University of Moratuwa

Bio-Medical Device Design

BM2210

Feasibility Report

Team A

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Contents

1. Introduction

This report delves into the feasibility of a proposed solution for a previously identified problem – specifically, the issue related to conducting a gait analysis of children's legs. Beginning with the ideation and concept screening phases, we embark on a comprehensive exploration of the viability of the proposed product.

2. Need Statement

"A way to perform gait analysis in children to detect gait abnormalities.."

An imperative need exists for a method to comprehensively analyze the inability to detect gait abnormalities in children, which are often a result of incorrect gestures during childhood development. As many young individuals adopt improper stepping methods, gait abnormalities can manifest, potentially leading to conditions such as osteoarthritis. Traditionally, parents and elders have resorted to manual leg manipulation as a remedy, but it is increasingly evident that early intervention through precise analysis of gait patterns and bone structures during childhood is essential for effective treatment strategies.

3. Ideation

A brainstorming session was conducted on 19th September 2023 to create new ideas for this need statement. Newly proposed ideas that were generated through this brainstorming session are given below.

Figure 1: Brainstorming Canvas

4. Initial Concept Selection

After analyzing the above-proposed ideas, we chose some ideas because of some reasons. Feasibility and non-inversibility are the reasons that we considered. Gait abnormalities are very common among children but usually, we check them by using X-rays, looking at their walking patterns. But X-rays are sometimes harmful to our body cells. So, considering these causes we have chosen two solution ideas as given below.

4.1 Wearable shoes to detect gait abnormalities

The idea of this solution is a wearable shoe which is a walking abnormality detector. The system employs advanced pressure sensors strategically placed within footwear or on walking surfaces to capture the pressure distribution patterns during walking. We are going to hand over this product to the patient through the doctor. He or She should wear the product and walk for one or two days and after that, they should return to the doctor. From a mobile application, we will display the average weight distribution of that person's feet by analyzing the data given by the circuit that we placed in the shoe. We can detect walking abnormalities by comparing them with a normal weight distribution of feet.

4.2 Placing trackers for gait analysis.

We mainly use wearable trackers, and inertial measurement unit sensors which contain a three-axis accelerometer and three-axis gyro sensor to detect the movements of knees and ankles. Gyro sensors are used to sense the rate of change of angular movements of body parts. So, we can measure angular velocity, and angle and detect their abnormalities by using these sensors. The system incorporates advanced data analysis algorithms and machine learning techniques to interpret the collected data. These algorithms can identify normal and abnormal joint movement patterns and provide insights into joint health and performance.

4.3 Analyze gait using a pressure mattress.

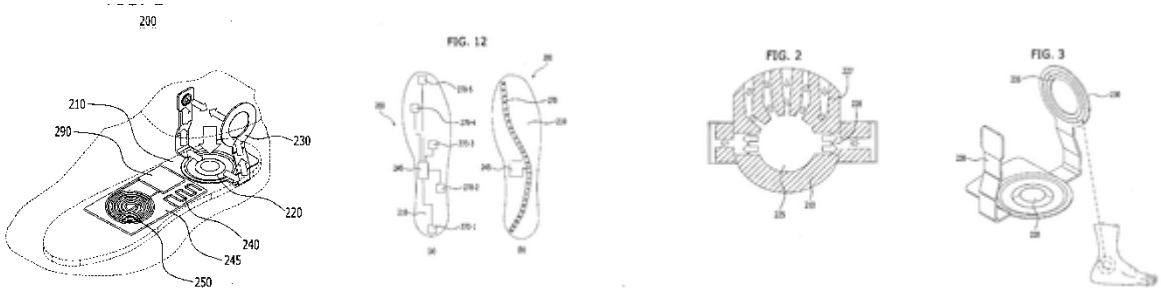
pressure mat is a specialized mat or sensor array that contains numerous pressure-sensitive elements. These sensors can be capacitive, piezoresistive, or other technologies capable of measuring the force applied to each sensor. Abnormal gait patterns give various deviations from normal gain patterns. Abnormalities can include irregular weight distribution, altered timing of foot movements, or variations in the COP trajectory.

5. Concept Screening

5.1 Intellectual Property (IP)

5.1.1 Wearable shoes to detect gait abnormalities

In this wearable shoe, there is a pressure sensing unit installed in the base to sense pressure, An acupressure unit has been installed to apply acupressure to the user's foot in response to the pressure sensing unit's readings. This wearable device further comprises a wireless communication unit that can be synchronized with an external mobile terminal. In addition to the pressure sensing unit, it also includes a flexible cushion. In this wearable device, it contains a battery to supply electric power, and a wireless charging coil provided in the base to charge the battery when placed in an external electromagnetic field.



[Patent 01] https://patents.google.com/patent/EP3061386B1/en?oq=EP3061386B1

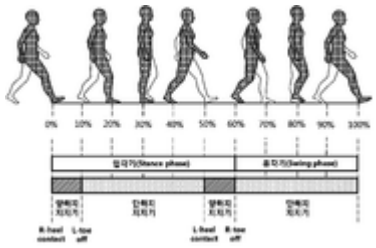
5.1.2 Placing trackers for gait analysis

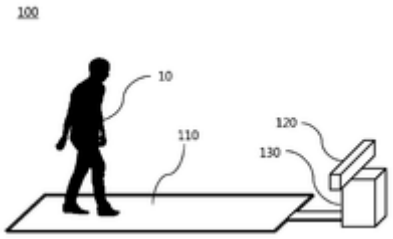
Analyzing human body motion with a device, system, and methods that use body-worn sensors. The gadget, which is frequently designed to be worn on the user's wrist, arm, neck, belt, or another area, has a CPU, an output device (typically a wireless transceiver), and at least one accelerometer, angle, location, direction, or physiological condition sensor. The CPU can be set up to perform several different tasks, including tracking sensor readings and analytical findings, identifying motion kinds, evaluating routine user behavior, and establishing typical baselines. When large departures from baseline values occur, a variety of algorithms may be employed to identify them, and the output device may then send data or warnings based on the type of departure.

[Patent 02] https://patents.google.com/patent/KR20230038133A/en?oq=KR20230038133A

5.1.3 Analyze gait using a pressure mattress.

This invention relates to an apparatus and a method for diagnosing a human body non-alignment syndrome using sole pressure and movement information of a human body, using a pressure mattress, which is capable of temporally synchronizing and collecting sole pressure of natural walking and movement information of a human body, and more accurately diagnosing a non-alignment syndrome by accurately grasping the characteristics of a whaling operation through single and related analysis by By the current innovation, To more accurately and quickly diagnose, it is possible to connectively analyze sole pressure, movement of upper and lower legs, sole pressure changes in each step for walking, and movement of a related musculoskeletal system on a time basis based on information measured in real-time through a sole pressure sensor and a 3D sensor. As a result, it is possible to make a trustworthy and impartial diagnosis. Additionally, a 3D sensor with a measurement limitation is used to correct for 3D data on a human body's movement based on measurements made by the 3D sensor using sole pressure patterns for each walking step and changes in sole pressure as a function of walking steps. Thus, it is conceivable to increase the accuracy of the data needed to identify a non-alignment syndrome and to create equipment that can do a thorough diagnostic of a non-alignment syndrome at a reasonable price. In locations where the equipment is required, such equipment is easily distributable.





[Patent 03] https://patents.google.com/patent/KR101902551B1/en?oq=KR101902551B1

5.2 Regulatory

Our product is classified as an FDA Class II medical device. It operates as a non-invasive monitoring device, and it is required to undergo a 510(k) clearance process before entering the market. This clearance ensures that our device complies with regulatory standards and is safe and effective for its intended use, as mandated by the FDA's rigorous evaluation procedures.

5.3 Reimbursement

Securing reimbursement for our biomedical product, which incorporates pressure distribution analysis in a smart shoe with Wi-Fi connectivity and open-source compatibility, presents a formidable challenge. Even with FDA clearance, it's vital to convince healthcare payers of its value in a healthcare environment with limited insurance coverage and government-funded hospitals. Aligning our innovative technology with existing reimbursement standards is crucial for its adoption and accessibility in this context.

5.4 Business Model

Since we are planning to first implement our solution in Sri Lanka, the price range of the product should be affordable and should suit the regulatory bodies. Since all the factors such as **revenue stream, price of the product, margin structure, sales investment, uniqueness of the product, IP protection, necessary clinical and regulatory hurdles, and reimbursement** can change dramatically based on these factors, it is very important to think about these aspects when designing the business model for each solution.

5.4.1 Wearable shoes to detect gait abnormalities.

Walking abnormality detector wearable shoes aren't available in Sri Lanka. This proposed wearable shoe can be built since the sensors that are needed can be found locally. And the price will be low relatively. And since the product is a wearable shoe, it will be easily used by the customer also. Therefore, the marketability of the product will be high.

5.4.2 Placing trackers for gait analysis.

These kinds of tracking devices are not available in Sri Lanka. And the needed sensors to build the product are also rare to find in Sri Lanka for an affordable budget. Since the patients have to carry this product around their respective body parts it won't be that much comfortable for the patient, therefore it will be hard to market the product and it will be hard to find sales investors for the product also.

5.4.3 Analyze gait using a pressure mattress.

Pressure mattress that can be used to detect walking abnormalities is accessible in Sri Lanka. And since we have to use an array of pressure sensors and collect data from all of those sensors, the initial capital will be high. However, the innovation won't be unique since there are already those kinds of pressure mattresses available in the laboratories. Therefore, marketability can be low.

5.5 Screening Matrix

We have already analyzed the feasibility of the products. The following screening matrix represents the process and abbreviations are employed as follows.

I. IP: Intellectual Property
II. RR: Regulatory Requirements
III. RI: Reimbursement
IV. BM: Business Model

Idea	IP	RR	RI	BM
01. Wearable shoes to detect gait abnormalities				
02. Placing trackers for gait analysis				
03. Analyze gait using a pressure mattress.				

Table 02: Risk analysis

The objective and concept abbreviations are as follows:

01. Wearable shoes to detect gait abnormalities.
02. Placing trackers for gait analysis.
03. Analyze gait using a pressure mattress.

Objectives	Weight	Invasive ICP (baseline)	1	2	3
Device must accurately give measurements	5	0	0	-1	1
The device must be Non-invensive	4	0	1	1	1
The device must cover the parameters of the whole leg	4	0	-1	1	-1
The materials and components can be easily found	4	0	1	-1	0
The device continuously measures the required parameters	3	0	1	-1	-1
The device must suitable for the children	3	0	1	0	1
Final Score			10	-4	5

Table 02: Objective and Concept Screening

6. Final Concept Selection

Following the screening analysis process, We have chosen to perform an analysis of pressure distribution via a shoe, as well as employing motion trackers for the analysis of bone patterns.

6.1 Prototype description

Pressure-Measuring Footwear:

This component consists of specially designed shoes equipped with the capability to measure the pressure distribution across the feet. The primary purpose of this component is to conduct gait analysis for the detection of incorrect postures. Embedded within the sole of each shoe are electronic load cell weighing sensors, strategically positioned in regions deemed critical for accurate weight distribution analysis. To ensure a comprehensive and reliable dataset, a minimum of 9 load cells is employed. It's worth noting that increasing the number of sensors enhances precision. The signals generated by each load cell are subsequently routed to a Microcontroller Unit (MCU) equipped with Wi-Fi connectivity. This enables direct communication with external devices such as computers or mobile phones, facilitating real-time data transfer and analysis.

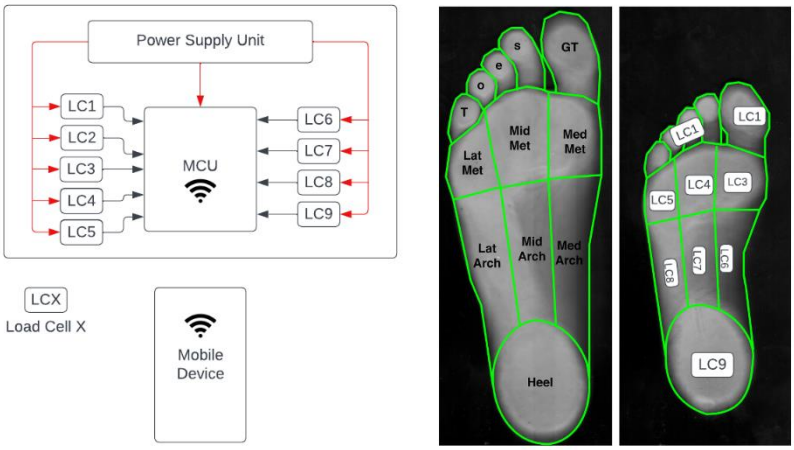


Figure 2: Block diagram of wearable shoe

6.2 Technical Feasibility

- Load Cells:

The use of 50kg load cells with a precision of 0.1% is technically sound for the intended purpose of measuring pressure distribution. These load cells offer the necessary sensitivity to capture subtle variations in pressure across different foot regions.

- Sensor Configuration:

The requirement for nine load cells aligns to measure pressure distribution across nine main parts of the foot. This is the minimal configuration. Increasing the number of sensors results in more precision. This configuration ensures comprehensive data collection, enhancing the accuracy and relevance of the results.

- Control Unit (ESP32):

The selection of the ESP32 as the control unit demonstrates technical feasibility. ESP32 is a versatile microcontroller with built-in Wi-Fi capabilities, making it suitable for data collection and communication tasks.

- Availability:

The availability of these load cells in the local market makes them easily accessible, reducing procurement challenges and ensuring a timely project implementation.

- Data Processing and Analysis:

The project's ability to communicate with external devices, collect data from multiple load cells, and perform calculations and analysis on the ESP32 is technically feasible. The ESP32's processing power and memory resources enable real-time data processing, ensuring the timely generation of results.

6.3 Concept Exploration and Testing

The testing phase of our pressure distribution measurement system for footwear is a critical aspect of ensuring the product's accuracy, safety, and reliability. To begin, our primary concern is user comfort and safety. We engage a diverse group of participants representing various foot patterns, including high arch (pes cavus), neutral arch, and low arch/flat-footed (Pes Planus) individuals (figure 1). These participants wear the footwear embedded with load cells for a specified duration, offering valuable insights into the product's usability and any potential discomfort.

In parallel, we conduct extensive pressure measurement testing. By monitoring and recording pressure data continuously while participants engage in common activities like walking or standing, we aim to validate the accuracy of our measurements. This data is then analyzed to calculate the average pressure across different foot sections. We cross-reference the results with known foot patterns to detect any discrepancies, ensuring that our system provides precise and reliable data. We can test our product with incorrect postures, apply unconventional pressure distributions to different sections, and also perform testing with patients in this domain with proper legal permission."

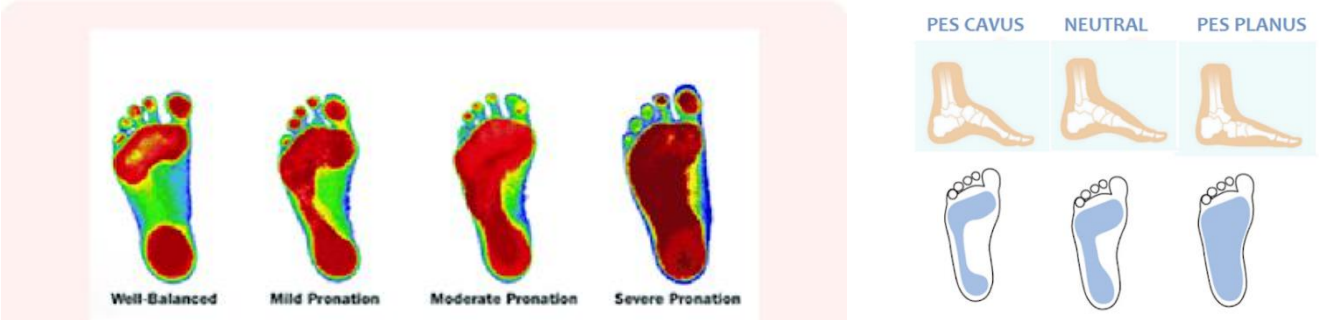


Figure 3

7. Conclusion

In conclusion, we can observe that wearable shoe is the most suitable and feasible solution to detect gait abnormalities because there are not any harmful methods for human. Sometimes, gate abnormalities can be caused to many health disorders. So, if we can identify it earlier, we may prevent these disorders. Our product has met this goal and doctors can easily detect these abnormalities, especially children.

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Appendix: Brainstorm Canvas

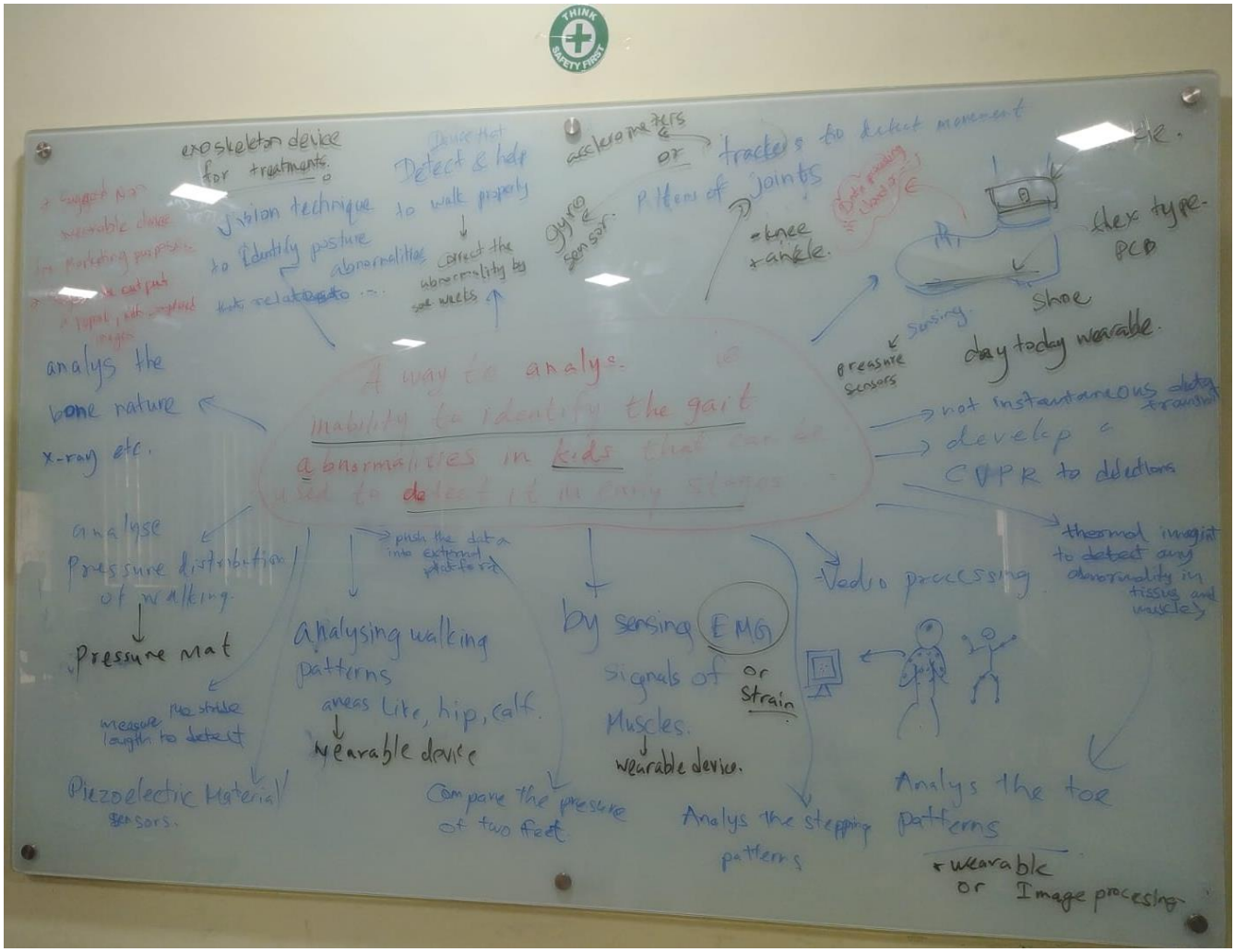

Figure 4

Figure 5: Source: “Bio-design: The Process of Innovating Medical Technologies” [1]

Stage 4: Concept Screening

Table 4.2.1 Device classification has direct implications on the number and complexity of the requirements imposed by the FDA.

Class	Examples	Description	FDA requirements
I	Bandages, tongue depressors, bedpans, examination gloves, hand-held surgical instruments	Class I devices present minimal potential harm to the person they are being used on and are typically simple in design.	With Class I devices, most are exempt from premarket clearance. There is no need for **clinical trials** or proof of safety and/or efficacy since adequate predicate experience exists with similar devices. However, they must meet the following “general controls”: • Registration of the establishment with the FDA. • Medical device listing. • General FDA labeling requirements. • Compliance with quality system regulation (**QSR**), with the exception of design controls, unless specifically called out in the regulation.
II	X-ray machines, powered wheelchairs, surgical needles, infusion pumps, suture materials	**Class II** devices are often non-invasive, but tend to be more complicated in design than Class I devices and, therefore, must demonstrate that they will perform as expected and will not cause injury or harm to their **users**.	Class II devices are generally cleared to market via the **510(k)** process, unless exempt by regulation. They must meet all Class I requirements, in addition to the “special controls” which may include: • Special labeling requirements. • Mandatory performance standards. • Design controls. • Post-market surveillance.
III	Replacement heart valves, silicone breast implants, implanted cerebellar stimulators, implantable pacemakers	Class III devices are high-risk devices. These are typically implantable, therapeutic, or life-sustaining devices, or high-risk devices for which a predicate does not exist.	Class III devices must generally be approved by the **PMA** regulatory pathway, although a small number are still eligible for 510(k) clearance. (FDA has begun the process of requiring PMAs for all of these.) Class III devices must meet all Class I and II requirements, in addition to stringent regulatory approval requirements that necessitate valid scientific evidence to demonstrate their safety and effectiveness, before they can be used in humans.