Development of a Fall Risk Asessment Tool Using Gait Analysis

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DEVELOPMENT OF A FALL RISK ASSESSMENT TOOL USING GAIT ANALYSIS

by

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ABSTRACT

DEVELOPMENT OF A FALL RISK ASSESSMENT TOOL
USING GAIT ANALYSIS

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In the United States, falls are one of the leading causes of fatal and non-fatal injuries for people of all ages. Current clinical methods to assess fall risk are impractical, and often do not use individuals' actual performance. With current technological advances, and the Internet of Things (IoT), the tools are available to create a digital system that can take into account an individual's actual performance in making a fall risk assessment. A digital insole based sensory computing system can collect and analyze human gait patterns to develop a fall risk assessment platform with great accuracy.

The presented research considers current clinical methods and describes a computerized self-service platform that successfully addresses different gait variables and metrics critical to accurate fall risk assessment. The system incorporates a shoe insole with pressure sensors, and an accelerometer. Collected foot data are transferred to an analytics visualization platform. A wide range of gait pattern recognition metrics, and gait data analyses features are then displayed on the platform enabling specific fall risk assessment.

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CHAPTER 1

1. INTRODUCTION

Falls are a major cause of fatal and non-fatal injuries among adults of all ages. Fall injuries cause immobility, disability and sometimes death. According to data from the US Centers for Disease Control and Prevention (CDC), an older adult is treated for a fall in an emergency room every 11 seconds, and an older adult dies from a fall every 19 minutes [1]. In the United States, more than 2.8 million injuries from falls are treated annually, and these are associated with 27,000 deaths [1]. In 2015, the total cost of fall injuries was $50 billion USD, which was covered 75% by Medicare and Medicaid tax-payer contributions [1]. Wisconsin reportedly has the highest rate of death from falls among the elderly in the nation [2]. With a total of 1,365 residents 65 and above who died from falls in 2016, Wisconsin's death rate from falls was twice the national average [2]. Since fall are not preventable but can be predictable, detection of increased fall risk can lead to effective fall prevention and reduce significantly morbidity, mortality, and healthcare costs.

1.1 FALL RISK ASSESSMENT

The consequences of a fall are manifold. There are physical, mental, social and economic consequences from falls based on severity. Falls cause injuries to the head and brain, bones, arms, ankles, and hips. People who fall often experience traumatic shocks and fear from falling again. As a result, they reduce daily activities to prevent falls, which in turn makes them weaker and depressed. Falls can cause social embarrassment, isolation and reductions in social activities due to the fears of falling.

Study of the epidemiology of falls is in vogue. Much work has been done to understand the cause of falls after they have taken place. There are however fewer initiatives focusing on predicting falls, and on warning systems for potential falls in order to prevent them. This is possibly because there are so many interrelated variables associated with falls that are difficult to predict. There are factors, conditions, activities and various other physical traits that contribute to falls. With the benefits of pervasive computing and ubiquitous system architectures, it is possible to incorporate multiple risk factors into a digital system that can accurately assess risks for a fall.

1.2 GAIT ANALYSIS

Among many ways to diagnose the physical condition of a person with a digital system to make accurate predictions using various computational capabilities, gait analytics offers particularly useful information on human locomotion with direct relationships to falls [15]. Studying gait attributes can indicate a person's physical foot strength, which is controlled by the nervous system. Abnormal foot conditions may indicate lower body weaknesses which pose difficulties in walking and, in turn, balance. Hence many researchers focus on gait attributes and pattern recognition in conjunction with machine learning and other computational methodologies to investigate fall detection and fall prediction. Gait analysis is the foundation for critical physical variables to be incorporated into a digital solution that can assess fall prediction most accurately.

1.3 ANALYTICAL PLATFORM

While there are many computer and mobile applications developed to incorporate sensor data from various devices, there is no unified platform that can incorporate and connect all sensory data in one place. This is the objective of the current research work:

to establish a common platform for fall risk assessment that can integrate data from multiple different sources. Gait analytics is the first and most crucial contribution to this platform. A user can visually observe the gait patterns and attributes all in one place to make a judgment about whether or not a studied individual has significant risk for falls based on actual performance.

This research work shows the design and implementation of a unified platform, to incorporate multiple sources of sensor-based data. An insole is used to collect gait data from walking, stepping, and standing. Raw data is collected to calculate supination and pronation times, balance, pressure points, pressure distribution, stride length and foot abnormalities. Using real time data, an individual's gait pattern can be observed to make a fall risk assessment with quantitative data.

1.4 OBJECTIVES

The primary objective of this research work is to offer a digital sensor based computerized analytical system alternative to current clinical practices of fall risk assessment which rely on questionnaires. In the next chapter, current clinical practices are discussed, along with their limitations. In the following chapter, a computerized fall risk assessment tool is presented using actual patient performance.

CHAPTER 2

2. BACKGROUND

According to the Centers for Disease Control and Prevention (CDC), “falls are the leading cause of injury and death in older Americans” [1]. Deaths by fall across ages have been increasing for the past decade (Figure 1).

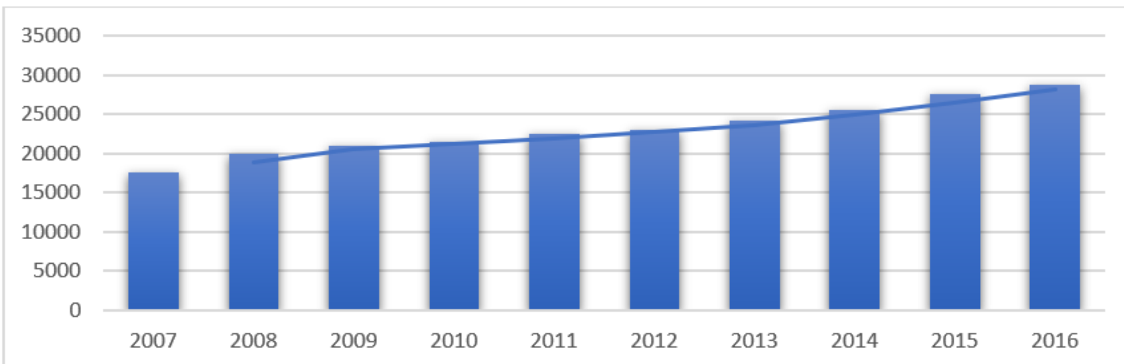


Fig [1]: Number of deaths by falls, USA 2007-2016 [1]

In response to the emerging statistics various fall prevention initiatives have been undertaken by health care institutes, and researchers. There are several clinical practice guidelines, and screening & assessment techniques. These are mostly based on historical data about an individual’s health, not on actual performance in real time [4] [13] [19].

2.1 FALL RISK FACTORS

A fall can be triggered by several factors that can be characterized in multiple categories. Some researchers categorize these into intrinsic and extrinsic factors, while others describe them in various interaction terms. Below is the combination of both categories-

Physical: Biological attributes, poor vision, gait and balance problems, muscle, orthostatic, postural hypotension, postural instability.

Behavioral: Fear of falling, medications, sleep deprivation, hygiene, lack of exercise, mental state.

Demographic: Age, gender, history of falls.

Environmental: Surface, wet floors, obstacles, climate.

Factors are not limited to those listed above, there are additional interrelated factors that may also need to be considered. A proper understanding of the factors is vital to definition of a solution that addresses them effectively.

Current clinical practices to assess an individual's fall risk mostly rely on fall history, medication review, physical examination, and functional and environmental assessments. Clinical assessments by healthcare providers, in conjunction with individual treatment for self-care fall assessment, have been shown to reduce falls by 24% [5]. A similar result was found by the US Preventive Services Task force, which emphasizes follow-up with clinical caregivers [6]. The American Geriatrics Society supplied a recommendation guide for physicians to screen older patients, which includes multicomponent/multifactorial intervention, medication assessment, exercise schedule, vision evaluation, foot and footwear assessment that establish the clinical assessment [7]. They recommend regular annual screening of adults 65 and above to perform fall risk assessment. A major clinical guideline is provided by the CDC, under the STEADI algorithm, which is discussed in the next section.

2.2 CLINICAL ASSESSMENT TOOLS

The most common clinical fall assessment tools currently used include the following-

i. Morse Fall Scale (MFS)

ii. St. Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY)

iii. Hendrich II Fall Risk Model

iv. John Hopkins Fall Risk Assessment Tool

v. Stopping Elderly Accidents, Deaths, and Injuries (STEADI) Algorithm

All five tools are heavily dependent on some form of questionnaire. A patient is verbally asked questions from the forms, and answers are recorded. Subsequent scores provide a risk assessment. Often patients do not need further follow-up since results from the tests are satisfactory. A common feature of the current clinical tools is to analyze the cause of past fall experiences, which then can be addressed by providing counselling or medication to avoid such circumstances in future. In addition to the common tools in an office-based timed assessment, Mayo Clinic providers perform the following tests under their guideline, which tests are more functional than the above [8]-

a. 5X STS – Five Times Sit to Stand – this test assesses physical strength

b. SLS – Single Leg Stance – this test assesses balance

c. TUG – time up and go – this test assess gait

The popular clinical fall risk assessment tools are demonstrated below with the actual models used for evaluation.

2.2.1 Morse Fall Scale

The Morse Fall Scale was developed in 1985, and assesses six key factors- history of falling, secondary diagnosis, ambulatory aid, IV/heparin lock, gait/transferring, and mental status. On a scale of 0-30, a person is evaluated based on these key factors to determine the potential risk of falling. It is a rapid and simple method. The scale is demonstrated below-

Item	**Scale**	**Scoring**
1. History of falling; immediate or within 3 months	No 0 Yes 25	________
2. Secondary diagnosis	No 0 Yes 15	________
3. Ambulatory aid Bed rest/nurse assist Crutches/cane/walker Furniture	 0 15 30	________
4. IV/Heparin Lock	No 0 Yes 20	________
5. Gait/Transferring Normal/bedrest/immobile Weak Impaired	 0 10 20	________
6. Mental status Oriented to own ability Forgets limitations	 0 15	________

Fig [2]: Morse Fall Scale [9]

2.2.2 St. Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY)

The STRATIFY scale was developed in 1997, and emphasizes behavioral attributes. The key factors in this tool are- recent history, agitation, visual impairment, toileting, and transfer and mobility. The responses are recorded in Yes/No answers which are converted to a score. At the end, a combined score of 0 = low, 1 = moderate, and 2 or above is considered high risk for fall. The tool is demonstrated below-

Questions
1) Did the patient present to hospital with a fall or has he or she fallen on the ward since admission (recent history of fall)? 2) Is the patient agitated? 3) Is the patient visually impaired to the extent that everyday function is affected? 4) Is the patient in need of especially frequent toileting 5) Does the patient have a combined transfer and mobility score of 3 or 4 (calculate below)- Transfer score: Choose one of the following options which best describes the patients level of capability when transferring form a bed to a chair: 0 = unable 1 = needs major help 2 = needs minor help 3 = independent Mobility score: Choose one of the following options which best describes the patient's level of mobility: 0 = immobile 1 = independent with the aid of a wheelchair 2 = uses walking aid or help of one person 3 = independent Combined Score (transfer + mobility): __________ Total Score from questions 1-5: _______________ 0 = low risk | 1 = moderate risk | 2 or above = high risk

Fig [3]: STRATIFY Fall Scale [10]

2.2.3 Hendrich II Fall Risk Model

The Hendrich II Fall risk model was developed in 2003 and addresses acute and chronic illnesses as pre-existing conditions triggering falls. The tool provides a determination of risk based on gender, mental status, emotional condition, symptoms of dizziness, known categories of medications, and some limited physical tests such as push up, and get-up-and-go test. The categories are evaluated with risk points, which are then combined and suggest a high risk if the accumulated score is higher than 5. The model is demonstrated below-

Risk Factor	**Risk Points**	**Score**
Confusion/Disorientation/Impulsivity	4	
Symptomatic Depression	2	
Altered Elimination	1	
Dizziness/Vertigo	1	
Gender (Male)	1	
Any administered Antiepileptics (anticonvulsants)	2	
Any Administered Benzodiazepines	1	
Get Up and Go Test		
Ability to rise in single movement	0	
Pushes up, successful in one attempt	1	
Multiple Attempts but successful	3	
Unable to rise without assistance during test	4	
(A score of 5 or greater = High risk)	**TOTAL**	

Fig [4]: Hendrich II Fall Risk Model [11]

2.2.4 John Hopkins Fall Risk Assessment Tool (JHFRAT)

The John Hopkins model is an evidence-based initiative, developed by John Hopkins Medicine in 2005. The key factors assessed in the JHFRAT model are- age, history, elimination, medications, use of patient care equipment, mobility, and cognition.

Scores in each category determine the risk of fall. A score greater than 13 determines high fall risk, and below 6 is no risk of fall. The tool is demonstrated below-

Criteria	**Points**
Age 60 - 69 years (1 point) 70 -79 years (2 points) greater than or equal to 80 years (3 points)	
Fall History One fall within 6 months before admission (5 points)	
Elimination, Bowel and Urine Incontinence (2 points) Urgency or frequency (2 points) Urgency/frequency and incontinence (4 points)	
Medications On 1 high fall risk drug (3 points) On 2 or more high fall risk drugs (5 points) Sedated procedure within past 24 hours (7 points)	
Patient Care Equipment One present (1 point) Two present (2 points) 3 or more present (3 points)	
Mobility (choose all that apply) Requires assistance or supervision for mobility, transfer, or ambulation (2 points) Unsteady gait (2 points) Visual or auditory impairment affecting mobility (2 points)	
Cognition (choose all that apply) Altered awareness of immediate physical environment (1 point) Impulsive (2 points) Lack of understanding of one's physical and cognitive limitations (4 points)	
Total Fall Risk Score	

Fig [5]: John Hopkins Fall Risk Assessment Tool [12]

2.2.5 Stopping Elderly Accidents, Deaths and Injuries (STEADI) Algorithm

The STEADI Algorithm [13] is the most advanced tool and is the most commonly used in clinics. It was developed by the CDC in 2013, and emphasizes screening, assessing, and intervening to address fall risk factors by using clinical and community strategies. The initiative is supported by American and British Geriatrics Societies Clinical Practice guidelines. It also uses a scoring method via questionnaire to categorize low, moderate or high-risk patients. Below is a demonstration of the algorithm-

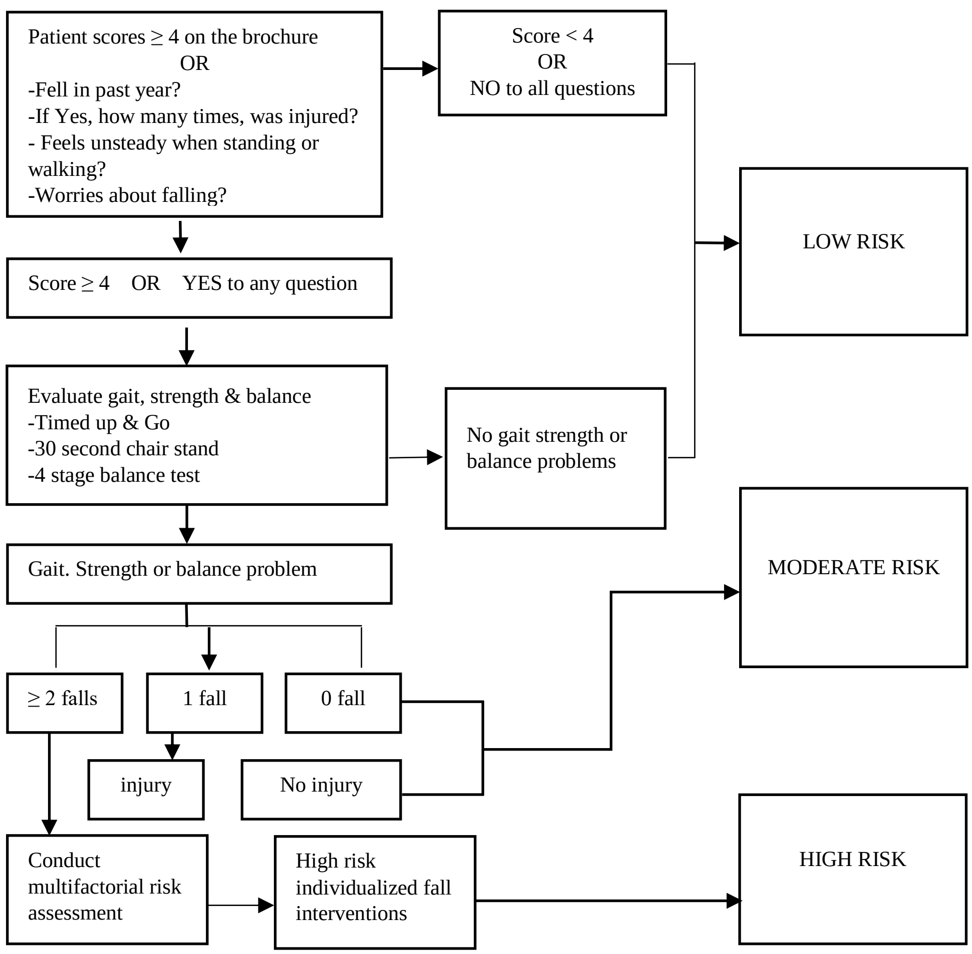


Fig [6]: Stopping Elderly Accidents, Deaths, and Injuries (STEADI) Algorithm [13]

2.3 CLINICAL TOOLS' LIMITATIONS

The current clinical tools and practice descriptions make their limitations apparent. All the tools are qualitative, and not based on the specific physical condition of a person, which greatly affects the outcome. The key limitations are-

- **2.3.1** Conscientious responses: In the current tools, a patient's response are the only source of truth, and may not describe the actual medical truth. Potential conscientious response can impact a caregiver's suggestive risk assessment.
- **2.3.2** Absence of information on actual patient performance: Without actual evaluation of a person's condition there are factors such as strength, stamina, vision, hearing, and gait that are not examined.
- **2.3.3** Impractical to use: An assessment based on questionnaire filled by the patient is not only impractical, but also threatening to the person. For example, improper responses can potentially lead to inappropriate medical conclusions.
- **2.3.4** Mostly history based: All the questions are based on history, and not present condition.
- **2.3.5** Low Accuracy: Scores derived from verbal responses often do not provide results with high accuracy, since they lack personalized assessment [44].

2.4 SCOPE OF POTENTIAL WORK

Current clinical tools are directed towards analyzing causes from history of falls, rather than assessing risks for falls in future. The scope of potential work encourages development of a practical, and highly accurate tool that can successfully address an individual's actual performance. While there are many ways to do this, the most crucial work is in gait analysis, since falls are usually triggered by gait imbalance.

CHAPTER 3

3. RELATED WORK

Much work has been devoted to improving fall risk assessment, focusing primarily on fall detection rather than fall prediction. Falls maybe inevitable, but certain measures and technological aspects can be used to assist in predicting falls and encouraging the taking of actions to mitigate the risks and potential dangers. The most significant work to improve current fall risk assessment clinical methods is elaborated upon here.

3.1 TAXONOMY

An evaluation of the literature in this domain, focusing on fall risk and fall prediction, suggests the visual taxonomy offered here-

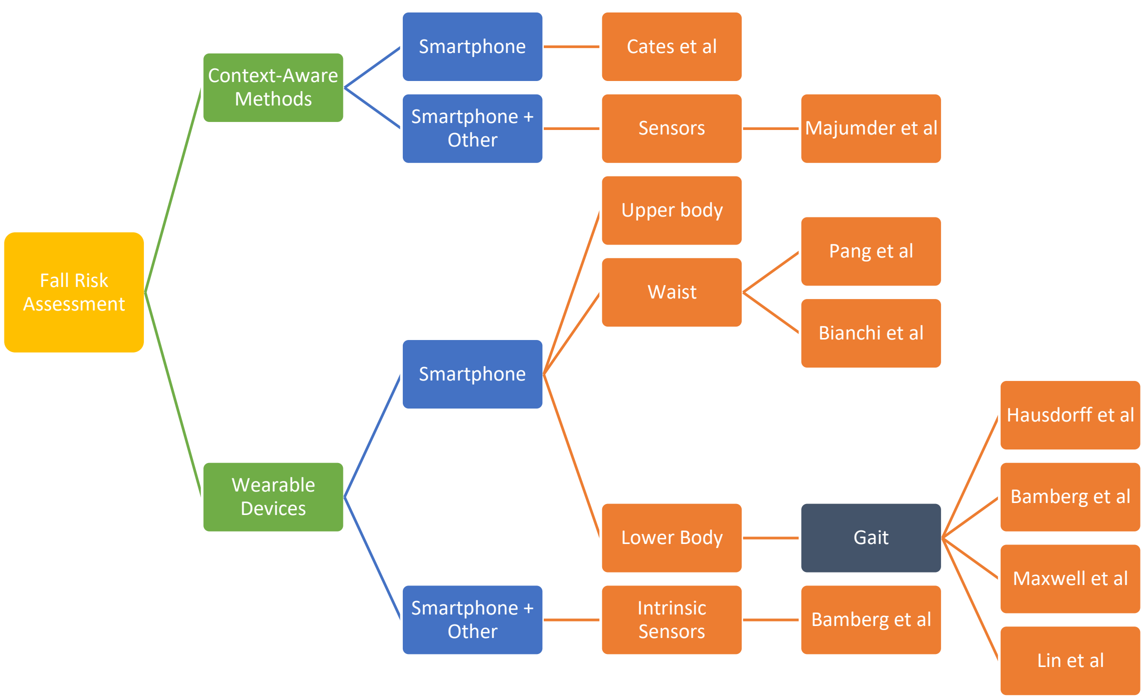


Fig [7]: Taxonomy of fall risk assessment computational methods

3.1.1 Majumder et al. [14] have developed a digital system- “smartPrediction” which uses real-time smartphone based sensory modules to predict falls. They created a shoe that contains pressure sensors with a Wi-Fi communication module that unobtrusively transmits data to a smartphone. A machine learning program processes the data and generates an alert message when an abnormality in gait is detected which suggests a potential fall. They have reported 97.2% accuracy in analyzing gait with their fall prediction model.

3.1.2 Hausdorff et al. [15] conducted a 1-year prospective study in community-living older adults to observe their gait patterns. They monitored stride-to-stride fluctuations in gait rhythm and subsequent falls along with other factors that may have contributed to falls. They have demonstrated the potential use of gait analysis for predicting falls ($p = 0.0001$) from stride time and showed promising outcomes when factoring strength, balance, gait speed and mental health altogether.

3.1.3 Bamberg et al. [16] developed a wireless wearable system that provides gait analysis using accelerometers, and three orthogonal gyroscopes, four force sensors, two bidirectional bend sensors, two pressure sensors, and electric field height sensors. They have recorded successful gait patterns and detected gait abnormalities using their “GaitShoe” system. With its reported high accuracy, this system demonstrates a significant promising system design using various interconnected sensory modules.

3.1.4 Bark et al. [17] designed and developed a force sensing shoe for gait analysis and monitoring which incorporated weight and center of pressure trajectory in human subjects. They have discovered significant results of gait pattern recognition from force and weight and concluded that minor adjustments in footwear improved gait.

3.1.5 Cates et al. [18] composed a novel fall classification model with accelerometer and gyroscope using high and low acceleration activities. Using a large number of daily life activities, they mirrored falls and using a support vector machine cross-validation method they reported 99.9% accuracy to recognize a fall from the accelerometer data. They designed an insole for the detection system with the sensors and inserted the insole in a shoe.

3.1.6 Pang et al. [19] carried out a systematic review of all currently available wearable devices to detect falls and reported promising results in using single lightweight sensors to distinguish among different falls- near falls, actual falls, and risk of fall. Among all wearable sensors studied in the review, accelerometers, gyroscope and insole force inducers were most used. The waist was the most common location for the wearable device and the investigators reported ≥ 85.7% sensitivity and ≥ 90% specificity for near fall detection.

3.1.7 Maxwell et al. [20] designed a wearable insole pressure system that can collect gait data from four main spatial foot regions using foot plantar pressure patterns. Collected data was then used to simulate loss of balance events and identify changes in the biomechanical gait stability parameters. Using the system, they have found useful gait metrics for early detection of fall risk which in turn allow implementing proactive fall prevention strategies.

3.1.8 Bianchi et al. [21] constructed a system that uses acceleration and air pressure data from wearable device attached at the waist and analyzed the collected data to detect falls by eliminating false positive detections. Using the sensors and a decision tree classifier to label falls, they have reported accuracy of 96.9%, along with sensitivity

97.5% and specificity of 96.5%. Their use of a second sensor has improved the outcome in detecting and identifying fall events.

3.1.9 Howcroft et al. [22] compared various fall-risk classification models using their designed wearable sensor-based system that uses gait data for fall occurrences. They performed tests using different sensor types, location and tasks. The best performing model was a neural network using dual task gait data and input parameters from head, pelvis and left shank accelerometers. Their approach suggested that a quantitative gait-based fall risk assessment system with high accuracy can be designed.

3.1.10 Lin et al. [23] designed a system named Smart Insole that consists of electronic textile-based pressure sensors integrated into the insole to fully measure plantar pressure while walking or stepping. The insole also contains a three-axis accelerometer, three axis gyroscopes, and magnetometer to capture gait characteristics in motion. They have reported very accurate outcomes in gait analysis but insignificant results in fall detection. Their design has a very low-cost insole, incorporating all the sensors, which is very easy to implement.

CHAPTER 4

4. REQUIREMENT ANALYSIS AND SYSTEM DESIGN

When analyzing fall risk variables, the most significant feature to focus on is the gait. In general, a fall occurs when normal balance is disturbed. Among the reasons for imbalance, in a study of 1042 individuals aged 65 and over, tripping was reported in 53% of cases, dizziness in 8% and blackouts in 6% [24]. Tripping usually occurs in association with foot imbalance or foot movement disparity. Hence, the study of gait is critical and should receive the most emphasis to identify fall risk as a result of tripping.

4.1 GAIT CYCLES

A gait cycle is measured from heel strike to another heel strike between steps. The cycle consists of a stance phase and a swing phase [26]. The stance phase is the duration of time the foot is on the ground. 60% of one gait cycle is spent in this phase. The next phase, Swing phase, is the period the foot is off the ground, proceeding to go to stance phase. 40% of one gait cycle is spent in this phase. A normal gait cycle is demonstrated in the figure 8 [25]-

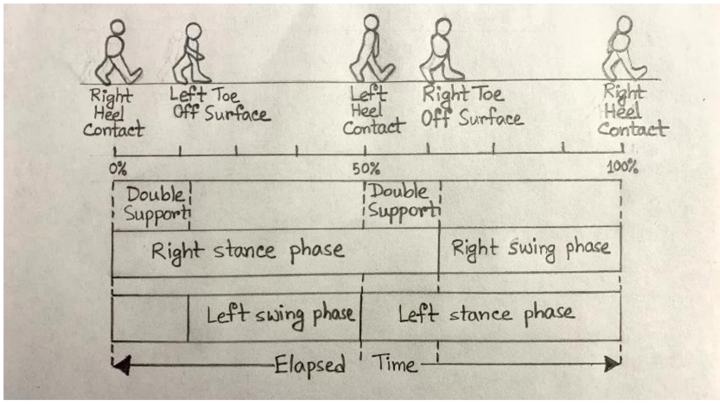


Fig [8]: The normal gait cycle [25]

4.2 FOOT BALANCE

In general, the foot swing in taking a step while walking or running is associated with eight phases [27]: Initial Contact > Loading Response > Midstance > Terminal Stance > Pre swing > Initial Swing > Initial Swing > Mid Swing > Late Swing. During these phases, an impact of Minimum Foot Clearance (MFC) determines the moving speed and is an indication of probability of fall as a result of foot imbalance. The foot center of mass (CoM) is represented by the formula [28] [29]-

$$XCoM = CoM\ position + \frac{CoM\ Velocity}{\sqrt{\frac{gravity}{l}}}$$

Where, XCoM = extrapolated center of mass, and l = distance between ankle and the end of inverted-pendulum movement

By using this formula, a margin of stability (MoS) is defined from the movement, which is directly correlated to the gait cycles [29].

4.3 GAIT ANAYTICS IN FALL RISK ASSESSMENT

As discussed in the related works chapter, causes for falls are multifactorial, however the majority of falls share one common feature- they occur during stepping or walking [24] [30]. Stride length and stride-to-stride distance variation are the two most important metrics in gait, and researchers have found significant correlations with these in predicting falls [32]. There are also correlations between stride time and swing time variation and fall risk [30]. Even a small number of variations in gait can lead to a greater risk of falls. Maki [32] showed a stride length variation of just 1.7cm had an odds ratio for falling of 1.95 with 95% accuracy [31].

4.4 FEATURES EXTRACTION

For the gait analysis-based system to work, some crucial gait features need to be extracted using sensory systems. Based on the literature, the most critical metrics and features directly correlated to a fall risk are follows [22] [27] [30] [31] [32]-

i. Steps (stride length, frequency)

ii. Supination/Pronation (L & R stride symmetry)

iii. Pressure Points

iv. Timing (L & R stance/swing, double stance)

v. Balance

Supination and Pronation are two important features to investigate in gait analytics. Supination is when a foot experiences body weight on the outside of the foot, whereas an inward roll of the foot with weight shifted to the forefoot is called pronation.

Fig [9]: Pronation, Neutral, Supination

4.5 DESIGN OVERVIEW

The design of a practical fall risk assessment tool should include several modules, both wearable, and stationary. To collect gait data, an insole with sensors is most convenient. The data needs to be collected either in the insole, or in a separate device such as a Smartphone. A computer with a large screen might present best the analytical data with some visual graphics. Justifications for the design modules and instruments are-

4.5.1 InSole – A digital sensory insole with pressure sensors, and an accelerometer can capture gait data during activities. A pressure sensor would activate when force is applied from the planar system. Locomotion would activate the accelerometer, which would capture the motion in 3 axes. The combination of data types would give gait parameters desired for the system.

4.5.2 Smartphone – An insole sensor can capture the data, but a triggering device is required to start and stop the data capture. A smartphone is best for this task. Subject profiling can also be done in the smartphone application.

4.5.3 Computer – A computer with a large screen could be used to display the end results, post calculation of the gait parameters. The computer can be minimally configured. Once data arrives in the computer, it would be able to demonstrate the calculations visually with graphics.

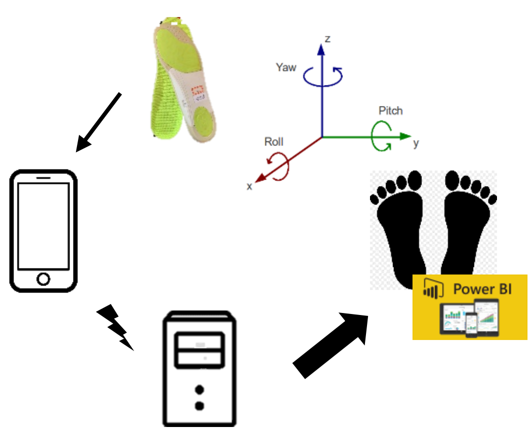


Fig [10]: Design Overview of the Platform

4.6 DESIGN CONSIDERATIONS

The design of a practical fall risk assessment tool would have to maintain some fundamental design considerations to make it functional and compliant with medical rules and technology regulations. Some of the major considerations are explained below-

4.6.1 Historical Data – In order to make a real time gait analytics platform, the history of fall or past gait knowledge can be safely ignored. Historical trend in data is important for forecasting, but not necessary for analyzing present day condition.

4.6.2 Demographics Independent – The idea of a unified and universal platform would require the design to be gender, age, height, and weight independent. The analysis of a walk, steps, and gait parameters needs to be displayed directly to the platform without any restrictions. The user should determine what is normal and abnormal based on the visual representations of the data.

4.6.3 Aesthetics – The platform needs to be aesthetically pleasing and easy to use so that the user can understand the presented data. The understanding of the analytics is greatly enhanced when data is presented cleanly and in a user-friendly format.

4.6.4 Security and privacy – The system design must maintain security and privacy, since this system would be handling health data using the internet. Certain risk mitigation actions need to be taken, in compliance with PHI and to follow HIPAA guidelines.

CHAPTER 5

5. IMPLEMENTATION DETAILS

5.1 INSOLE DESIGN

A pair of insoles comprised of various sensors, including pressure sensors and an accelerometer can collect gait data most accurately [42]. Alternatives to insoles are smartphone, motion detectors, pressure mat, and inertial sensors. None of them can collect instantaneous gait data as precisely as insoles, since they are directly connected to both feet.

A specific smart insole is proposed. The insole top is made with rubber texture, and bottom hard-shell. These insoles are size dependent, and gender independent. Both insoles have embedded sensors in them. Since sensors are significantly small and low cost, it is convenient to insert 5 pressure sensors, and 1 accelerometer inside each insole. A small microcontroller is also placed inside the insole which interfaces with all the sensors. The microcontroller has a Bluetooth module that broadcasts data when any of the sensors is activated, and data is retrieved programmatically.

Fig [11]: Designed Insole product with embedded sensors

5.1.1 SENSORS

The insoles have 5 pressure sensors, placed according to human foot placement dynamics. They are located under the- 1) toe, 2) forefoot, 3) mid-foot, 4) back-foot, and 5) heel. When pressure is applied on any of the pressure sensors, this records as a value of 1 which is passed to the microcontroller.

The insoles also have a 3-axis accelerometer. It is placed under the forefoot. When foot locomotion occurs, the accelerometer detects the yaw, roll, and pitch of the movement. When activated, it sends data continuously to the microcontroller.

5.1.2 MICROCONTROLLER

The interfacing control unit for the sensors is a small microcontroller which is supplied by the vendor of the insole. The API is also supplied, using which the data from the sensors can be collected programmatically. It also comes with a Bluetooth module and a battery. The Bluetooth does not require pairing, as it broadcasts the data with an encryption key.

5.1.3 BATTERY

The insole has a lithium-ion battery built into it. It has roughly 400mAh capacity which can keep the insoles active for approximately 24 hours. The battery is rechargeable and utilizes a micro-USB port located on the side of the insoles. A full charge takes 1 hour to complete.

5.2 DATA COLLECTION APPLICATION

An android application has been developed that can interface with the insole to read and collect data. The application records an ID of the subject, to uniquely identify the study and then proceeds with a set of instructions directing the test subject to perform certain activities that generate the gait data. After completion of the activities, the mobile application can send the captured data to a cloud web server for storage. The application is displayed below-

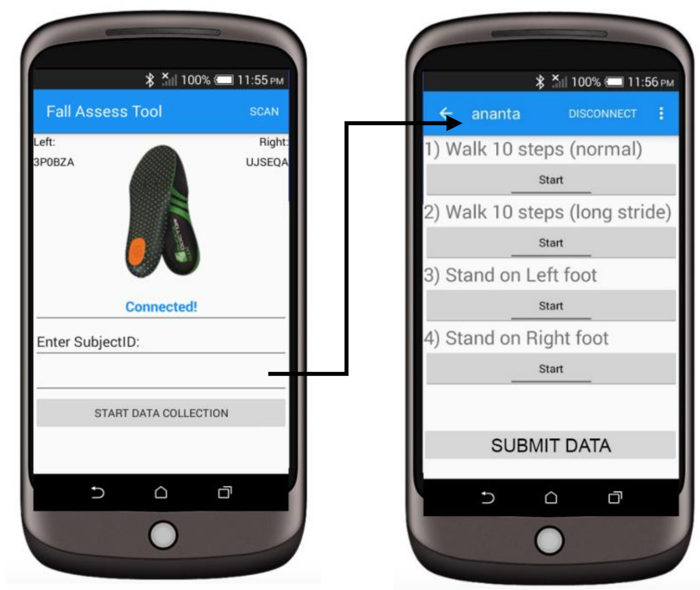


Fig [12]: Mobile Application for Data Collection

The flow of events of the mobile application is demonstrated below-

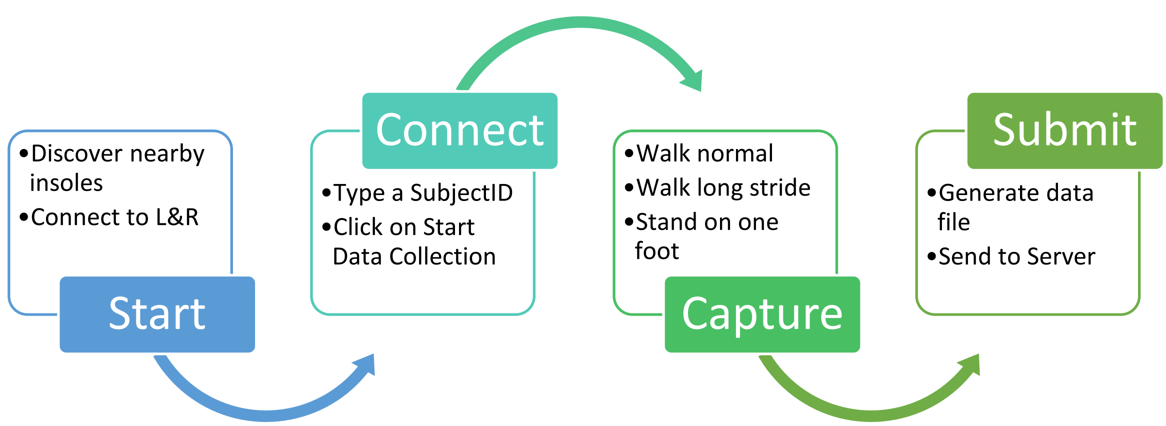


Fig [13]: Mobile Application flow of events

5.2.1 INSOLE CONNECTIVITY

The API implements a Bluetooth module that can successfully call and retrieve all the nearby devices that are broadcasting on the specific channel. The device identifier denotes whether it is a left or right insole. The mobile application then determines available slots for the insoles and establishes a Bluetooth connection.

```
Intent intent = new Intent(MainActivity.this, ControlActivity.class);
intent.putExtra(ControlActivity.LEFT_DEVICE, devices.get("left"));
intent.putExtra(ControlActivity.RIGHT_DEVICE, devices.get("right"));
intent.putExtra(ControlActivity.USER_ID_KEY, userName.replace(" ", "_"));
startActivity(intent);
```

5.2.2 SUBJECT ID

Once connection is established, the textbox asking for a SubjectID displays and requests input. The acceptable input is A-Z, and 0-9 with no special character or spaces allowed. The subject ID is stored as the file name, and also displays on the next screen. Duplicate entry replaces the existing file in the mobile device.

5.2.3 DATA COLLECTION VIEW

Four buttons are displayed in the next view, combining labels for instructions and buttons to start and end the capture window. Clicking on any of the buttons triggers a capture session to the insole. Insole data is recorded, and immediately sent to the mobile device real time along with timestamp.

```
private void writeGaitDataChanged(long date, BleDevice device, GaitOriginal gaitOrig, GaitPoint gaitPoint) {
    HashMap<String, Object> infos = new LinkedHashMap<>();
    infos.put("name", device.name);
    infos.put("time", DATE_FORMAT.format(new Date()));
    infos.put("impactLevel", gaitOrig.impactLevel);
    infos.put("touchdown", getTouchdownString(gaitOrig.touchdown));
    infos.put("ectropion", gaitPoint.ectropion);
    infos.put("forefoot", gaitPoint.forefoot);
    infos.put("heel", gaitPoint.heel);
    infos.put("sole", gaitPoint.sole);
    infos.put("varus", gaitPoint.varus);

    Log.e("GaitData", infos.values().toString());
    gaitWriter.println(infos.values().toString());
    gaitWriter.flush();
}
```

5.2.4 SUBMIT

After the collection of data according to the various activities instructed, when the submit data button is pressed, the file that was created in the beginning of the session is closed and is sent to a web server.

```
private static PrintWriter openFile(String userId, Date date, String questionId, String fileName) {
    File dataDirectory = new File(Environment.getExternalStorageDirectory().getAbsolutePath() + "/insole.data/" +
    userId);
    dataDirectory.mkdirs();
    if (!dataDirectory.exists()) {
        throw new IllegalStateException("Failed to create data directory: " + dataDirectory.getAbsolutePath());
    }
    try {
        String name = questionId + "_" + DATE_FORMAT.format(date) + "_" + fileName + ".txt";
        return new PrintWriter(new FileOutputStream(new File(dataDirectory, name)));
    } catch (FileNotFoundException e) {
        throw new RuntimeException("Failed to open file: " + fileName, e);
    }
}
```

5.3 DATA TRANSMISSION

After proceeding with the instructions provided in the mobile application, following performance of 4 categories of activities, a file is generated with all the raw sensor data. At this stage the file is ready for transmission to the web server. An HTTP transmit call is made in the app which ships the file to a container in the destination Apache server. Any file storage capable server can be used for this stage. The credential for the storage system is stored within the app, in order to authenticate and be able to write to the destination. The server is protected with HTTPS and TLS protocol, so data remains encrypted for its duration in the remote location.

An alternate route for the data transmission is to manually retrieve the TXT file from the mobile device using a USB cable.

Fig [14]: Data Transmission Paradigm

5.4 DATA SAMPLE

The mobile application makes the call to the insole to send data as per the designed algorithm. The sampling is set to 10Hz, so data is recorded every 1/10th second and transmitted to the mobile device from all sensors. This has proven to be sufficient for sampling. Accurately capturing changes in gait for the sampling rate have been suggested in various research reports. Once captured the data appears as below-

Table [1]: Data Sample (text file)

Timestamp	Pressure Points	Accelerometer		
01/31/2019 12:02:01 PM	a: 0 b: 0 c: 0 d: 0	x: -0.03125	y: 0.09375	z: 0.96875
01/31/2019 12:02:02 PM	a: 0 b: 1 c: 1 d: 0	x: 0.3125	y: 0.0625	z: 1.03125
01/31/2019 12:02:03 PM	a: 0 b: 0 c: 1 d: 0	x: -0.03125	y: -0.21875	z: 0.96875
01/31/2019 12:02:04 PM	a: 1 b: 0 c: 0 d: 1	x: -0.125	y: -0.0625	z: 0.96875
01/31/2019 12:02:05 PM	a: 0 b: 1 c: 0 d:1	x: -0.25	y: 0.4375	z: 0.71875
01/31/2019 12:02:06 PM	a: 1 b: 1 c: 1 d: 0	x: -0.5	y: -0.125	z: 0.65625
01/31/2019 12:02:07 PM	a: 1 b: 1 c: 0 d: 0	x: -0.0625	y: 0.0625	z: 1.0
01/31/2019 12:02:08 PM	a: 1 b: 0 c: 1 d: 0	x: -0.0625	y: 0.0625	z: 0.96875
01/31/2019 12:02:09 PM	a: 1 b: 0 c: 1 d: 0	x: -0.0625	y: 0.0625	z: 0.96875
01/31/2019 12:02:10 PM	a: 1 b: 1 c: 0 d: 1	x: -0.0625	y: 0.0625	z: 0.9375
01/31/2019 12:02:11 PM	a: 1 b: 1 c: 0 d: 0	x: -0.0625	y: 0.0625	z: 0.96875
01/31/2019 12:02:12 PM	a: 1 b: 0 c: 1 d: 0	x: -0.03125	y: 0.0625	z: 0.96875
01/31/2019 12:02:13 PM	a: 0 b: 1 c: 0 d: 0	x: -0.21875	y: 0.125	z: 1.09375
01/31/2019 12:02:14 PM	a: 1 b: 1 c: 0 d: 0	x: -0.5	y: -0.28125	z: 1.03125
01/31/2019 12:02:15 PM	a: 0 b: 0 c: 1 d: 0	x: 0.34375	y: -0.03125	z: 0.9375
01/31/2019 12:02:16 PM	a: 0 b: 0 c: 1 d: 1	x: 0.40625	y: -0.15625	z: 0.96875
01/31/2019 12:02:17 PM	a: 1 b: 0 c: 0 d: 1	x: 0.15625	y: -0.0625	z: 1.03125
01/31/2019 12:02:18 PM	a: 0 b: 0 c: 0 d: 0	x: -0.09375	y: 0.03125	z: 1.0

5.5 PLATFORM DESIGN

The final component of the system is the fall risk assessment platform design. For this purpose, a commercially available product from Microsoft- PowerBI has been used. It is a free-to-download data analytics tool. PowerBI is primarily a visualization tool, that is popular in the business intelligence community. It requires Windows operating system for the software. Using the tool, a dashboard style fall risk assessment tool has been designed with sample data shown-

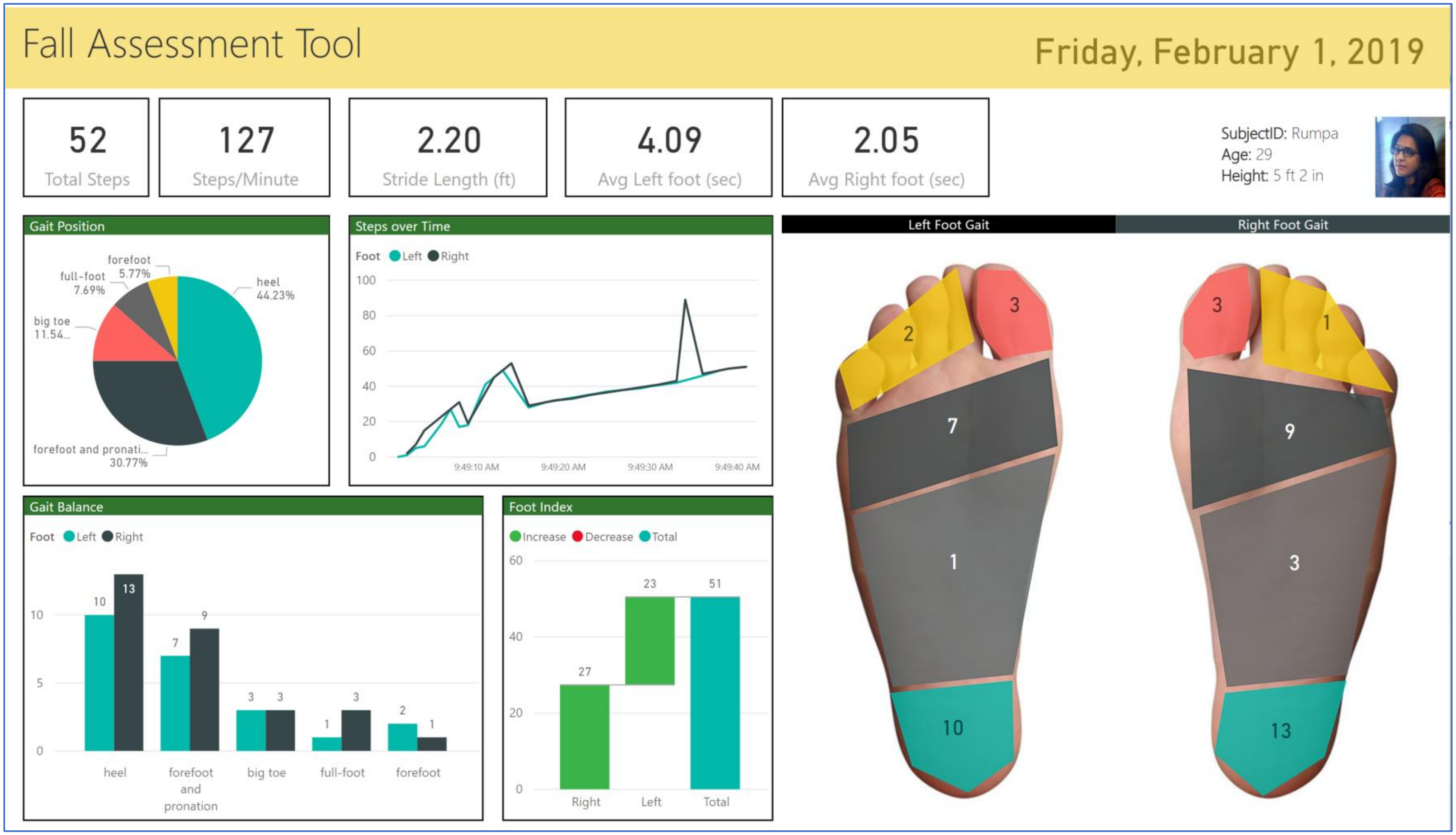


Fig [15]: Fall Risk Assessment Platform

The primary function of this tool is to make gait data analytics self service, in other words, the charts and graphs are all interactive and clickable. Clicking any of the data bars, or elements makes the other parameters change so that an assessment can be made based on selected parameters. A potential use is exploring what-if scenarios, by clicking on one element and slicing and dicing the others in order to reflect the changes of the selected parameters. For example, clicking on the left big toe can reveal how many times it was used while walking, and at the same time report the steps and stride parameters using that region. This proves to be useful when analyzing gait visually looking at changes in other gait metrics simultaneously.

The elements of the platform are-

5.5.1 GAIT METRICS

The values can be presented in a card format, where starting on the top left are listed the number of steps, then the estimated number of steps per minute and the corresponding average stride length (ft). Average duration of standing on one foot is also displayed in the next two cards. These calculations are made from the data captured in the previous phase using the data collection application interfaced with the insole.

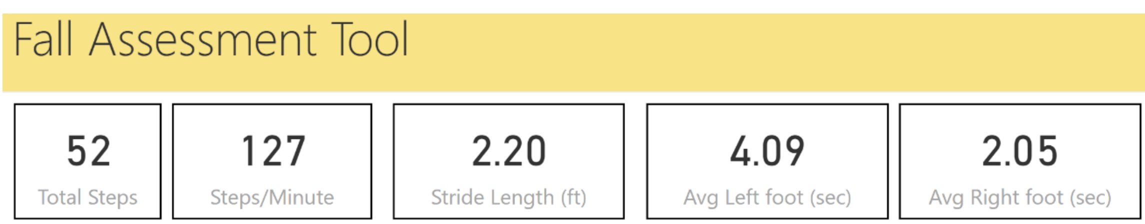


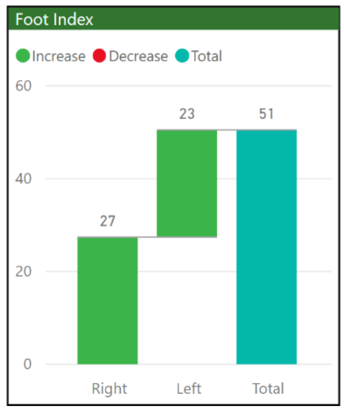
Fig [16]: Cards denoting gait metrics

The calculation for each is designed in the PowerBI tool, as a measure or as a count within the dataset. For example, a formula written in DAX data query language to calculate the steps per minute is retrieve by counting the number of steps and estimated that to a minute-

```
StepsPerMinute = INT(COUNT(Gait[Foot])/AVERAGE(Gait[Time]))
```

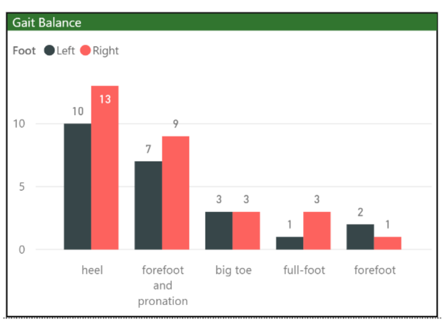
5.5.2 FOOT INDEX

The foot index denotes the cadence ratio of left and right foot within the assessment period. This shows an increase of pressure depth of one foot or the other based on the gait metric selected, such as big toe, or forefoot. In a normal gait, each foot pressure ratio should appear normally distributed, one not too different than the other. If one shows higher or lower pressure than the other, that would indicate a potential gait abnormality.



5.5.3 GAIT BALANCE

This chart shows the number of times each position of each foot has been pressured during the walk assessment. In a normal walk, all the positions would be normally distributed, as they would not deviate from one another too much.



5.5.4 FOOT PRESSURE MAP

The most prominent metric displayed in the tool is the pressure map of both feet. This visual demonstrates which part of the foot was pressured, and how frequently. This assists in discovering any foot discomfort or abnormalities when compared with other gait metrics. Selecting one or more of the areas would filter the other visuals so that more focused and granular analytics can be conducted.

5.5.5 ADDITIONAL METRICS

The gait metrics demonstrated in this tool are the most useful ones that would assist in fall risk assessment. However, this tool is capable of handling more metrics and more diverse sensor-based data. The metrics are easy to develop. The idea is to grasp a gait pattern by looking at real time performance of a subject and be able to make a fall risk assessment based on the data.

CHAPTER 6

6. APPLICATION OF THE DEVELOPED TOOL

This practical fall risk assessment tool is designed to enable medical caregivers to make better decisions based on actual patient performance, and not historical data.

6.1 USE CASE

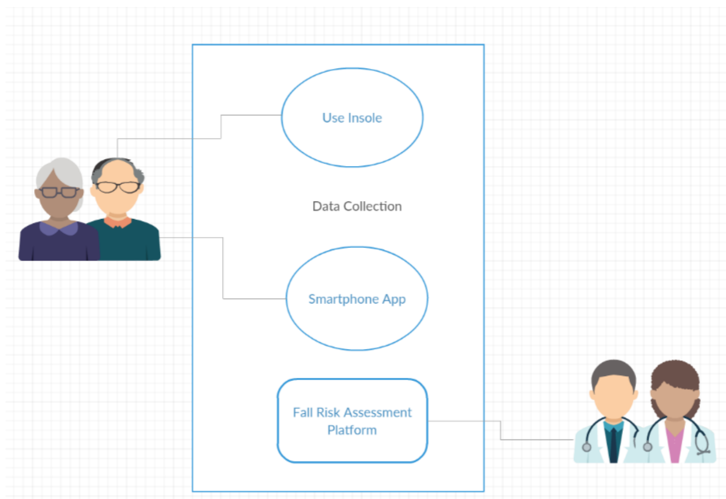


Fig [17]: Use Case Diagram

6.2 CLINICS AND PRIMARY CARE PROVIDERS

As discussed in Chapter 2, current techniques are mostly history-based questionnaires. The primary equipment for the proposed platform is a pair of insoles, a smartphone, and a computer connected to internet. The patients would follow the instructions from the app, as demonstrated in Chapter 5, with or without assistance. The app can be used by the patient or by someone assisting the patient. The data is available in real-time and fed into the platform and is then displayed for a doctor or caregiver to make further assessments.

6.3 GAIT DETECTION

This tool is most useful in analysis and detection of gait patterns and abnormalities. A caregiver can see promptly various metrics to determine whether the patient has any gait abnormalities. Foot fractures, broken bones, osteoarthritis, stress arthritis, and foot disorders. can be easily discovered from use of the tool. The visual interactive data analytics can reveal and identify various gait patterns.

6.4 FALL RISK ASSESSMENT SCORING

At present, fall risks are scored based on use of the tools currently available. Scores are calculated from various decision factors, and historical data. A good application of this tool can be to utilize similar scoring concepts for a fall risk assessment. For example, a person with a foot index measurement higher for one foot than the other may suggest a higher fall risk than equivalent foot indices. Similarly, depending on height of a person a stride length too short, or too long would show a high fall risk.

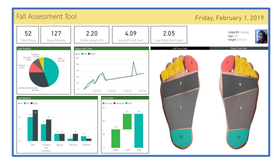
Since this is a graphical tool, a numerical score of a fall risk is not possible unless further algorithmic approaches are implemented. However, an alternative is to visually demonstrate impaired gait metrics as a person's walking pattern is displayed and closely analyzed. Here, visual interpretation of gait is acting as a substitute for the usual scoring mechanism in making fall risk assessment.

6.5 PLATFORM INDEPENDENT

Since the designed tool does not depend on a specific platform, as it is more internet browser based than a native operating system based, this can prove very useful when caregivers would like to use a handheld portable device such as a tablet.

6.6 REALTIME ASSESSMENT

Shown in the figure below, the time it takes for a complete gait assessment is less than 10 minutes in total starting from inserting the insoles, to collecting data and transmission over the internet, to the application of the fall risk assessment tool. This is actual patient performance evaluated in real time.

1) Wear Insole	2) Start Mobile App	3) Perform the instructed actions	4) Transfer Data	5) Refresh Assessment Tool
				
1 min	1 min	4 min	1 min	2 min

Total: 9 minutes

6.7 EXTENDED CAPABILITIES

One of the design objectives is to make this tool as versatile as possible, so that further sensor-based data can be accommodated. This tool can successfully house the enhanced capabilities with its greater scalability feature. Not only insole data, but any other type of data can be incorporated easily into the tool and visually represented together with gait data. For example, if a blood pressure monitor or a glucose monitor can export raw data then PowerBI can easily import the data and incorporate these with gait data.

CHAPTER 7

7. EVALUATION OF THE DEVELOPED TOOL

Evaluation of fall risk assessment strategies involves a range of tests, standards, compliances, and accuracy analyses. The proposed tool requires observation of its use, and whether caregivers can assess fall risk by using the platform and gait information.

7.1 TEST CASES

With an approved protocol by the Institutional Review Board [43], 10 subjects were recruited with written informed consent to test the developed tool. Various types of test cases were created, to check the functionality and effective use of the tool. The test subjects were instructed to model normal and abnormal walking to check variance in gait representation (Table 2).

At the end of the subject trials, the tool demonstrated whether a subject's gait data showed any sign of abnormality. A normal stride length for an adult is between 2.2-2.5ft [27]. When subjects walked in slow pace or fast, the stride length and stepping numbers in the tool displayed corresponding values to specify the circumstance. When subjects modeled walking with irregular pronation and/or supination, the tool showed skewed graphics, but it did not provide the exact ratio of feet pressures to indicate which part of the foot was responsible for it. This constraint is due to the number and position of the pressure sensors in the insole. For all subjects, the success rate to detect a normal gait and an abnormal gait from visual demonstration from the developed tool showed an accuracy between 95-98% based on the test cases applied during the studies.

Table [2]: Test Cases & Results

Test Scenario	Expected Result	Actual Result	Pass/Fail
Normal Walk	Gait normally distributed	Visuals all appear symmetrical, and numbers in range	Pass
Abnormal Walk	Gait sporadic, visuals skewed	Numbers and visuals not aligned	Pass
One foot damage	Visuals represent the damaged foot	One foot data appears to be abnormal	Pass
Long strides	Numbers would demonstrate the fact	Stride length shows high number	Pass
Pronation/Supination	Specific foot would demonstrate the fact	Besides the leg showing abnormal data, not exact number is found	Failed, need more sensors
Swing phase detection	Normal and abnormality detected	Average steps, stride length aligned	Pass
Works for all demographics	No biased, or inference data	Visuals are independent of demographics	Pass

7.2 EFFECTIVE USE

The objective of the work reported here has been to demonstrate a prototype performance-based fall risk assessment tool. From a user perspective, the tool presents all the data collected from the insoles in a user-friendly way, so that a medical caregiver can easily grasp the condition of the patient and make evidence-based recommendations. Further, the tool provides sufficient instructions on use and what to use in the tool. The charts are labeled, all the data fields are self-explanatory and thus the tool can adequately provide gait data to a viewer easily and efficiently. In addition to the data labels and graphics headers, a formal data definition guide can also be provided as a supplement to a caregiver incorporating all the modules and metrics available in the tool for their effective use.

7.3 COST AND COMPLEXITY

The tool is comprised of few complex modules. With only gait data as input, the tool demonstrates all the variables and metrics very easily and in a user-friendly way. Usually as more features are added, the more complex a system becomes (Figure 18).

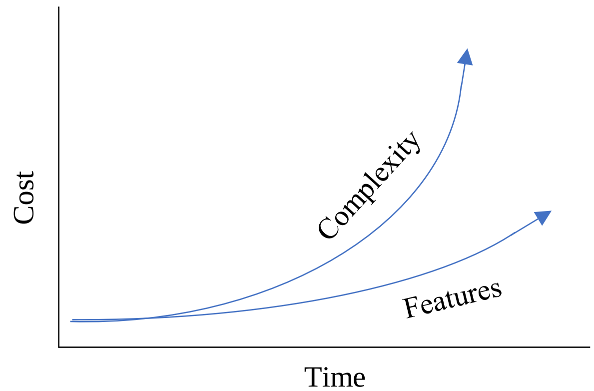


Fig [18]: Costs of Complexity

The cost of the overall system is estimated as-

i. Insole - $15-$20

ii. Smartphone- $50-$100

iii. PowerBI – Free

iv. Platform – Free

v. Computer – Generally available in almost all facility

7.4 QUALITY EVALUATION

According to ISO 25000 standards, a software product quality evaluation is determined by characteristics of the product in eight (8) categories. They are defined in the ISO/IEC 25010 model, as-

Table [3]: ISO/IEC 25010 Model

Quality	**Criteria**
1) Functional Suitability	Functional completeness, correctness, appropriateness
2) Performance Efficiency	Time behavior, resource utilization, capacity
3) Compatibility	Co-existence, interoperability
4) Usability	Appropriateness, recognizability, learnability, operability, user error protection, user interface aesthetics
5) Reliability	Maturity, Availability, fault tolerance, recoverability
6) Security	Confidentiality, integrity, non-repudiation, authenticity, accountability
7) Maintainability	Modularity, reusability, analyzability, modifiability, testability
8) Portability	Adaptability, install ability, replaceability

Table [4]: Tool Evaluation based on ISO/IEC 25010 Model

Quality	**Score (max: 10)**	**Justification**
1) Functional Suitability	**10**	Implemented gait functions are complete, and performs properly
2) Performance Efficiency	**10**	Total runtime is less than 10min, much more efficient than manual methods
3) Compatibility	**10**	Platform independent, demographic independent
4) Usability	**10**	Very easy to use, minimal learning for a new user, and fast operability
5) Reliability	**8**	Available online, so always on but errors are possible from incorrect user input
6) Security	**10**	Data is transmitted with security precautions, and results are authenticated, and permission granted only to authorized medical personnel
7) Maintainability	**10**	Easy to modify, add/remove features
8) Portability	**9**	Quick installation, modules can be easily replaceable

7.5 SECURITY AND PRIVACY

Security risks attend use of tools such as the one reported on here. There are certain measures that must come into consideration when transporting health related data across electronic media. Guidelines are provided by HIPAA (Health Insurance Portability and Accountability Act) privacy rules. The specific relevant rule is the one on electronic Protected Health Information (ePHI).

According to the guidelines, health related data that is produced, collected or transmitted via internet needs to be safeguarded by the application [34]. This platform adheres to these rules. The data is collected in the insole and transmitted to the mobile application which stores the data encrypted in the phone. When transmitting to the web server, the data is decrypted on the fly and gets sent to the server as a text file. The server uses TLS (transport layer security) and HTTPS (hypertext transport protocol secure) in its architecture, so that all the data remains encrypted before and after transmission.

7.6 LIMITATIONS

This fall risk assessment tool comes with certain limitations in its architecture and usability. The limitations do not affect the performance of the designed tool but instead they suggest enhancements for future.

7.6.1 NO FALL PREDICTION ALGORITHM

The tool does not implement an algorithm that can successfully predict a fall. It provides a visual representation of the patient's current gait and offers the provider specific data to make an educated judgment of the patient's condition. This greatly limits the tools capabilities. Since PowerBI has more advanced data analytics capabilities, this limitation can be addressed in the future.

7.6.2 LACK OF GUIDELINES

The tool provides a graphical overview of the gait analysis, it does not supply medical guidelines to the caregiver. It is completely dependent upon the user's interpretation to decide any future course of action.

7.6.3 RISK OF MISINTERPRETATION

Since a human caregiver makes the judgment of a person's fall risk, there are potential risks of misinterpretation of the presented data. A person may interpret a stride length or pronation/supination time in one way, whereas it should be understood in a different way.

7.6.4 DATA ERRORS

The system can report erroneous data if the user does not perform the data capture properly. The insoles may not report data, or the cellphone may not have the registered button pressed which would result in bad or no data.

7.6.5 INSTRUMENT LIMITATIONS

The insoles are prototypes, and thus they come with some limitations. If Bluetooth is out of range, or loss of connectivity with the smartphone occurs, then data would be lost during transmission. Similarly, if the smartphone loses connection with the internet then it would not send the data to the server. These limitations can be addressed by improving the instruments.

CHAPTER 8

8. CONCLUSION AND FUTURE WORK

This work presented here is of a novel design for a unified and platform independent Fall Risk Assessment tool which is offered as a potentially cost effective, easy to implement, and versatile clinical tool.

8.1 SUMMARY

The work reported here demonstrates a gait analytics tool that can successfully display details of a person's real time gait and allows a user to analyze the gait using a slicing and dicing approach, by tweaking various parameters.

Using a pair of sensory insoles, a smartphone, and a computer equipped with the tool a medical caregiver can easily visualize a person's gait balance, and any gait impairment, and make an educated judgment on the potential and probability of a fall in the near future.

8.2 IMPACTS OF THE TOOL

From the development of this tool, the groundwork for an all-in-one medical analytical tool is demonstrated. Using just gait data, a fall risk assessment is made. In the future when other sources of data might be incorporated in this tool, a more diverse range of problems, interactions and concerns can be easily identified. This also shows the great potential for a unified health monitoring platform that allows self-analytical capabilities by an individual or caregiver. Such predictive analytical tool is a cost-effective alternative for providing health support.

8.3 CONTRIBUTIONS OF THIS THESIS

Quality of life in the future may be significantly dependent on pervasive computing. Medical tools, such as the one proposed in this communication, offer prospects for better informed medical decision-making.

8.4 FUTURE WORK

The tool can be further tested and evaluated in clinical settings. This tool's novel design offers accurate results but use of the tool in patients with increased fall risk, especially elderly population, will lead to improvements in the effective accuracy of the tool. A prospective longitudinal cohort study can be most beneficial for further evaluation.

In addition, a digitally computed fall risk scoring method can be implemented using machine learning approaches. The underlying platform- PowerBI offers various data analytical capabilities so machine learning can be applied. Also, with implementing fall prediction algorithms, the tool can make fall risk predictions from collected gait data in real time with higher accuracy.

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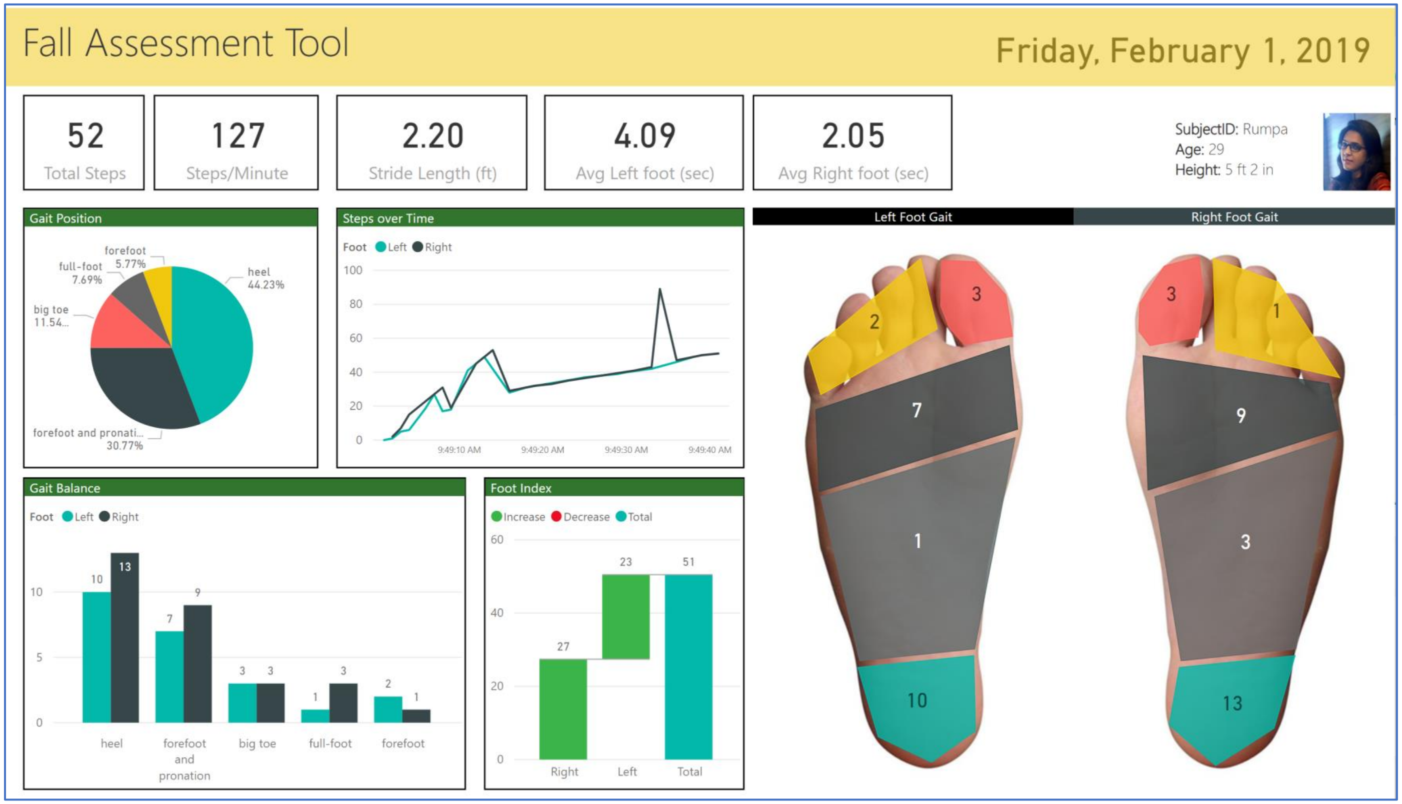
APPENDIX

A.1 NORMAL GAIT

Below is how a normal gait would appear in the developed tool-



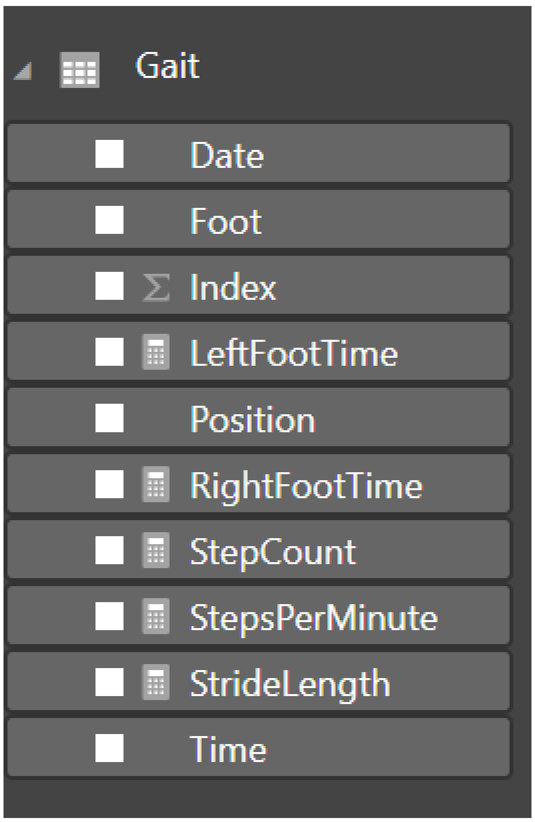
A.2 ABNORMAL GAIT

Below is how an abnormal gait would appear in the developed tool-

A.3 DEVELOPMENT TOOLS USED

- Smartphone: 1) Android OS 4.4 above
  2) Android Studio v3.3
- Computer: 1) Windows 10 Pro
  2) Microsoft PowerBI v2.67.5404.801
  3) Edge Browser/Google Chrome

A.4 POWERBI DATASET DESIGN



A.5 LINK TO THE TOOL

http://tinyurl.com/fallrisktool