**	**144.26**	**138.16**	**76.83**	**65.55**	**11.84**	**1191.02**	**1341.16**	**10.30**	**0.00**	**16.52**	**10.37**	**12.47**

Appendix XIX DT-Walk validity testing against WinTrack for Limb Load Asymmetry

WinTrack LLA											
S. No.	**R1_Left**	**R1_Right**	**R2_Left**	**R2_Right**	**R3_Left**	**R3_Right**	**Weight**	**Left_Mean**	**Right_Mean**	**Difference**	**SLLA (%)**
1	36	42	39	39	35	43	78	36.67	41.33	4.67	5.98
2	29	39	30	38	30	38	68	29.67	38.33	8.67	12.75
3	29	26	26	29	30	25	55	28.33	26.67	1.67	3.03
4	20	35	20	35	19	36	55	19.67	35.33	15.67	28.48
5	38	40	38	40	39	39	78	38.33	39.67	1.33	1.71
6	23	47	22	48	24	46	70	23.00	47.00	24.00	34.29
7	41	20	39	22	43	18	61	41.00	20.00	21.00	34.43
8	25	35	26	34	23	37	60	24.67	35.33	10.67	17.78
9	19	32	22	29	19	32	51	20.00	31.00	11.00	21.57
DT-Walk LLA											
S. No.	**R1_Left**	**R1_Right**	**R2_Left**	**R2_Right**	**R3_Left**	**R3_Right**	**Weight**	**Left_Mean**	**Right_Mean**	**Difference**	**SLLA (%)**
1	36.68	41.32	36.72	41.28	36.68	41.32	78	36.69	41.31	4.61	5.91
2	29.54	38.46	29.76	38.24	29.63	38.37	68	29.64	38.36	8.71	12.82
3	28.35	26.65	28.34	26.66	28.40	26.60	55	28.37	26.63	1.73	3.15
4	19.54	35.46	19.59	35.41	19.60	35.40	55	19.58	35.42	15.85	28.81
5	38.36	39.64	38.38	39.62	38.36	39.64	78	38.37	39.63	1.26	1.62
6	22.70	47.30	22.89	47.11	22.92	47.08	70	22.84	47.16	24.33	34.75
7	40.96	20.04	41.14	19.86	41.07	19.93	61	41.06	19.94	21.12	34.62
8	24.74	35.26	24.76	35.24	24.61	35.39	60	24.71	35.29	10.59	17.64
9	19.97	31.03	19.98	31.02	20.02	30.98	51	19.99	31.01	11.02	21.61

Appendix XX DT-Walk LLA Intra Rater Reliability

DT-Walk LLA Intra Rater Reliability									
S. No.	**Weight**	**RA1_LL1**	**RA1_RL1**	**Load Difference**	**R1_SLLA**	**RA1_LL2**	**RA1_RL2**	**Load Difference**	**R2_SLLA**
1	78	36.68	41.32	4.64	5.95	36.72	41.28	4.56	5.85
2	68	29.54	38.46	8.92	13.11	29.76	38.24	8.48	12.47
3	55	28.35	26.65	1.70	3.09	28.34	26.66	1.68	3.06
4	55	19.54	35.46	15.93	28.96	19.59	35.41	15.82	28.76
5	78	38.36	39.64	1.27	1.63	38.38	39.62	1.24	1.59
6	70	22.70	47.30	24.60	35.14	22.89	47.11	24.22	34.60
7	61	40.96	20.04	20.93	34.31	41.14	19.86	21.29	34.90
8	60	24.74	35.26	10.51	17.52	24.76	35.24	10.47	17.46
9	51	19.97	31.03	11.06	21.69	19.98	31.02	11.03	21.63

Appendix XXI DT-walk PPA Intra Rater Reliability Reading

PPA Intra Rater Reliability Reading						
S. No.	**RA1_LL1**	**RA1_RL1**	**PPA1**	**RA1_LL2**	**RA1_RL2**	**PPA2**
1	9173.85	5720.73	23.18	3365.15	4843.89	18.01
2	5836.41	9087.63	21.79	6435.40	4134.85	21.76
3	6818.62	11005.09	23.49	6347.43	9988.33	22.29
4	4144.00	4762.00	6.94	4417.59	3887.21	6.39
5	7405.01	5844.73	11.78	6737.84	4750.25	17.30
6	6645.52	5245.27	11.78	8232.94	6518.08	11.63
7	7149.48	6213.48	7.00	4408.97	3766.40	7.86
8	4206.00	5924.00	16.96	4487.63	5924.85	13.80
9	5822.00	3750.00	21.65	5655.00	3805.00	19.56

Appendix XXII DT-Walk LLA Inter Rater Reliability

Rater 1											
S. No.	**RA1_LL 1**	**RA1_RL 1**	**RA1_LL 2**	**RA1_RL 2**	**RA1_LL 3**	**RA1_RL 3**	**Left_Mea n**	**Right_Mea n**	**Load Difference**	**Weigh t**	**SLLA (%)**
1	36.68	41.32	36.72	41.28	36.68	41.32	36.69	41.31	4.61	78	5.91
2	29.54	38.46	29.76	38.24	29.63	38.37	29.64	38.36	8.71	68	12.82
3	28.35	26.65	28.34	26.66	28.40	26.60	28.37	26.63	1.73	55	3.15
4	19.54	35.46	19.59	35.41	19.60	35.40	19.58	35.42	15.85	55	28.81
5	38.36	39.64	38.38	39.62	38.36	39.64	38.37	39.63	1.26	78	1.62
6	22.70	47.30	22.89	47.11	22.92	47.08	22.84	47.16	24.33	70	34.75
7	40.96	20.04	41.14	19.86	41.07	19.93	41.06	19.94	21.12	61	34.62
8	24.74	35.26	24.76	35.24	24.61	35.39	24.71	35.29	10.59	60	17.64
9	19.97	31.03	19.98	31.02	20.02	30.98	19.99	31.01	11.02	51	21.61

Rater 2											
S. No.	**RA2_LL 1**	**RA2_RL 1**	**RA2_LL 2**	**RA2_RL 2**	**RA2_LL 3**	**RA2_RL 3**	**Left_Mea n**	**Right_Mea n**	**Load Difference**	**Weigh t**	**SLLA (%)**
1	36.68	41.32	36.67	41.33	36.68	41.32	36.68	41.32	4.65	78	5.96
2	29.77	38.23	29.67	38.33	29.59	38.41	29.68	38.32	8.65	68	12.71
3	28.34	26.66	28.34	26.66	28.36	26.64	28.35	26.65	1.70	55	3.09
4	19.47	35.53	19.51	35.49	19.48	35.52	19.49	35.51	16.03	55	29.14
5	38.35	39.65	38.37	39.63	38.30	39.70	38.34	39.66	1.32	78	1.70
6	23.04	46.96	22.77	47.23	22.96	47.04	22.92	47.08	24.15	70	34.50
7	41.11	19.89	40.99	20.01	40.96	20.04	41.02	19.98	21.04	61	34.49
8	24.72	35.28	24.69	35.31	24.78	35.22	24.73	35.27	10.54	60	17.56
9	19.90	31.10	19.98	31.02	19.85	31.15	19.91	31.09	11.18	51	21.91

Appendix XXIII DT-walk PPA Inter Rater Reliability

PPA Inter-rater

Rater 1										
S. No.	**RA1_LL1**	**RA1_RL1**	**PPA1**	**RA1_LL2**	**RA1_RL2**	**PPA2**	**RA1_LL3**	**RA1_RL3**	**PPA3**	**Mean PPA (%)**
1	9173.85	5720.73	23.18	3365.15	4843.89	18.01	6792.08	5218.99	13.10	18.10
2	5836.41	9087.63	21.79	6435.40	4134.85	21.76	6755.88	10713.95	22.66	22.07
3	6818.62	11005.09	23.49	5408.93	9714.03	28.47	6347.43	9988.33	22.29	24.75
4	4144.00	4762.00	6.94	4417.59	3887.21	6.39	3425.61	3865.55	6.03	6.45
5	7405.01	5844.73	11.78	6737.84	4750.25	17.30	8845.63	5382.64	24.34	17.81
6	6645.52	5245.27	11.78	8232.94	6518.08	11.63	6095.45	4683.71	13.10	12.17
7	3173.96	3788.17	8.82	7149.48	6213.48	7.00	4408.97	3766.40	7.86	7.90
8	4206.00	5924.00	16.96	4487.63	5924.85	13.80	2349.69	3838.03	24.05	18.27
9	5822.00	3750.00	21.65	5655.00	3805.00	19.56	5768.00	4038.00	17.64	19.61

Rater 2										
S. No.	**RA1_LL1**	**RA1_RL1**	**PPA1**	**RA1_LL2**	**RA1_RL2**	**PPA2**	**RA1_LL3**	**RA1_RL3**	**PPA3**	**Mean PPA (%)**
1	9361.65	6491.55	18.10	9114.67	5332.59	26.18	8826.99	6762.83	13.24	19.17
2	4126.78	5986.62	18.39	6977.77	10360.16	19.51	7855.46	11910.37	20.51	19.47
3	6424.81	9754.28	20.58	6126.30	10046.92	24.24	5452.78	9329.53	26.23	23.68
4	3780.26	4509.20	8.79	5195.24	5647.04	4.17	3917.82	4535.83	7.31	6.76
5	9528.91	13041.35	15.56	12432.07	18832.56	20.47	6558.84	9244.22	16.99	17.68
6	6807.38	5168.93	13.68	8232.94	6518.08	11.63	7275.14	6121.21	8.61	11.31
7	2874.80	3333.75	7.39	5712.96	4818.28	8.50	2538.54	3124.34	10.34	8.74
8	6031.49	4433.28	15.27	4368.55	5896.42	14.88	4471.21	7123.33	22.87	17.68
9	6124.00	3880.52	22.42	6797.99	4487.38	20.47	5515.67	3550.88	21.67	21.52

Appendix XXIV DT-Walk validity testing against WinTrack for Plantar Pressure Asymmetry

WinTrack PPA										
S. No.	**RA1_LL1**	**RA1_RL1**	**PPA1**	**RA1_LL2**	**RA1_RL2**	**PPA2**	**RA1_LL3**	**RA1_RL3**	**PPA3**	**Mean PPA (%)**
1	12451.00	8056.00	21.43	5879.00	3919.00	20.00	8830.00	7099.00	10.87	17.43
2	6631.00	4057.00	24.08	5255.00	7403.00	16.97	5919.00	3551.00	25.01	22.02
3	5078.00	8301.00	24.09	7561.00	4418.00	26.24	3733.00	5070.00	15.19	21.84
4	5046.00	6426.00	12.03	6030.00	5534.00	4.29	5873.00	6373.00	4.08	6.80
5	10632.00	5420.00	32.47	6889.00	5228.00	13.71	6489.00	3843.00	25.61	23.93
6	5476.00	5090.00	3.65	6117.00	4198.00	18.60	6666.00	4810.00	16.17	12.81
7	6032.00	5015.00	9.21	5111.00	4690.00	4.30	4891.00	3951.00	10.63	8.04
8	2084.00	4585.00	37.50	5730.00	3752.00	20.86	8208.00	5633.00	18.60	25.66
9	7401.00	3686.00	33.51	2407.00	4204.00	27.18	5916.00	7776.00	13.58	24.76
DT-Walk PPA										
S. No.	**RA1_LL1**	**RA1_RL1**	**PPA1**	**RA1_LL2**	**RA1_RL2**	**PPA2**	**RA1_LL3**	**RA1_RL3**	**PPA3**	**Mean PPA (%)**
1	9173.85	5720.73	23.18	3365.15	4843.89	18.01	6792.08	5218.99	13.10	18.10
2	5836.41	9087.63	21.79	6435.40	4134.85	21.76	6755.88	10713.95	22.66	22.07
3	6818.62	11005.09	23.49	5408.93	9714.03	28.47	6347.43	9988.33	22.29	24.75
4	4144.00	4762.00	6.94	4417.59	3887.21	6.39	3425.61	3865.55	6.03	6.45
5	7405.01	5844.73	11.78	6737.84	4750.25	17.30	8845.63	5382.64	24.34	17.81
6	6645.52	5245.27	11.78	8232.94	6518.08	11.63	6095.45	4683.71	13.10	12.17
7	3173.96	3788.17	8.82	7149.48	6213.48	7.00	4408.97	3766.40	7.86	7.90
8	4206.00	5924.00	16.96	4487.63	5924.85	13.80	2349.69	3838.03	24.05	18.27
9	5822.00	3750.00	21.65	5655.00	3805.00	19.56	5768.00	4038.00	17.64	19.61

List of Publication

Manuscripts

1. Understanding the need, content, structure, and feasibility of wearable device in knee osteoarthritis: a qualitative study of clinician's perspective using focus group discussion
   Journal: Indian Journal of Natural Sciences
   Indexing: Web of Science
   Status: Published- February 2023 Issue
2. Validity and reliability of dt-walk for assessment and biofeedback of asymmetries in limb loading and plantar pressure in knee osteoarthritis.
   Targeted Journal: International Journal of Intelligent Systems and Applications in Engineering
   Indexing: Scopus
   Status: Published April 2023
3. Lower limb biomechanical alterations in knee osteoarthritis: a systematic review
   Journal: Journal of Orthopedics, Trauma, and Rehabilitation
   Indexing: Scopus
   Status: Under Review
4. Prevalence of asymmetry in limb loading and spatiotemporal gait parameters among individuals with unilateral knee pain: A cross-sectional study
   Journal: Journal of Bodywork and Movement Therapies
   Indexing: Scopus
   Status: Under Review
5. Prevalence of asymmetry in limb loading and spatiotemporal gait parameters in bilateral knee osteoarthritis: A cross-sectional study
   Journal: Journal of Bodywork and Movement Therapies
   Indexing: Scopus
   Status: Under Review

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Ref: IJONS/PUB-76/VOL-13/FEB/294/2023 **DT: 26.12.2022**

To

Amber Anand[1], Sumit Raghav[1], Senthil N.S Kumar[2] and Suresh Mani[3]
[1]Ph.D. Scholar, Department of Physiotherapy, Lovely Professional University, Phagwara, Punjab, India
[2]Chief Executive Officer (Rehabilitation), Association of People with Disability, Bangaluru, Karnataka, India
[3]Associate Professor, Department of Physiotherapy, Lovely Professional University, Phagwara, Punjab, India
***Corresponding author**

Dear Sir/Madam

Sub: Acceptance Letter to Author(s)*

Congratulation!!! According to my record, your manuscript entitled "**Understanding The Need, Content, Structure and Feasibility of Wearable Device in Knee Osteoarthritis: A Qualitative Study of Clinician's Perspective using Focus Group Discussion**" has been accepted for publication in the Indian Journal of Natural Sciences **(IJONS) VOL- 13 / ISSUE 76 / FEBRUARY 2023**. Furthermore, you are responsible for any error in the published paper due to your oversight. Thank you very much for submitting your article to the Indian Journal of Natural Sciences (IJONS).

Naturally Yours

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RESEARCH ARTICLE

Understanding The Need, Content, Structure and Feasibility of Wearable Device in Knee Osteoarthritis: A Qualitative Study of Clinician's Perspective using Focus Group Discussion

Amber Anand[1], Sumit Raghav[1], Senthil N.S Kumar[2] and Suresh Mani[3*]

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Received: 11 Oct 2022 Revised: 20 Nov 2022 Accepted: 26 Dec 2022

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ABSTRACT

Knee is one of the most commonly affected joints in osteoarthritis of the lower limb. It is evident that several potential biomechanical alterations may occur due to changes in joint structure leading to altered weight-bearing patterns and may contribute to further progression of the disease and vice versa. This study aimed to understand the clinician's perspective on the needs, content, structure, and feasibility of a wearable device for assessment, training, and monitoring of biomechanical deviations in knee osteoarthritis using a qualitative exploratory study design. Twenty-four physiotherapists having a minimum clinical experience of three years participated in one of the three focus group discussions. Participants who expressed their willingness to participate by filing the e-consent form were included in the discussion. Participants were in favor of using the wearable device for assessment, telemonitoring, feedback, activity tracking, and adherence to exercise. The appearance, comfort, and ease to use, cost of the device, and easy-to-understand user interface with local and cloud storage were the primary factors responsible for the acceptance of wearable technology among the participants. The device should assess and give real-time feedback to users for asymmetries in limb loading, plantar pressure, and spatiotemporal gait parameters. The study recommends for development of wearable technology to support assessment and training not only for osteoarthritis but also for other conditions where gait and balance are affected. It is essential to take into account clinicians' views to identify the clinical issues, features, functionality, and applicability for developing such devices.

Keywords: wearable, knee osteoarthritis, focus group discussion, design, structure.

52194

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Paper ID:
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Acceptance Letter

Author's Name:

*Amber Anand, Senthil NS Kumar, Rajesh Singh, Suresh Mani**

Paper Title:

Validity and reliability of DT-walk for assessment and biofeedback of asymmetries in limb loading and plantar pressure in knee osteoarthritis.

Dear Author (s),

We are pleased to notify you that the paper you referenced above has been reviewed and acceptedfor publication in the International Journal of Intelligent Systems and Applications in Engineering (ISSN: 2147-6799)

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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

Amber Anand[1], Senthil NS Kumar[2], Rajesh Singh[3], Suresh Mani[4]*

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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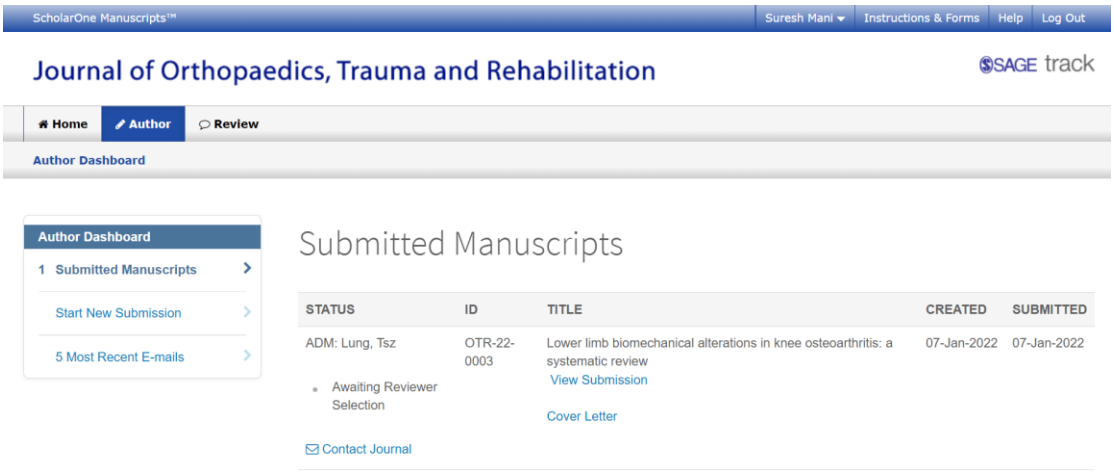

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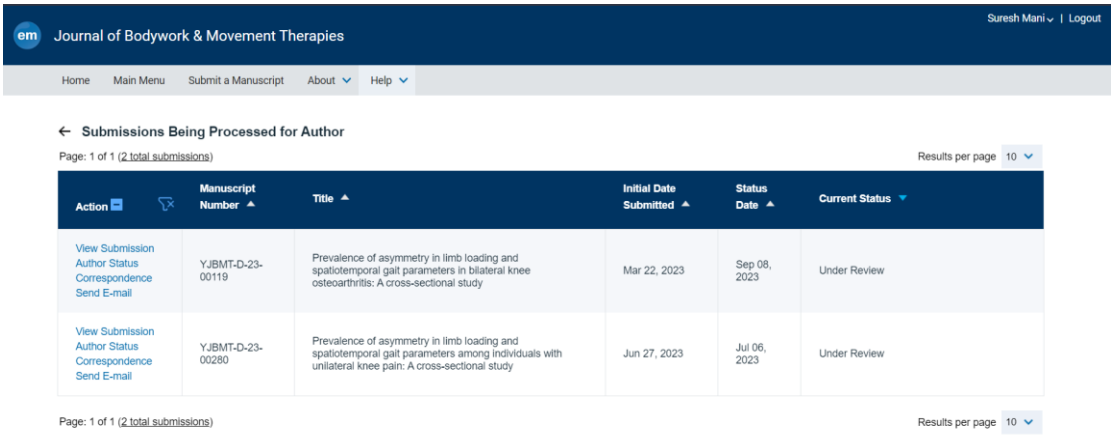

List of Conference Presentations

Conference Presentation 1

Certificates No. 173672

Certificate of Participation

This is to certify that Prof./Dr./Mr./Ms. Amber Anand

has **Presented E-poster/Oral presentation on** Is there any need to evaluate limb load asymmetry in clinical practice for patients with knee Osteoarthritis.

presentation in International Conference of Pharmacy (ICP-2019) on the theme of " Pharmacy: Realigning the focus on health" held on 13 -14th September 2019 organized by School of Pharmaceutical Sciences, Lovely Professional University, Punjab in a collabration with Indian Pharmacy Graduates' Assocaition (IPGA) Phagwara chapter.

Date of Issue: 14-09-2019
Place of Issue: Phagwara (India)

Prepared by
(Administrative Officer-Records)

Dr. Bimlesh Kumar
Organizing Secretary

Monica Gulati

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Conference Presentation 2

Serial No. 31CP2022PRPP8-64

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This is to certify that Prof./Dr./Mr./Ms. Amber Anand has successfully participated as Delegate & Presented Poster/ ~~Oral Presentation~~ on Prevalence of asymmetries in limb loading, plantar pressure, & spatiotemporal gait parameters among individuals with knee osteoarthritis: A cross-sectional study in the 3rd International Conference of Pharmacy (ICP-2022) on the Theme of "Practice, Promotion & Publication of Innovation : A Way of Transforming Health" held on 09th & 10th November 2022 organized by School of Pharmaceutical Sciences in a collaboration with Indian Pharmaceutical Association (IPA) at Lovely Professional University, Punjab.

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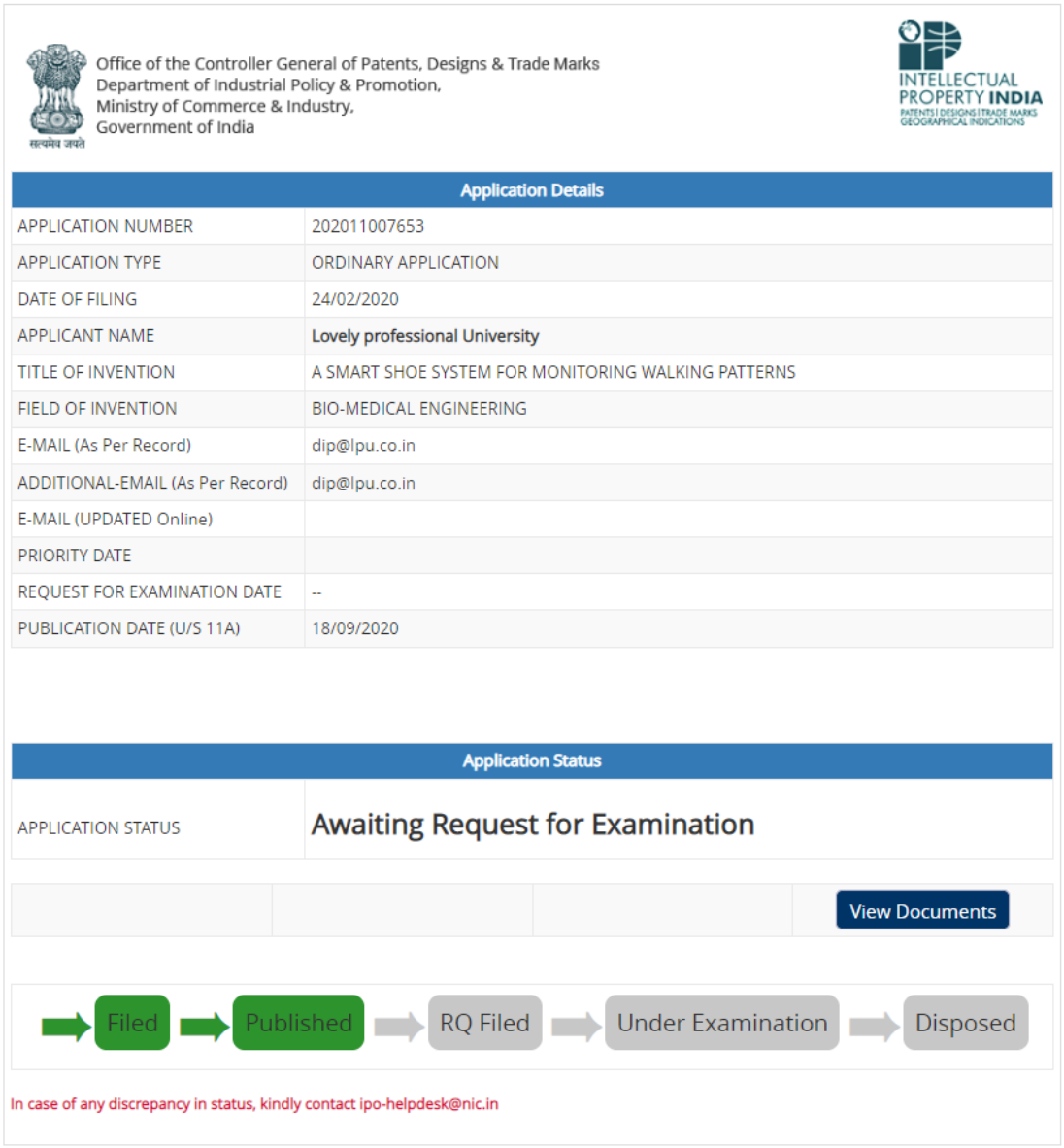
List of IPR Generated- Patent

1. A smart shoe system for monitoring walking patterns.

Application No. *202011007653*

Publication Date: *24th February 2020*

Status: *RQ Filing awaited*



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Application Details	
APPLICATION NUMBER	202011007653
APPLICATION TYPE	ORDINARY APPLICATION
DATE OF FILING	24/02/2020
APPLICANT NAME	Lovely professional University
TITLE OF INVENTION	A SMART SHOE SYSTEM FOR MONITORING WALKING PATTERNS
FIELD OF INVENTION	BIO-MEDICAL ENGINEERING
E-MAIL (As Per Record)	dip@lpu.co.in
ADDITIONAL-EMAIL (As Per Record)	dip@lpu.co.in
E-MAIL (UPDATED Online)	
PRIORITY DATE	
REQUEST FOR EXAMINATION DATE	--
PUBLICATION DATE (U/S 11A)	18/09/2020

Application Status	
APPLICATION STATUS	Awaiting Request for Examination

View Documents

Filed → Published → RQ Filed → Under Examination → Disposed

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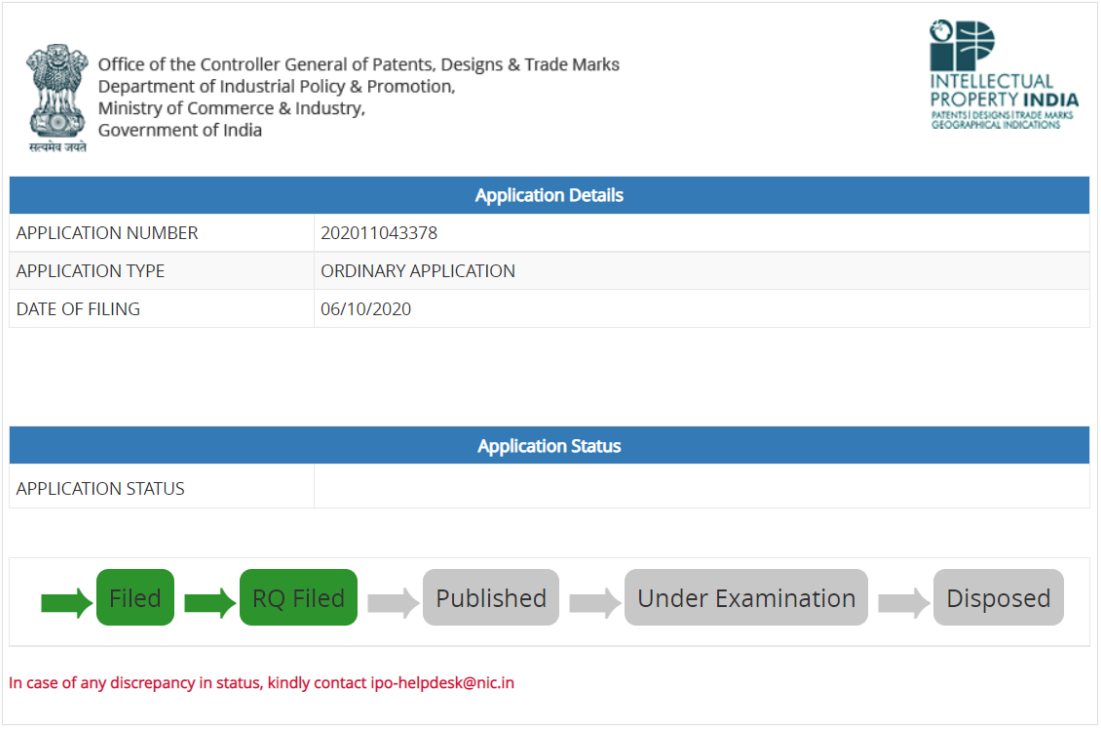
2. **Wearable real-time analyzer and trainer for static and dynamic limb load asymmetry.**

Application No. *202011043378*

Publication Date: *Not applicable*

(Direct application with full specification for Grant of Patent)

Status: *RQ Filed*



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Application Details	
APPLICATION NUMBER	202011043378
APPLICATION TYPE	ORDINARY APPLICATION
DATE OF FILING	06/10/2020

Application Status	
APPLICATION STATUS	

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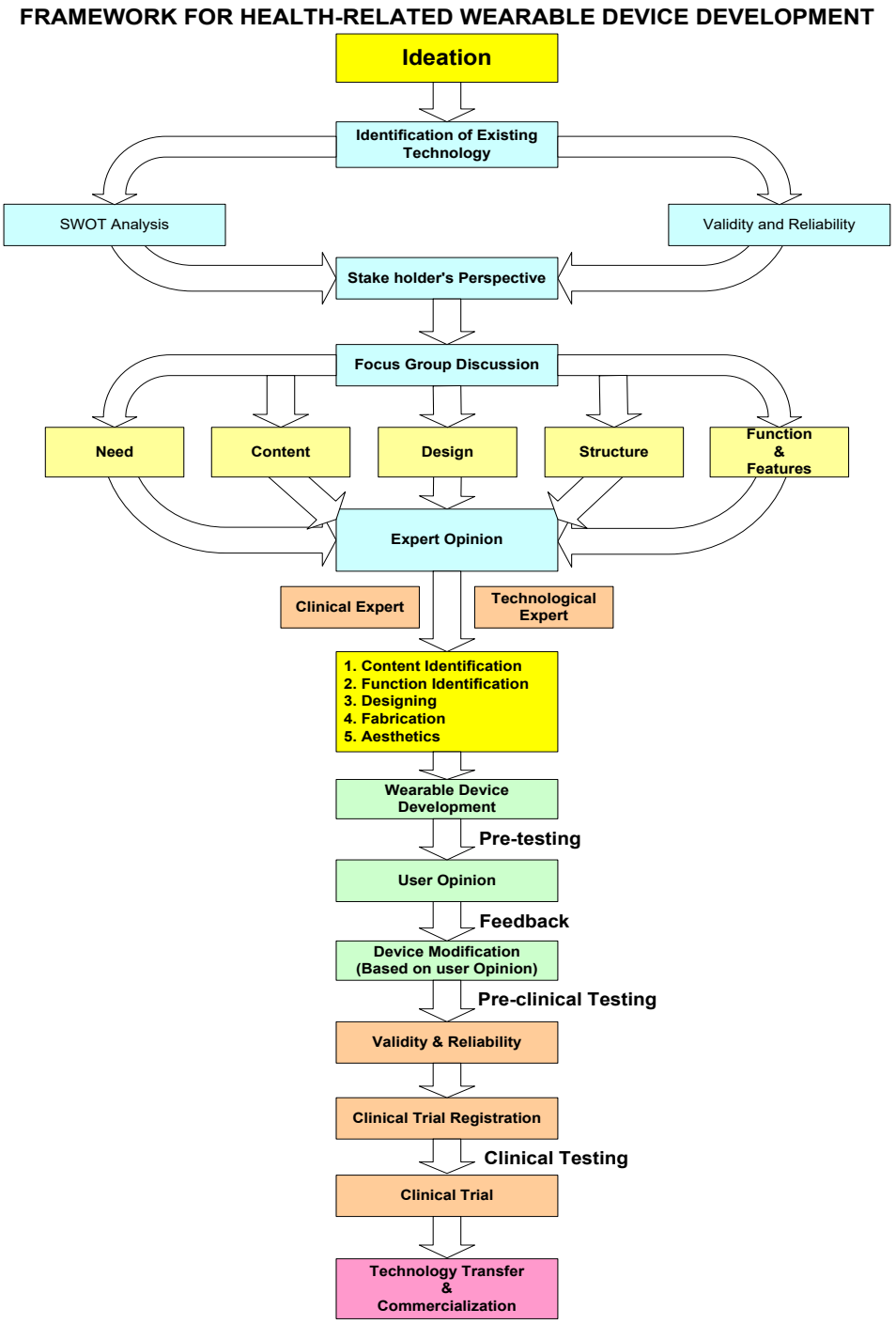
1. Title: Framework for health-related wearable device development

   Type: Graphical Abstract

   Registration No.: L-123566/2023

   Status: Grant awaited



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1.	पंजीकरण संख्या/Registration Number	:	**L-123566/2023**
2.	आवेदक का नाम, पता तथा राष्ट्रीयता Name, address and nationality of the applicant	:	LOVELY PROFESSIONAL UNIVERSITY , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN
3.	कृति के प्रतिलिप्यधिकार में आवेदक के हित की प्रकृति Nature of the applicant's interest in the copyright of the work	:	OWNER
4.	कृति का वर्ग और वर्णन Class and description of the work	:	LITERARY/ DRAMATIC WORK THE PURPOSE OF THE PRESENT WORK IS TO DEVELOP THE FRAMEWORK FOR HEALTH RELATED WEARABLE DEVICE.
5.	कृति का शीर्षक Title of the work	:	FRAMEWORK FOR HEALTH-RELATED WEARABLE DEVICE DEVELOPMENT.
6.	कृति की भाषा Language of the work	:	ENGLISH
7.	रचयिता का नाम, पता और राष्ट्रीयता तथा यदि रचयिता की मृत्यु हो गई है, तो मृत्यु की तिथि Name, address and nationality of the author and if the author is deceased, date of his decease	:	AMBER ANAND , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB--144411 INDIAN DR. SURESH MANI , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB--144411 INDIAN DR. SENTHIL N S KUMAR , ASSOCIATION OF PEOPLE WITH DISABILITY, BENGALURU, KA RNATAKA-560084 INDIAN
8.	कृति प्रकाशित है या अप्रकाशित Whether the work is published or unpublished	:	UNPUBLISHED
9.	प्रथम प्रकाशन का वर्ष और देश तथा प्रकाशक का नाम, पता और राष्ट्रीयता Year and country of first publication and name, address and nationality of the publisher	:	N.A.
10.	बाद के प्रकाशनों के वर्ष और देश, यदि कोई हों, और प्रकाशकों के नाम, पते और राष्ट्रीयताएँ Years and countries of subsequent publications, if any, and names, addresses and nationalities of the publishers	:	N.A.
11.	कृति में प्रतिलिप्यधिकार सहित विभिन्न अधिकारों के स्वामियों के नाम, पते और राष्ट्रीयताएं और समनुदेशन और अनुज्ञप्तियों के विवरण के साथ प्रत्येक के अधिकार का विस्तार, यदि कोई हो। Names, addresses and nationalities of the owners of various rights comprising the copyright in the work and the extent of rights held by each, together with particulars of assignments and licences, if any	:	LOVELY PROFESSIONAL UNIVERSITY , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN
12.	अन्य व्यक्तियों के नाम, पते और राष्ट्रीयताएं, यदि कोई हों, जो प्रतिलिप्यधिकार वाले अधिकारों को समनुदेशित करने या अनुज्ञप्ति देने के लिए अधिकृत हों Names, addresses and nationalities of other persons, if any, authorised to assign or licence of rights comprising the copyright	:	N.A.
13.	यदि कृति एक 'कलात्मक कृति' है, तो कृति पर अधिकार रखने वाले व्यक्ति का नाम, पता और राष्ट्रीयता सहित मूल कृति का स्थान। (एक वास्तुशिल्प कृति के मामले में कृति पूरी होने का वर्ष भी दिखाया जाना चाहिए) If the work is an 'Artistic work', the location of the original work, including name, address and nationality of the person in possession of the work. (In the case of an architectural work, the year of completion of the work should also be shown).	:	N.A.
14.	यदि कृति एक 'कलात्मक कृति' है जो किसी भी माल या सेवाओं के संबंध में उपयोग की जाती है या उपयोग किए जाने में सक्षम है, तो आवेदन में प्रतिलिप्यधिकार अधिनियम, 1957 की धारा 45 की उप–धारा (i) के प्रावधान के अनुसार व्यापार चिह्न रजिस्ट्रार से प्रमाणन शामिल होना चाहिए। If the work is an 'Artistic work' which is used or capable of being used in relation to any goods or services, the application should include a certification from the Registrar of Trade Marks in terms of the provision to Sub-Section (i) of Section 45 of the Copyright Act, 1957.	:	N.A.
15.	यदि कृति एक 'कलात्मक कृति' है, तो क्या यह डिजाइन अधिनियम 2000 के अंतर्गत पंजीकृत है? यदि हां, तो विवरण दें। If the work is an 'Artistic work', whether it is registered under the Designs Act 2000, if yes give details.	:	N.A.
16.	यदि कृति एक 'कलात्मक कृति' है, जो डिजाइन अधिनियम 2000 के तहत एक डिजाइन के रूप में पंजीकृत होने में सक्षम है, तो क्या यह औद्योगिक प्रक्रिया के माध्यम से किसी वस्तु पर प्रयुक्त की गई है और यदि हाँ, तो इसे कितनी बार पुनरुत्पादित किया गया है? If the work is an 'Artistic work', capable of being registered as a design under the Designs Act 2000,whether it has been applied article though an industrial process and ,if yes ,the number of it is reproduced.	:	N.A.
17.	टिप्पणी, यदि कोई हो/Remarks, if any	:	THE WORK IS ORIGINAL AS DONE BY THE FACULTY AND STAFF OF LOVELY PROFESSIONAL UNIVERSITY.

डायरी संख्या/Diary Number: 630/2023-CO/L

आवेदन की तिथि/Date of Application: 09/01/2023

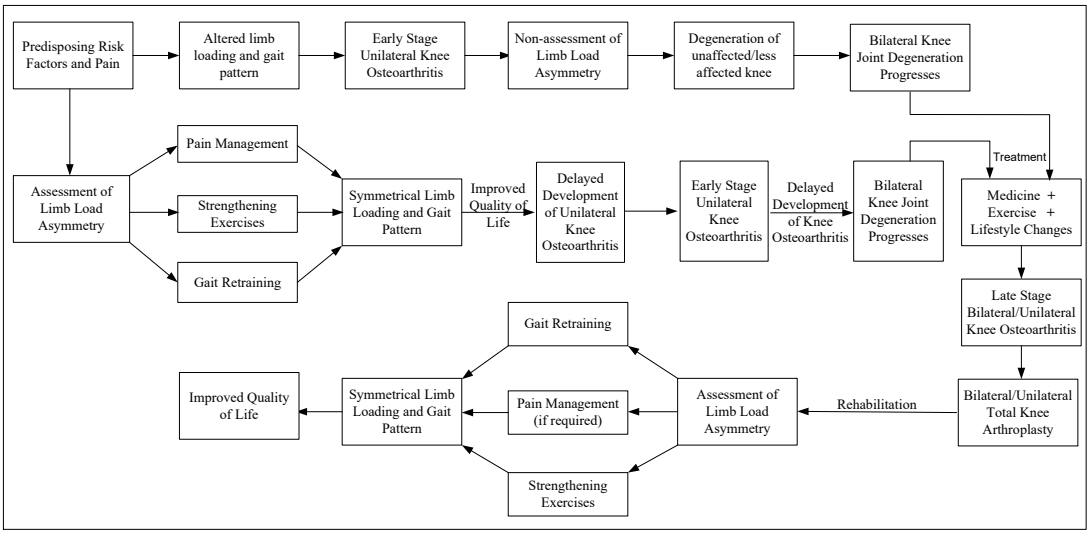
Registrar of Copyrights

2. Title: A conceptual framework for assessment, prevention, and management of knee osteoarthritis based on limb loading.

   Type: Graphical Abstract

   Registration Number: L-124575/2023

   Status: Granted



INTELLECTUAL PROPERTY INDIA

सत्यमेव जयते

Extracts from the Register of Copyrights

प्रतिलिप्यधिकार कार्यालय, भारत सरकार | Copyright Office, Government Of India

दिनांक/Dated:09/06/2023

1.	पंजीकरण संख्या/Registration Number	:	**L-124575/2023**
2.	आवेदक का नाम, पता तथा राष्ट्रीयता Name, address and nationality of the applicant	:	LOVELY PROFESSIONAL UNIVERSITY , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN
3.	कृति के प्रतिलिप्यधिकार में आवेदक के हित की प्रकृति Nature of the applicant's interest in the copyright of the work	:	OWNER
4.	कृति का वर्ग और वर्णन Class and description of the work	:	LITERARY: DRAMATIC WORK THE PURPOSE OF STUDY TO DEVELOP A CONCEPTUAL FRAMEWORK FOR ASSESSMENT, PREVENTION, AND MANAGEMENT OF KNEE OSTEOARTHRITIS BASED ON LIMB LOADING.
5.	कृति का शीर्षक Title of the work	:	A CONCEPTUAL FRAMEWORK FOR ASSESSMENT, PREVENTION, AND OF KNEE OSTEOARTHRITIS BASED ON LIMB LOADING.
6.	कृति की भाषा Language of the work	:	ENGLISH
7.	रचयिता का नाम, पता और राष्ट्रीयता तथा यदि रचयिता की मृत्यु हो गई है, तो मृत्यु की तिथि Name, address and nationality of the author and if the author is deceased, date of his decease	:	AMBER ANAND , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN DR. SURESH MANI , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN DR. SENTHIL NS KUMAR , ASSOCIATION OF PEOPLE WITH DISABILITY, BENGALURU, KARNATAKA-560084 INDIAN
8.	कृति प्रकाशित है या अप्रकाशित Whether the work is published or unpublished	:	UNPUBLISHED
9.	प्रथम प्रकाशन का वर्ष और देश तथा प्रकाशक का नाम, पता और राष्ट्रीयता Year and country of first publication and name, address and nationality of the publisher	:	N.A.
10.	बाद के प्रकाशनों के वर्ष और देश, यदि कोई हो, और प्रकाशकों के नाम, पते और राष्ट्रीयताएँ Years and countries of subsequent publications, if any, and names, addresses and nationalities of the publishers	:	N.A.
11.	कृति में प्रतिलिप्यधिकार सहित विभिन्न अधिकारों के स्वामियों के नाम, पते और राष्ट्रीयताएं और समनुदेशन और अनुज्ञप्तियों के विवरण के साथ प्रत्येक के अधिकार का विस्तार, यदि कोई हो। Names, addresses and nationalities of the owners of various rights comprising the copyright in the work and the extent of rights held by each, together with particulars of assignments and licences, if any	:	LOVELY PROFESSIONAL UNIVERSITY , LOVELY PROFESSIONAL UNIVERSITY, JALANDHAR, DELHI-GT ROAD, PHAGWARA PUNJAB-144411 INDIAN
12.	अन्य व्यक्तियों के नाम, पते और राष्ट्रीयताएं, यदि कोई हों, जो प्रतिलिप्यधिकार वाले अधिकारों को समनुदेशित करने या अनुज्ञप्ति देने के लिए अधिकृत हों Names, addresses and nationalities of other persons, if any, authorised to assign or licence of rights comprising the copyright	:	N.A.
13.	यदि कृति एक 'कलात्मक कृति' है, तो कृति पर अधिकार रखने वाले व्यक्ति का नाम, पता और राष्ट्रीयता सहित मूल कृति का स्थान। (एक वास्तुशिल्प कृति के मामले में कृति पूरी होने का वर्ष भी दिखाया जाना चाहिए) If the work is an 'Artistic work', the location of the original work, including name, address and nationality of the person in possession of the work. (In the case of an architectural work, the year of completion of the work should also be shown).	:	N.A.
14.	यदि कृति एक 'कलात्मक कृति' है जो किसी भी माल या सेवाओं के संबंध में उपयोग की जाती है या उपयोग किए जाने में सक्षम है, तो आवेदन में प्रतिलिप्यधिकार अधिनियम, 1957 की धारा 45 की उप-धारा (i) के प्रावधान के अनुसार व्यापार चिह्न रजिस्ट्रार से प्रमाणन शामिल होना चाहिए। If the work is an 'Artistic work' which is used or capable of being used in relation to any goods or services, the application should include a certification from the Registrar of Trade Marks in terms of the provision to Sub-Section (i) of Section 45 of the Copyright Act, 1957.	:	N.A.
15.	यदि कृति एक 'कलात्मक कृति' है, तो क्या यह डिजाइन अधिनियम 2000 के अंतर्गत पंजीकृत है? यदि हां, तो विवरण दें। If the work is an 'Artistic work', whether it is registered under the Designs Act 2000, if yes give details.	:	N.A.
16.	यदि कृति एक 'कलात्मक कृति' है, जो डिजाइन अधिनियम 2000 के तहत एक डिजाइन के रूप में पंजीकृत होने में सक्षम है, तो क्या यह औद्योगिक प्रक्रिया के माध्यम से किसी वस्तु पर प्रयुक्त की गई है और यदि हाँ, तो [illegible] कितनी बार पुनरुत्पादित किया गया है? If the work is an 'Artistic work', capable of being registered as a design under the Designs Act 2000,whether it has been applied to any article though an industrial process and ,if yes ,the number of times it is reproduced.	:	N.A.
17.	टिप्पणी, यदि कोई हो/Remarks, if any	:	THE WORK IS ORIGINAL AS DONE BY FACULTY AND STAFF OF LOVELY PROFESSIONAL UNIVERSITY

Registrar of Copyrights

डायरी संख्या/Diary Number: 5413/2023-CO/L

आवेदन की तिथि/Date of Application: 02/03/2023

Budget and Funding

Budget

S. No.	Item	Cost (in INR)
1.	Sensors and Raw Material	30,000
2.	Customized PCB Designing and Printing	35,000
3.	3D Outer Aesthetic Case, Private Communication Network	47,000
4.	Software Development	57,280
5.	Stationery and Printing	5,000
6.	Miscellaneous	10,000
	Total	**1,84,280**

Funding

The research project was majorly self-funded by the research scholar. However, the university provided funding of Rs. 57,280/- for the software development of the prototype device vide a seed fund with reference number ***LPU/DRD/SEED/SAC/060622/22315***.