

Development of vibrated insole (Vibin) shoes prototype in preventing diabetic foot ulcers

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Published online: January 31, 2025

Accepted for publication: January 15, 2025

DOI:10.7752/jpes.2025.01023

Abstract:

Introduction: The global incidence of diabetes mellitus has increased by 11 million cases. If untreated, diabetes can lead to the development of diabetic foot ulcers (DFUs). Poor blood circulation, a common pathology diabetes can exacerbate DFUs. Vibration wound therapy has been shown to enhance the healing process of DFUs, through the use of vibrating insoles which improves microcirculation and helps prevent the onset of DFUs. **Objective:** To develop a prototype of vibrating insole shoes for the DFU prevention due to problems in blood circulation in diabetic patients. **Methods:** The researchers use Vibin's product development in the Research and Development (R&D) method with the ADDIE model which consists of literature study, design, manufacture, assembly, feasibility testing and evaluation. There were 8 healthy male and female students as the subjects with body weight less than 70 kg, with shoe sizes 39, 40, 41 or 42, doing regular moderate physical activity (valued by Global Physical Activity Questionnaire or GPAQ), and not experiencing heart disease, hypertension, diabetes mellitus, and no history of foot injury. Subjects were wearing insole vibrating shoes while walking on a treadmill for 30 minutes in speed not more than 3.0 mph.

Keywords: Diabetic foot, vibrating insole, shoes

Introduction

Diabetes mellitus (DM) is a disease with big number that continues to increase in the world. The incidence of DM worldwide has increased more than 11 million cases in 1990 to 22,935,630 cases in 2017 worldwide (Liu et al., 2020). According to data from the International Diabetes Federation (IDF) in 2021, the number of diabetics in the world reached almost 57 million people in the age group of 20-70 years (IDF, 2021). In Indonesia, from blood sugar checks, DM cases increased from 6.9% in 2013 to 8.5% in 2018 (Ministry of Health of the Republic of Indonesia, 2018). The risk of death is even greater in uncontrolled DM, because it can cause many complications, such as diabetic foot syndrome (Yunir et al., 2022). DM has an impact on the occurrence of chronic limb-threatening ischemia (CTLI), especially in the lower extremities. Lower extremity peripheral artery disease, or which often refers to peripheral artery disease (PAD) does not only include atherosclerotic diseases but also various pathogenesis, such as vasculitis, fibromuscular dysplasia. However, atherosclerotic disease of the extremity arteries is the majority form of PAD (Takahara, 2021). Untreated PAD will immediately develop into Diabetic Foot Ulcer (DFU) (Wang et al., 2022).

The prevalence of DFU patients in Indonesia is 15%. The incidence of DFU each year is 2% among all DM patients and 5-7.5% among DM patients with peripheral neuropathy (Sari et al., 2020). DFU ulcers are found in various areas of the foot, including digits, hallux, forefoot, midfoot, hindfoot, ankle, distal cruris, medial cruris, proximal cruris, knee to femur. DFU presents varying degrees of severity. If left untreated, DFU can progress to Diabetic Foot Infection, potentially leading to tissue necrosis and, ultimately, amputation (Mponponsuo et al., 2021). The prolonged wound healing observed in people with type 2 DM is attributed to hyperglycemia, systemic inflammation, and reduced microcirculation leading to amputation. Amputation caused by DFU accounts for half of the non-traumatic lower limb amputations. However, 40% of leg amputations can be prevented with good wound care (Lung et al., 2020).

Two main problems experienced by diabetic foot sufferers, are peripheral artery disease (PAD) and diabetic neuropathy. Poor blood flow supply is an important pathological factor that leads to the development and worsening of DFUs. Neuropathy in people with DM occurs due to the metabolic problems caused by hyperglycemia (Deng et al., 2023). The production of myoinositol which is essential for regular neuronal

transmission, decreases due to the accumulation of sugar products in nerve cells. The chemical conversion of glucose results in increased oxidative stress and vasoconstriction in nerve cells, leading to ischemia and subsequently promoting nerve cell damages and death (Syabariyah et al., 2023). Therefore, an integrated management approach for diabetes mellitus (DM) is necessary, with exercise, such as walking, being a key component (Haris et al., 2024).

Walking is a recommended exercise for people with DM because of being able to increase glucose uptake, also improves DM risk factors such as obesity and hypercholesterolemia (Dempsey et al., 2016). However, a significant portion of people with DM do not engage in regular exercises, which exacerbates the progression of DM towards more severe complications. Foot reflexology has proven to reduce HbA1C which is an indicator of chronic DM and Ankle Brachial Index which is an indicator of decreased peripheral tissue perfusion (Yodsirajinda et al., 2016). Low-Strength High-Frequency Vibrations can improve muscle contractility and blood microcirculation (Yu et al., 2017). Vibration Wound Therapy has also improved the healing of diabetic neuropathic ulcers in terms of healing speed, wound closure area, healing score, and increased Nitric oxide levels (Haba et al., 2024; Syabariyah et al., 2023). The use of low-frequency vibrations has improved healing in patients with DFU (Mahran et al., 2013). Applying intermittent vibrations to the metatarsal has been shown to improve Skin Blood Flow diabetic foot (Ren et al., 2019).

Despite advances in wound care, gaps persist in preventative strategies. Patients with diabetes often face barriers to engage in preventative care, such as the limited awareness of early interventions. Extensive evidence suggests that vibration therapy enhance tissue perfusion and address various risk factors associated with DM. Consequently, individuals with DM may benefit from the use of leg vibration devices to improve blood microcirculation. This intervention can potentially prevent the onset of diabetic neuropathy and DFU. Currently, vibration therapy can be administered by using various foot massage tools. However, existing devices are often stationary, limiting their usability. Furthermore, vibrating shoes have been developed to provide mobility and therapeutic benefits even though they lack the capability to adjust the vibration frequency, presenting a significant limitation in their effectiveness.

DFUs impose a significant burden on healthcare systems and patients, leading to prolonged hospitalizations, reducing mobility, and lowering quality of lives. Despite advancements in therapeutic devices, portable and user-friendly options for preventative care remain scarce. The development of a wearable device is essential to address this unmet need. Vibin, a vibrating insole, addresses these gaps by integrating vibration technology into a portable, user-friendly device. Vibin is a prototype vibrating insole which can be used for walking or running. Vibin provides vibration on the foot that can be used at any time by simply connecting the insole to a smartphone via bluetooth. The vibin can also adjust the vibration to the user's comfort level. The use of Vibin may enable individuals with DM of sustaining leg tissue perfusion, thereby mitigating the risk of developing DFU. This article presents the development and initial testing of Vibin, highlighting its potential to revolutionize DFU prevention. Future research will encompass trials involving diabetic patients.

Material & methods

Study Design

This research uses the Research and Development (R&D) model. Development research is a research method used to produce a specific product and to test the effectiveness of the product. This development research uses the ADDIE model (CHRMF, n.d.). The ADDIE model consists of five stages, including Analyze, Design, Development, Implementation, and Evaluation. This research has been reviewed and approved by the Ethics Committee of the Faculty of Dentistry, Universitas Airlangga (927/HRECC. FODM/VIII/2023).

The steps to implement ADDIE are presented in the Figure 1.

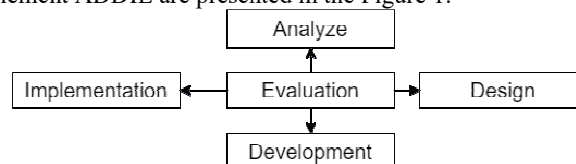


Figure 1. Flow Chart of Research Design

The description of the method in this study focuses on the planning and calculation procedures, the manufacture of Vibrating tools, and the calibration and testing of each sensor.

1) Analyze

The analyze steps based on the literature study include planning block diagram and wiring based on its work, designing program code for the instrumentation prototype, determining the components needed at the time of manufacturing the tool, designing the instrumentation prototype along with its PCB, calibrating- each sensor on the instrumentation prototype, planning the application design, and planning the application block code on the MIT App Inventor.

2) Design

At this stage, the design or creation of application design and insole vibrating is carried out, as well as the design and development of other supporting devices such as storyboards and application flowcharts. The design team began to design the content of the application and vibrating the insole in accordance with the prototype that had been studied according to the literature study. The design of the app's content is tailored to the user's characteristics, ensuring a better user experience and in accordance with their needs and desires. MAX30102 was chosen as a sensor compared to other infrared sensors to measure physical pressure parameters, because of simpler data reading and space utilization in device arrangement combined with the MLX90614 sensor which has been tested for its validity as a temperature measuring tool. Wemos D1 Mini microcontroller was chosen because of the ability to use bluetooth technology in data transmission, as well as the 0.96" OLED that could display stress parameter measurement data; therefore, the use of space in device arrangement would be complex. In addition, for prototype power, we used a lippo battery that could last for 60 minutes. There are 2 vibration sensors located on the metatarsal head. In addition to being able to be used for walking, the vibrating insole-could also be used for running so that a thick upper of the shoe, a soft and elastic insole and an outsole made of pheyllon and rubber materials were chosen (Figure 2).

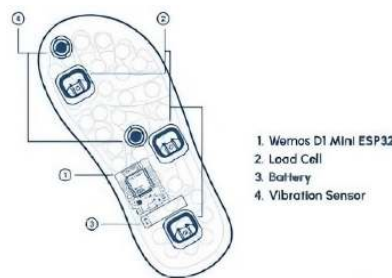


Figure 2. Machine Specifications

3) Development

The tool development process began with design modeling and layout, followed by the creation of prototype Using project board and manufacturing Program Prototype instrumentation. The next step of assembling components with tools and materials included- Wemos D1 mini ESP32, cable, insole, outsole sensor vibration, the upper of the shoe made of Phyllon and fiber, lippo batteries, solder, tin and paste. There were four sizes assembled, namely 39, 40, 41, and 42. Then it continued with the laying of Insole at outsole and the upper of the shoe. After all components were made, testing, calibration, and accuracy testing of the tool were carried out. If the results were not in accordance with the criteria, then improvements were made - for the preparation of the code. The process continued with the production of prototypes of physical parameters by using the PCB along with the box. If the results meet the criteria, the stage of making the tool is considered complete. All processes of creating the tool are shown in the Figure 3.

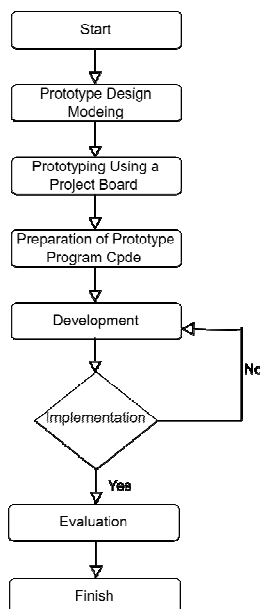


Figure 3. Manufacturing Design Flow Chart Instrumentation Prototype

4) Implementation

There are several minimum device specifications needed for the application in implementing the use of the application with the Android platform. The device must have sufficient memory and be able to connect to the internet for accessing to the additional information that is not available offline. Before being officially implemented, the developed applications will undergo to application trials and validation done by material experts and media experts. After gaining validation, the app that is considered feasible will be tested to the user subject. The prototype vibrating insole test on the subject was carried out to determine the functionality and comfort of the prototype vibrating insole when used.

The test was carried out on 8 students of Medical Faculty of Malang State University (female and male), which meet these criteria : body weight is less than 70 kg, having shoe sizes 39, 40, 41 or 42, doing regular moderate physical activity (valued by Global Physical Activity Questionnaire or GPAQ), and not experiencing heart disease, hypertension, diabetes mellitus, and no history of foot injury. Subjects were wearing insole vibrating shoes while walking on a treadmill for 30 minutes in speed not more than 3.0 mph. The insole vibrating shoes were connected to the Vibin app in mobile phone with bluetooth to activate and regulate vibration. The results of the test can be known for the functionality of vibration and comfort from the use of vibrating insole shoes as well as the condition of the pulse when using it on the treadmill. The effectiveness test of using Vibin on DFU prevention will be confirmed in the next study.

5) Evaluation

We carry out the evaluation at each stage so that the results of the developed vibrating insole prototype can function properly. At the implementation stage, the evaluation is carried out by improving the prototype from the results of respondents. The subjects filled the assessment sheet on a likert scale with the following details (Table 1.)

Table 1. Prototype feasibility assessment

Aspects	Indicator	Assessment Scale					Comment
		1	2	3	4	5	
Product	Quality of materials used						
	Comfort when used while walking						
Feature	The usefulness of features in health sandals						
	Quality of vibration features in vibration insoles						
	Battery life in use						
	The effectiveness of using the app on product vibration settings						

Results

Table 2. Characteristic of respondents

No	Sex	Age	Activity level	Weight (kg)	Average speed of walking (mph)	Shoe size
1	F	19	Moderate	50	3.0	39
2	F	19	Moderate	52	2.8	39
3	F	19	Moderate	55	3.0	40
4	M	20	Moderate	60	3.0	40
5	M	20	Moderate	58	3.0	41
6	F	19	Moderate	48	2.9	41
7	M	20	Moderate	57	3.0	42
8	M	19	Moderate	56	3.0	42

From Table 2, we can see that all respondents have a daily moderate physical activity level, measured by GPAQ. We recruited male and female respondents because they could give different perception in valuing the comfort.

We do not use respondents with low physical activity to avoid fatigue or muscle injury during the exercise. Respondents walked in a various speed in range of 2.8 to 3.0 mph for 30 minutes.

Table 3. Result of Product Feasibility Assessment

Aspects	Indicator	Respondent							
		1	2	3	4	5	6	7	8
Product	Quality of materials used	5	5	5	5	5	5	5	5
	Comfort when used while walking	5	5	5	5	4	5	4	5
Feature	The usefulness of features in health sandals	4	4	3	4	3	4	4	4
	Quality of vibration features in vibration insoles	4	3	3	4	4	4	4	4
	Battery life in use	3	3	3	4	4	4	4	4
	The effectiveness of using the app on product vibration settings	4	4	4	4	3	3	3	4

From Table 3, all respondents gave positive feedback on quality materials used for the insole and shoes, while majority (80%) feel comfortable using the shoes for walking on the treadmill. However, respondents expressed dissatisfaction with certain features due to several limitations of the product. Notable weaknesses including the absence of a battery charge indicator make it challenging to predict charging duration. Moreover, a one-hour charge can power the insole for 30 minutes, adequate for daily walking. Additionally, the product lacks a power button to turn off the battery, causing the Vibin to remain on until the battery is depleted. These issues are targeted for improvement in the forthcoming Vibin 2nd version.

Discussion

Exercise, coping strategies, and continuous health education are very important in managing diabetes and lowering HbA1c levels (Haris et al., 2024). Several studies support that low-frequency vibration therapy can help improve blood perfusion and assist wound healing in diabetic patients (Mahran et al., 2013; Yu et al., 2017). This therapy helps enhance peripheral blood flow in the feet, an area susceptible to DFU due to neuropathy and peripheral artery disease (PAD) (Ren et al., 2019). Vibin, with its adjustable frequency of up to 60 Hz, has the potential to provide these benefits practically and integrate into the daily activities of diabetic patients, which conventional, generally static vibration therapy devices cannot offer.

Prototype vibrating insole has several advantages over the vibrating device that has been created previously. Vibin uses soft materials which comfortable to use for diabetics. Diabetics are advised to avoid footwear made from hard materials, as such shoes can potentially cause injuries to their plantar (Gerrard et al., 2020). Reducing peak plantar pressure (PPP) is a key factor in preventing diabetic foot ulcers (Haris et al., 2021).

Individuals at high risk of developing foot ulcers is recommended to wear shoes with inner air insoles (80 mmHg) (Haris et al., 2023). In another research, it is shown that walking with a pressure of 160 mmHg for 10 min has a lower risk of DFU (Ramadhan et al., 2024). Future research must be conducted to prove that Vibin can reduce the peak plantar pressure as well.

In addition, Vibin is user-friendly, requiring only a connection to a Bluetooth application installed on a smartphone, allowing users to easily adjust the vibration frequency from 5Hz to 60Hz. It features a rechargeable battery and is made from comfortable shoe materials. The vibration points are strategically placed at the head of the first metatarsal and the middle of the second metatarsal, areas highly susceptible to developing DFU (Lindholm et al., 2019). This placement ensures that the vibration is effective and evenly distributed across the entire sole of the foot. The Vibin features a battery capacity that allows for more than 60 minutes of operation on a single charge, enabling two sessions of 30 minutes each. Additionally, it includes a soft insole, an customized outsole made of phylon and fiber, and a thick upper, ensuring comfort during walking or running.

The effectiveness of the Vibin is enhanced when utilized during walking, as it might promote better circulation and tissue perfusion in the lower extremities. This active engagement ensures more uniform distribution of the therapeutic vibrations, potentially improving outcomes for people with DM. Walking at a speed of 5-8 km/h at moderate speed (50-60%) of the maximum pulse rate (220-age) can improve arterial elasticity, eliminate tissue salamander blood flow deposition and decrease blood glucose (Moggetti et al., 2021). Even it is still in early steps and need further development, Vibin shows potential in mitigating the risk of DFU by diminishing neuropathy, peripheral vascular disease, impaired blood microcirculation in patients with DM.

Besides the physiological benefits, this study also indicates that Vibin has the potential to provide a positive psychological impact for diabetic patients. The uncertainty around complication risks often leads to

anxiety in patients, ultimately affecting their quality of life (Mponponsuo et al., 2021). By providing an easily accessible device that can be used anytime and adjusted for comfort, Vibin can give patients a sense of security in managing their health. Thus, this device not only helps prevent DFU but also enhances the overall quality of life for diabetic patients.

The process began with a comprehensive literature review to identify key design requirements. Prototypes were developed by using advanced materials and components, including Wemos D1 Mini microcontrollers and MAX30102 sensors. Testing involved 8 healthy participants to evaluate functionality and comfort. Feedback informed iterative improvements, ensuring the final product met both technical and user needs. The findings highlight Vibin's potential to improve patient outcomes through enhanced microcirculation and usability. Vibin's development underscores the importance of innovative, patient-centered approaches in diabetes care. The device's scalability and accessibility make it a valuable addition to preventative health strategies. Recommendations include exploring advanced features such as real-time data monitoring and integration with healthcare platforms.

Initial testing of Vibin demonstrated its potential as a practical tool for DFU prevention. Participants reported high levels of comfort and functionality, validating the prototype's design and usability. Vibin bridges the gap between traditional, stationary devices and the need for portable solutions, offering diabetic patients a convenient way to maintain foot health and prevent DFUs. This study advances the understanding of vibration therapy's role in enhancing microcirculation and preventing complications in diabetic patients. By integrating vibration technology into a wearable device, we can say that Vibin provides a scalable solution for diabetes management, potentially reducing the incidence of DFUs and associated healthcare costs. Future research should focus on clinical trials with diabetic patients to validate its efficacy further. Wounds, signs of ischemia (as seen from Ankle Brachial Index, Ankle Systolic Pressure, Transcutaneous oxygen pressure) and clinical manifestations are ways to determine the classification or degree of DFU (Wang et al., 2022). Therefore, future research must be carried out to test Vibin against all these indicators.

Conclusions

The prototype vibrating insole (Vibin) still needs improvement in the forthcoming Vibin 2nd version. The development of Vibin marks a significant step forward in DFU management by integrating vibration technology into an insole device that can be used daily. Although there are some technical limitations in this prototype, initial results indicate that Vibin has the potential values as a practical and effective DFU prevention solution. With further improvements in design and feature enhancement, Vibin could become a valuable health aid for diabetic patients, offering comfort and security in preventing serious complications such as DFU.

Conflicts of interest

The authors declare no conflict of interest in relation to this study.

Acknowledgment

This research was funded by the Decentralization Fund of the Faculty of Medicine, Universitas Negeri Malang, Indonesia in 2024. The authors extend their gratitude for the financial support provided

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