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Insole Design and Optimization Processes for Gait Analysis

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***Abstract*—Gait analysis is becoming increasingly central in various fields such as biomechanics, medicine, and sports. This complex study assesses how individuals walk, weighing in on aspects like bone alignment, joint range of motion, and neuromuscular activity. Its profound importance emanates from its capability to identify potential walking anomalies at an early stage, which can offset the need for invasive medical interventions and offer valuable insights for clinicians to make well-informed decisions. Inspiration for this in-depth gait analysis research was sourced from previous attempts that employed tools like step mats and cameras to track and analyze movement. Several design imperatives were consolidated within this framework, including the vital need of user safety, assuring comfort throughout usage, preserving system stability, and the undoubtedly significant feature of keeping the insole lightweight. These priorities were not merely for user comfort but were essential for the fidelity of the data being captured. In this paper, it is described the design and optimization processes of an insole for gait analysis following an agile methodology which involves the following stages: requirements, design, implementation and testing. This study delves deeply into the challenges of designing, implementing, and optimizing instrumented insoles for gait analysis. The requirements were successfully achieved by creating a 3mm-thick, flexible insole using TPU 95 material through 3D printing. This insole effectively encapsulates electronic components, ensuring comfort, durability, and safety.**

***Index Terms*—Gait analysis, insole, unobtrusive wearable**

I. INTRODUCTION

Acquisition systems for gait analysis can be found in literature based on wearable sensors, vision based devices and foot insoles considering presion and inertial sensors. Emerging as one of the key tools in this domain are instrumented insoles. Designed to fit comfortably within footwear, these insoles are perfectly positioned to capture detailed gait data from the primary source—the foot's sole. For them to serve their purpose effectively, they need to be not only ergonomic and user-friendly but also equipped with the right mix of electronic components for optimal data acquisition [1].

They then transition to discussing the shift to an SD card-based system, spotlighting the challenges inherent to its manual activation. Their discourse culminates in introducing their refined solution that seamlessly merges a WiFi module with an Alexa API, facilitating a more intuitive and remote user interaction. [1].

The remainder of the article is as follows: In Section 2, it provides a summary of the research works. In Section 3, the requirements, designs, implementation, and testing of the smart insole creation, along with all the issues and solutions, were addressed. Section 4 is dedicated to presenting the results of the testing phase, where the assessment of whether the established requirements were met will be discussed.

II. STATE OF THE ART

Gait analysis, an intrinsic tool for clinical diagnoses, has seen a significant evolution due to advancements in wearable technologies. A central pivot to this advancement is the design of insoles equipped with modern hardware to facilitate intricate data capture. In the early stages, insole designs for gait analysis were simplistic, focused on singular data points. Today's hardware is a culmination of years of engineering advancements and clinical needs. This section explores the current landscape of insole design from a hardware perspective. [2]

A. Sensing Modalities

One of the primary distinctions of modern insole analysis lies in the diverse sensing modalities employed [1]:

1) Inertial Sensors: These have become an integral part of gait analysis. Primarily placed in key areas of the insole, they meticulously record motion data. Their utility extends to capturing metrics like acceleration and angular velocity, giving a clear picture of the foot's movement during walking or running.

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2) Pressure Sensors: Their primary function is to record vertical ground reaction force (vGRF), a pivotal component in understanding how force is distributed across the foot during gait. The precise placement of these sensors across the insole creates a complete force map, giving significant information such as pressure points and weight distribution during different phases of gait.
3) Piezoelectric Sensors: A relatively newer addition, these sensors have a dual function. They can detect both deformation and impact forces. This ability to capture minute variations in gait is particularly useful for detecting subtle anomalies, especially in individuals with neurodegenerative conditions.
4) Electromyographic (EMG) Sensors: While not as commonly embedded within insoles, in specific specialized versions, these sensors offer insights into muscle activity. This is crucial for conditions where tremors or involuntary muscle movements play a role, adding an extra layer of data to gait analysis.

The advancements are illustrated in Figure 1. The model, proposed by Xie *et al.*in [1], incorporates several of the sensors previously mentioned.

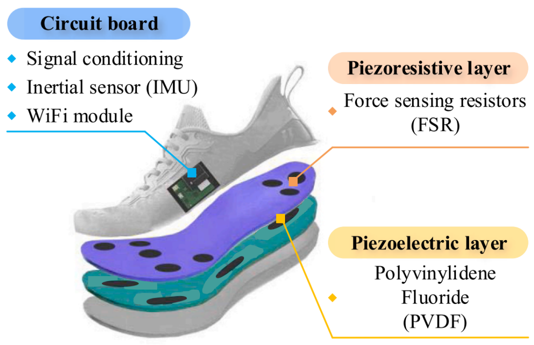

Fig. 1. Example of an insole design. Taken from [1]

B. *Integration and Miniaturization*

With the rapid advancements in microelectronics, there has been a paradigm shift in insole design. Sensors, once clumsy and obtrusive, have undergone significant miniaturization. This not only ensures the user's comfort but also allows for the embedding of multiple sensors within a single insole. The synergy of these sensors, provides a detailed overview of gait dynamics. [6]

For example, Zhao describes the current state-of-the-art in gait analysis data collection through the use of Shimmer Technology's Consensys Bundle Development Kit. This robust kit includes an assortment of Shimmer3 sensors such as a 9-DoF Inertial Measurement Unit (IMU), an Electrocardiogram (ECG), and Electromyogram (EMG) sensors. Each sensor node is not only compact, with dimensions of 65 mm x 32 mm x 12 mm, but also lightweight at 31 grams, making it well-suited for body-worn applications. The small size and light weight of these sensors allow for their integration into a confined space. [6]

C. *Wireless Capabilities*

The transition from wired connections to wireless systems has played an instrumental role in advancing the field of insole gait analysis. The modern gait analysis insoles harness the power of wireless technologies like Bluetooth and WiFi, enhancing the convenience, application range, and real-world data acquisition.

1) Bluetooth has been a game-changer in insole gait analysis. Its low energy consumption combined with a relatively good transmission range makes it perfect for real-time data transfer. The data collected from the sensors in the insoles can be instantly sent to a nearby computer, smartphone, or tablet for immediate analysis. [7]
2) While Bluetooth is excellent for short-range transmissions, WiFi capabilities in insoles elevate the scope of gait analysis. With WiFi-enabled insoles, data can be sent directly to cloud storage, allowing clinicians or researchers to access and analyze the data from anywhere in the world. This becomes especially valuable in longitudinal studies, where gait data over extended periods can offer insights into the progression of a condition or the efficacy of a treatment. [7]

For instance, LeMoyne highlights the evolution of accelerometer systems in gait analysis, shifting from tethered and data-logger approaches to robust wireless applications. These advancements have enabled wearable and wireless platforms, such as smartphones and portable media devices, to serve as reliable solutions for autonomous gait evaluation. [7]

Incorporating these advancements, today's gait analysis insoles are not only more accurate but also user-friendly and versatile. They offer a glimpse into the future of personalized healthcare, where devices adapt and respond to individual needs, powered by the synergy of hardware advancements and intelligent software algorithms.

D. *Recent Insole Approaches*

Sethi *et al.* [2] identified three major advancements in recent insole approaches, which can be grouped as follows:

1) Smart Adaptive Feedback: One of the most significant advancements in modern insoles is the shift from being passive data recorders to active advisors. These insoles do more than just monitoring foot pressure and movements. By using advanced algorithms, they offer real-time feedback to the user.

2) Machine Learning and Deep Learning Integration: The amount of data that these insoles can generate is astonishing. Advanced algorithms are employed to process this data, extract meaningful patterns, and offer actionable insights.

- Gait Pattern Analysis: Machine learning models are trained on thousands of different gait patterns, enabling them to detect anomalies in a user's gait. This is invaluable for early detection of potential issues.
- Predictive Analysis: Machine learning models can forecast potential risks based on the current walking patterns. For instance, it can alert users if their current walking pattern may lead to issues.

- Personalized Recommendations: Based on the data analysis, these algorithms can provide personalized suggestions, like exercises for foot health, show recommendations, or changes in walking/running form.

3) Self-calibrating Insoles: One of the challenges with wearable technology is ensuring that the data captured is accurate and relevant to the individual user. The newest insole designs faces these challenges by:

- User Profile Adaptability: Upon initial use, these insoles assess the user's weight, typical walking/running pattern, and shoe type. Using this data, they calibrate their sensors for optimal accuracy.
- Dynamic Re-calibration: As users change shoes, or even as their walking patterns change due to factors like fatigue, injury, or a new exercise regimen, these insoles continuously adjust their calibration settings to ensure that the data captured remains accurate.
- Automated Sensitivity Adjustments: Depending on user activity — whether they're jogging, hiking, or just walking — the insoles adjust sensor sensitivity, ensuring they capture the most relevant data for the activity at hand.

In conclusion, multi-sensor integration and improved data transmission technologies define the modern landscape of insole design for gait analysis. Traditional inertial and pressure sensors are increasingly being complemented with piezoelectric and electromyographic sensors, providing a more comprehensive picture of gait dynamics. The transition from wired to wireless data transmission systems employing Bluetooth and WiFi has transformed how and where gait data can be evaluated, allowing for real-time feedback and cloud-based longitudinal studies. Despite these advances, there are still areas that demand attention. Most notably, the creation of insoles capable of capturing a wider range of biometric data, the investigation of algorithms for better pattern identification, and the incorporation of self-calibrating characteristics for increased accuracy.

III. INSOLE DESIGN

Project management methodologies have played a crucial role in the development of projects since their inception. Traditional methodologies, such as the waterfall method, are notable for their linear flow of activities, making them popular choices. On the other hand, agile methodologies are designed for environments characterized by change and uncertainty. This study employs the agile methodology its rapid due to its prototyping capabilities, enabling data collection as the insole undergoes optimization.

A. Requirements for Insole Development

The requirements for designing the insoles are essential to ensure its effectiveness and safety during use, especially considering that these insoles will be worn by individuals.

1) The primary requirements: Focus on two key aspects: safety and comfort

- Safety: It is the top priority when designing these insoles. They must be safe to use without causing harm or discomfort to the individuals wearing them. This involves selecting materials that are both durable and safe, ensuring they do not cause discomfort or injuries during use. It is also essential to consider the stability of the insole to prevent slips or falls.
- Comfort: It is crucial to ensure that individuals can walk without any issues while wearing the insole. This involves designing them ergonomically and considering the distribution of body weight to reduce fatigue and discomfort during walking.

2) Secondary Requirements: In addition to the primary requirements of safety and comfort, there are also important secondary aspects to consider.

- Stability: The stability of the insole is essential to maintain proper foot positioning during walking. This helps prevent postural problems and injuries related to poor alignment.
- Lightweight: The lightweight nature of the insole is beneficial to ensure they do not add a significant burden to the user. This is particularly important to maintain comfort and prevent individuals from feeling like they are carrying extra weight while walking.

These secondary characteristics not only contribute to user safety and comfort but are also essential to ensure the accurate capture of relevant data. A user who feels uncomfortable or unsafe with the insole may alter their walking pattern, which would affect the quality of the collected data. Therefore, meeting these secondary requirements is crucial for the success of the project and to avoid the loss of significant information in gait assessment.

B. Design and Implementation

With the main and secondary requirements for the insoles established, the article proceeds with the design. The complete prototype is divided into two parts: the data collection part and the data storage part. Within each section, the article addresses the issues encountered during implementation and the solutions adopted.

1) Data Collection and data storage:: The insole incorporates a series of special sensors to measure precision and the individual's movement; as seen in Figure 2. The placement of the sensors was carefully considered based on the user's gait, with a focus on the rearfoot and forefoot regions. [4]

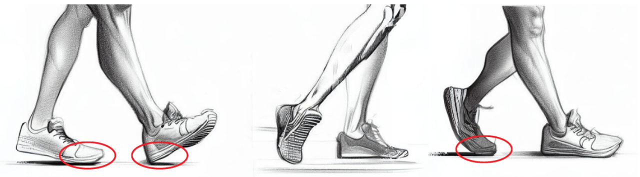

Fig. 2. Sketch of a where it represents the walk of a person and the key points for the sensors. Generated via [5].

Design decission 1 - Sensor Selection: Initially, the team considered placing six sensors, with one on the rear-foot and five on the forefoot, one for each toe. However, upon further analysis, they opted to simplify it to three sensors on the forefoot while retaining one on the rear-foot. Each of these sensors was included to capture relevant data about the foot that indicates identifiable aspects of a subject's gait.

Gait analysis primarily divides the walking cycle into the stance and swing phases. However, within these phases, various events occur that provide valuable insights into an individual's walking pattern. The team specifically focused on events such as heel strike, foot flat, heel rise, and toe-off, as these can help indicate subphases of the gait cycle [4].

To accurately capture these events, the team strategically positioned four pressure sensors within the insole. Here's how the sensor placement was determined:

- Heel Sensor: One sensor was placed in the heel or calcaneus region of the insole, as two events (heel strike and heel rise) are directly related to this area of the foot.
- Toe Sensor: Another sensor was positioned where the user's big toe would rest, corresponding to the toe-off event.
- Foot Flat Detection: Detecting the flat-footed phase was essential. While the distribution of weight between the other two sensors could indicate this phase, the team also placed sensors between these two locations to provide additional data on foot positioning. This choice was made to investigate if a user supinates (outward roll) or pronates (inward roll) during their gait.

In addition to pressure sensors, a gyroscope and accelerometer module were included in the insole design. These components enable us to capture and analyze movements during the user's gait cycle.In the Figure 3 you can show the position of the sensors and gyroscope.

To ensure user comfort and protect components from damage during use, all of these elements were carefully placed in a special insole created using a 3D printer and TPU 95 material. This design not only facilitates data collection but also improves the overall user experience.

Fig. 3. Sketch of a where the position where the sensors will be placed is represented. Generated via [5].

Design decission 2 - Location of Circuitry and Data Storage

In the initial stages of designing the insoles, the possibility of incorporating both the data collection and data storage circuitry directly into the insole was considered. However, as the design process progressed, a significant issue related to this decision became apparent.

The initial idea was to integrate all the electronic components within the insole itself. However, this presented significant challenges. Specifically, the insole would become too bulky and heavy, compromising the comfort and safety of the individuals wearing them. Furthermore, the circuitry could be exposed to damage due to repeated impact and pressure while walking.

To address this issue, the decision was made to separate the data collection circuitry from the data storage circuitry. The data collection circuitry remained within the insole, as it was essential for real-time recording and analysis of the gait pattern. However, the data storage circuitry was housed in an additional box that was attached to the user's calf muscle as shown in the Figure 4.

This separation solved several problems. Firstly, it prevented the insole from becoming uncomfortable and heavy, which would have made prolonged use difficult. Secondly, it protected the data storage circuitry from potential damage and ensured that the collected data was stored securely.

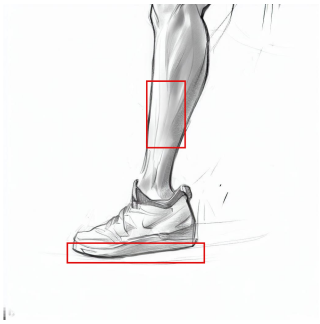

Fig. 4. Sketch of a review of the division of data collection with data storage. Generated via [5]

Design decission 3 - Data Transmission and Storage Method:

Initially, the plan was to transmit the data collected by the sensors via Bluetooth using the ESP32, taking advantage of its wireless capabilities. However, during testing, it became evident that this approach had several limitations and challenges.

One significant issue was data loss during transmission. The Bluetooth connection was prone to interference, leading to incomplete or corrupted data being received on the receiving end. This was problematic because accurate and complete data were crucial for a comprehensive gait analysis.

To address this challenge, an alternative solution was devised. Instead of relying solely on Bluetooth transmission, a secure and reliable method for data storage was introduced. A secure digital (SD) card module was integrated into the insole design. At the end of each gait analysis session, the data collected by the sensors would transferred to the SD card. This transfer ensured that no data was lost or corrupted during transmission.

Additionally, the use of an SD card offered the advantage of data redundancy. In case the data needed to be retransmitted or analyzed at a later time, the stored data on the SD card provided a reliable backup.

Design decission 4 - Activation of the Insole:

An important aspect addressed during the design and implementation of the insole was the method of activation. Initially, a manual approach was considered, which required both the user and the operator to connect the ESP32's battery simultaneously. However, significant drawbacks were identified with this approach.

The manual activation method was considered inconvenient for both the user and the operator, as it required precise synchronization when connecting the battery. This could result in delays and errors in activating the insole, impacting the efficiency of gait tests.

To address this issue and enhance the user experience, a more efficient and user-friendly solution was adopted. A voice-controlled switch was incorporated, allowing the insole to be activated through voice commands. This switch was designed to be compatible with virtual assistance devices like Amazon's ALEXA, enabling users to activate the insole simply by using their voice commands.

Additionally, a LED indicator was added to provide visual feedback on the activation status and proper functioning of the insole.

The voice-controlled switch and the status LED addressed several issues simultaneously. Firstly, they eliminated the need for precise synchronization between the user and the operator when connecting the battery, simplifying the activation process. Secondly, they provided a more intuitive and convenient way for the user to activate the insole using voice commands. Thirdly, the LED offered a clear visual indication of whether the insole was activated and functioning correctly, as well as whether the SD card was placed in the module.

The solution involved implementing a voice-controlled switch and an LED indicator to streamline activation and provide a smoother user experience during gait tests. This contributed to improving the usability and effectiveness of the device in gait analysis. Thanks to the ESP32 with its Bluetooth and WiFi capabilities, connectivity with ALEXA was achieved, allowing convenient voice control for insole activation.

In Figure 5 shows a Block Diagram of the connection order of the components.

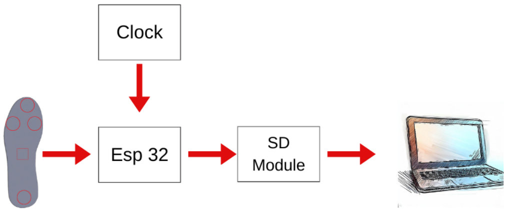

Fig. 5. Insole Block Diagram.

This carefully detailed design and implementation ensure that the insoles can collect precise data during different phases of the user's gait, contributing to a comprehensive analysis of their walking pattern. Additionally, the issues have been addressed and resolved to improve safety, efficiency, and user comfort, ensuring a product that meets the highest quality standards. Resulting in the following prototype shown in Figure 6.

Fig. 6. Developed Insole Prototype.

C. Insole Tests

To ensure that their innovative insole designs are not just technologically advanced but also practically viable, the team conducts rigorous tests. These tests serve two primary objectives: first, to verify that the insole remains comfortable and functional during various walking activities; and second, to ensure the integrity of the insole's data collection capabilities by checking for any loss of information or damage to cables during use.

1) Introduction: The test is designed to evaluate an individual's ability to walk in various trajectories, change directions, and navigate around obstacles. This test will provide insight into the individual's motor coordination, spatial awareness, and their ability to adapt to changing conditions.

2) Activities Description:

- Straight-Line Return Walk:
  Objective: Test the individual's ability to maintain a straight line and execute a precise 180º turn.
  Procedure: The individual begins at a marked starting point and walks in a straight line for a specified distance. Upon reaching the end of the walkway, they must complete a 180º turn and return to the starting position.
- L-Shaped Trajectory Walk:
  Objective: Assess the participant's ability to execute a 90º turn without veering off course.
  Procedure: Starting from a designated point, the participant will walk in a straight line, then make a 90º turn either to the left or right and continue walking. After covering a set distance, they return by tracing the same L-shaped trajectory in reverse.
- Diagonal Doorway Navigation:
  Objective: Evaluate the individual's ability to adjust their walking trajectory diagonally and navigate through a doorway.
  Procedure: The participant begins at a set start point, then moves diagonally towards a door, ensuring they pass through it. After clearing the doorway, they should

continue for a short distance, then return to the start point by retracing their steps.

- Obstacle Avoidance Walk:
  Objective: Assess how well the individual can adapt their path to avoid an obstacle without compromising their straight-line trajectory.
  Procedure: An obstacle (e.g., cone, box) will be placed at a certain point on the walkway. The individual will walk towards it and must navigate around it without breaking their stride or veering off their path, then return to the start.

3) Orientation Requirement: At the end of each activity, participants must ensure that they conclude facing the opposite direction to which they started. This tests their ability to maintain orientation even after various turns and maneuvers.

4) Repetition: If conditions allow, and to ensure consistency and accuracy in results, each of the four activities will be repeated three times. This results in a total of 12 recorded activities per individual.

5) Equipment and Setup: Marked walkway with non-slip surface. Obstacle (e.g., cone or box) for the obstacle avoidance activity. Stopwatch for timekeeping (optional). A doorframe or simulated door for the diagonal walk. Markings or indicators for starting and ending points.

6) Safety Precautions: Ensure the area is free from hazards. Participants should wear the designated footwear. Observers should be present to assist participants in case they lose balance.

IV. INSOLE TESTS RESULTS

Throughout the development and testing process of the smart insoles, successful compliance with established requirements and designs has been achieved. The primary goal was to create a solution that is safe and comfortable for users while being capable of accurately collecting gait data, and this goal has been remarkably achieved.

One of the most notable accomplishments is the creation of flexible insoles with a thickness of only 3 mm. This thinness ensures user comfort during walking, while flexibility allows the insoles to naturally adapt to foot movements. Furthermore, it has been demonstrated that these insoles are sufficiently robust to accommodate all necessary electronic components without compromising their durability or sensor integrity. The use of 3D printing with TPU 95 material has been instrumental in achieving this success, ensuring insole comfort, resilience, and safety. This innovative design surpasses established objectives and promises to be a valuable solution in gait analysis.

V. CONCLUSION AND FUTURE WORK

The decision to utilize the agile methodology for this project was pivotal. Gait analysis, being an intricate and continually evolving field, needed a development strategy that was flexible and could quickly adapt to the dynamic challenges and needs of the domain. The agile approach facilitated exactly this—a receptive and iterative development process that allowed the project to address unforeseen obstacles, fine-tune requirements based on real-world feedback, and consistently ensure alignment with end-user needs. The meticulous journey encompassed everything from selecting the appropriate materials, designing electrical schematics, and finally creating 3D-printed prototypes using flexible materials that seamlessly incorporated all the electronic components. Emphasis is given to the indispensable role played by each embedded sensor—be it for measuring pressure, detecting gyroscopic movements, or tracking acceleration—in ensuring granular and accurate data capture.

One of the standout facets of the study is the remarkable evolution witnessed in data collection methodologies. Earlier designs mandated data collection at hourly intervals. This was significantly optimized, with the process now condensed into a concise 20-minute window. This transformation not only amplifies operational efficiency but also enriches the frequency and depth of data insights. In a broader sense, this research gives a complete picture of the complexities and obstacles involved in creating an optimal instrumented insole for full gait analysis. It exemplifies the power of iterative design, user-centric thinking, and an uncompromising dedication to data precision. The insights and lessons learned from this study are crucial, and they have the potential to guide future projects in biomechanical instrumentation and beyond. While the advances in this subject are remarkable, there are limitations that must be addressed. Potential areas of future exploration include enhancing battery longevity, improving sensor durability, fine-tuning the electronic components to ensure they don't interfere or influence natural gait, and broadening data analytics capabilities.

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