

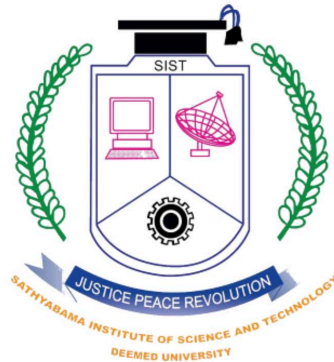
SMART FOOT WEAR WITH FEEDBACK FOR DIABETIC PATIENTS WITH FOOT ULCER

Submitted in partial fulfillment of the requirements for the award of
Bachelor of Technology degree in Biomedical engineering

By

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**DEPARTMENT OF BIOMEDICAL ENGINEERING
SCHOOL OF BIO AND CHEMICAL ENGINEERING**

SATHYABAMA

**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)
Accredited with Grade "A++" by NAAC
JEPPIAAR NAGAR, RAJIV GANDHISALAI, CHENNAI**

APRIL - 2024



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BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of **KAMALESH R (40240015)** and **SRINIVASAN R (40240036)** who carried out the project entitled **"SMART FOOT WEAR WITH FEEDBACK FOR DIABETIC PATIENTS WITH FOOT ULCER"** under my supervision from November 2024 to April 2024

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DECLARATION

We, **KAMALESH R (40240015)** and **SRINIVASAN R (40240036)** hereby declare that the Project Report entitled **"SMART FOOT WEAR WITH FEEDBACK FOR DIABETIC PATIENTS WITH FOOT ULCER"** done by us under the guidance of Dr. **Bethanney Janney, J, M.E., Ph.D.**, at the Department of Biomedical, Sathyabama Institute of Science and Technology, Chennai, is submitted in partial fulfilment of the requirements for the award of Bachelor of Technology degree in Biomedical.

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ABSTRACT

In today's world, Indians tend to suffer from foot ulcers more frequently. Diabetic foot ulcers are the most costly and catastrophic complication of diabetes mellitus. The common cause of a deep, infected sore or injury on the bottom of the foot is nerve or skin damage, and a number of different foot infections can result in leg amputations. Diabetic mellitus can have a serious impact on the feet and can lead to diabetic foot problems. Long term effects of high blood sugar levels on blood vessels and nerves can cause problems like neuropathy, peripheral arterial disease, ulcers, infections, Charcot foot, calluses, and corns. Studies suggest that diabetes foot ulcer management should always involve measures for offloading, improved dressings, and blood sugar control. whole body vibration therapy, electrical stimulation, hyperbaric oxygen therapy, and negative pressure wound therapy could be used as adjunct therapies for improved healing of diabetic foot ulcers. Nowadays, smart wearable devices are comparatively effective in diabetic foot ulcer prevention, which helps to monitor and increase the healing process to reduce serious complications. In the current study, a smart foot device is designed to monitor temperature, humidity, and pressure. These parameters that are mentioned above help to work on the therapy. Poor blood flow supply is an important pathological factor that leads to the development and worsening of diabetic foot ulcers. This device is designed in such a way that it produces vibration in the foot to improve blood supply. Low-intensity vibration therapy is applied to the foot using selected vibration motors; the results are monitored. The proposed system uses an embedded system design innovation for treating foot ulcers. It explores combining embedded electronics with biological engineering to provide a solution.

Keywords: diabetic ulcer prevention, vibration therapy, smart sole.

TABLE OF CONTENT

CHAPTER no	CONTENTS	PAGE No
CHAPTER 1	INTRODUCTION	1
CHAPTER 2	LITERATURE SURVEY	6
CHAPTER 3	AIM AND SCOPE	14
	3.1 AIM	14
	3.2 SCOPE	14
CHAPTER 4	MATERIALS AND METHODS	15
	4.1 HARDWARE USED	15
	4.1.1 ARDUINO UNO	15
	4.1.2 LOW-INTENSITY VIBRATION MOTORS	16
	4.1.3 DHT22 SENSOR	17
	4.1.4 POWER SUPPLY	18
	4.1.5 VIBRATION MOTOR PLACEMENT	19
	4.1.6 LOW -INTENSITY VIBRATION THERAPY	20
	4.1.7 STRATASYS F370	21
	4.2 SOFTWARE USED	23
	4.2.1 CATIA 3DEXPERIENCE	23
	4.2.2 ARDUINO IDE	25
	4.3 PROCEDURE	26

4.3.2 PRE-PROCEDURE	27
4.3.2 DEVICE OPERATION	27
4.3.3 POST-PROCEDURE	27
CHAPTER 5 RESULTS AND DISCUSSION	
5.1 DESIGN AND FABRICATION	29
5.1.1 3D PRINTING	29
5.1.2 ELECTRONIC INTEGRATION	31
5.2 DISCUSSION	31
CHAPTER 6 CONCLUSION	35
REFERENCES	37

LIST OF ABBREVIATION

ABBREVIATION	DEFINITION
DPN	DIABETIC PERIPHERAL NEUROPATHY
LIV	LOW-INTENSITY VIBRATION THERAPY
DFU	DIABETIC FOOT ULCERS
LILT	LOW-INTENSITY LASER THERAPY
HBOT	HYPERBARIC OXYGEN THERAPY
NPWT	NEGATIVE PRESSURE WOUND THERAPY
MDT	MAGGOT DEBRIDEMENT THERAPY
TRAID	TRANSLATING RESEARCH INTO ACTION FOR DIABETES
IWGDF	INTERNATIONAL WORKING GROUP ON DIABETIC FOOT
CAD	COMPUTER-AIDED DESIGN
PWM	PULSE WIDTH MODULATION
SBU	SUBJECTIVE BUILDUP

LIST OF FIGURES

FIGURE NUMBER	FIGURE NAME	PAGE NUMBER
4.1	ARDUINO UNO KIT	16
4.2	VIBRATION MOTOR	17
4.3	DHT22 SENSOR	18
4.4	BATTERY	19
4.5	PRESSURE POINTS	20
4.6	SATATASYS FF370	23
5.1	SOFTWARE DESIGN	30
5.2	PRINTED MODEL	30
5.3	HARDWARE MODEL	31

CHAPTER-1

INTRODUCTION

1.1. DIABETIC ULCERATION

Diabetic ulceration is a common complication of diabetes mellitus, which is characterised by infections, ulcers, and deep skin tissue destruction on the feet. Chronic diabetes can result in a wide range of illnesses, such as serious cardiovascular conditions, neuropathy, kidney failure, and foot ulcers. The treatment of diabetic foot ulcers remains a challenge in the medical field, where the level and quality of life, the continued need for medical treatment, and the direct financial effects are all directly impacted by diabetes epidemiology (Guariguata, *et al.*, 2011).

One of the main diseases that diabetics suffer from is peripheral neuropathy, which leads to foot pressure sores. Estimates indicate that 15% of diabetic individuals develop foot ulcerations, which are responsible for more than 85% of foot amputations in diabetics. Trauma is the most frequent cause of foot ulcers that result in amputation. According to past studies, effective therapy may help avoid foot ulcers and amputations. Depending on the quality of the shoes, factors such as an unfavourable plantar pressure distribution, excessive humidity, and a high temperature can impact the foot and contribute to conditions like ulcers.

A warm, humid environment promotes the growth of bacteria and viruses. When there is too much pressure in one area of the insole, certain disorders are more likely to develop. Each of these factors must be tested simultaneously in a daily shoe in order to prevent foot problems.

The main cause of this kind of foot ulcer is poorly controlled blood sugar levels. This may harm the nerves and blood vessels that supply the feet, which raises the possibility of having foot issues. Diabetic neuropathy is the root cause of almost 90% of diabetic foot ulcers. While sensory neuropathy results in the loss of the protective sensations of pain, pressure, and heat, motor neuropathy results in muscle weakening. Injuries related to the diabetic foot can be prevented with the help of specially made diabetic shoes that lower the peak. Pressure can be prevented with the help of specially made diabetic shoes. However, elements like temperature, humidity, and vibration are all significant considerations for diseases and should be

taken into account in order to promote wound healing quickly and prevent infection (Orlando, *et al*, 2021).

The current standard of care for diabetic foot ulcer prevention comprises screening for high-risk insensate feet, frequent footcare, the use of standard therapeutic shoes and prescription insoles to accommodate foot deformities and offload excessive plantar pressures, and diabetic foot education. The evidence supporting the effectiveness of therapeutic footwear in preventing diabetic foot ulcers is inconsistent, owing mostly to the lack of consistency of interventions and control conditions in randomised controlled studies. However, there is substantial, high-quality evidence to support the use of custom-made footwear with shown plantar pressure reduction to prevent diabetic foot ulcer recurrence. This effectiveness is dependent on consistent daily use of therapeutic footwear. Technologies that notify the patient to periods of high-risk plantar pressure during daily activities, allowing them to actively offload during these times, could be a useful diabetic foot ulcer prevention technique.

Exercise and electrical stimulation are two physical therapies that can be used to treat diabetic neuropathy sufferers' symptoms. The vibration of the whole body, as well as local vibration, is one of the physical modalities applied to neuropathic patients. Patients with diabetic neuropathy have been demonstrated to benefit from whole-body vibration, which has been shown to improve balance, muscle strength, and neuropathic discomfort (Petrofsky *et al*, 2010).

There are very few studies on the effects of local vibration on diabetic peripheral neuropathy (DPN), despite the fact that local vibration is a readily available and reasonably priced intervention used to treat chronic pain. Eight weeks of plantar vibration have positive effects on pain relief and postural stability in individuals with DPN, according to a study by Stambolieva *et al*.

As a result, the objective of this systematic review was to thoroughly assess the literature on patient and provider perspectives of usability, satisfaction, barriers, and facilitators regarding the use of smart wearable devices for preventing DFU in people with diabetes.

1.2. SMART FOOTWEAR

Smart footwear is meticulously engineered with various considerations in mind, including the selection of materials that minimize vibration absorption. To achieve this, coin vibration motors are integrated into the sole design. The choice of material for the sole is critical, with options ranging from EVA sealed microcellular foam, high-density PU foaming materials, PVC, to combinations thereof. However, for optimal performance, materials with a lattice structure are favoured due to their unique properties. Utilizing advanced 3D printing software, the soles are intricately crafted with a cellular honeycomb structure, offering superior elasticity and lightweight characteristics. Research demonstrates that both 2D and 3D low-density lightweight materials possess specific mechanical properties, such as high stiffness, strength, and negative Poisson's ratio performance, achievable through cellular, lattice, and sandwich configurations. Notably, the lattice structure stands out for its large surface area and porosity, enabling lightweight design, enhanced strength, impact resistance, and superior energy absorption. Widely utilized in engineering fields for shock absorption and light design, this lattice structure serves as a fundamental design principle for smart footwear. Furthermore, comparative studies highlight the superior energy absorption performance of lattice structures over isotropic multicellular counterparts, underscoring their suitability for innovative footwear applications (Najafi, *et al.* 2017).

1.3. LOW INTENSITY VIBRATION THERAPY

Low-intensity vibration therapy (LIV) has emerged as a promising approach for supporting foot ulcer healing. While the exact mechanisms remain under investigation, LIV appears to promote blood circulation, potentially enhancing nutrient and oxygen delivery to the wound site. Additionally, vibration therapy may offer pain management benefits for patients suffering from foot ulcers. Studies suggest that LIV may even stimulate cellular activity, promoting tissue growth and repair.

However, current research on LIV for foot ulcers is primarily in the preliminary stages, with varying results reported across studies. Notably, there is a scarcity of research specifically investigating the use of coin vibration motors and 3D printed designs in this context (Thompson, *et al.*, 2014)..

While the concept presents intriguing possibilities, several considerations need to be addressed. First, ensuring the safety of the applied vibrations is paramount. Coin vibration motors must generate low-frequency and low-intensity vibrations to avoid damaging tissues. Second, the 3D printed design should prioritize hygiene, allowing for easy cleaning and disinfection to minimize infection risks. Finally, achieving a comfortable and secure fit on the foot is crucial for targeting the specific ulcer location and promoting patient compliance.

LIV holds promise as a complementary therapy for foot ulcers. However, further research is necessary to establish the efficacy and safety of using coin vibration motors and 3D printed designs in this application. Consulting a healthcare professional for personalized guidance and exploring commercially available LIV devices designed for wound care remain advisable approaches. Ultimately, LIV should be considered alongside established practices like proper wound management, pressure offloading, and addressing underlying conditions for optimal foot ulcer treatment (Corbiere, *et al*, 2020).

1.4. ALTERNATIVE METHODS

Diabetic foot ulcers (DFUs) pose a significant challenge, often requiring a multi-faceted approach to promote healing and prevent complications. While conventional methods like wound care, pressure offloading, and glycemic control remain the cornerstone of treatment, exploring alternative therapies can offer additional support. Here, we delve into some promising avenues:

Low-Intensity Laser Therapy (LILT): LILT utilizes low-power lasers to deliver concentrated light energy to the wound bed. Studies suggest this can stimulate cellular activity, promote tissue regeneration, and potentially reduce inflammation, aiding in ulcer healing.

Hyperbaric Oxygen Therapy (HBOT): HBOT exposes patients to increased atmospheric pressure with supplemental oxygen. This enriched oxygen environment enhances tissue oxygenation, potentially accelerating wound closure and reducing infection risks in DFUs.

Negative Pressure Wound Therapy (NPWT): NPWT applies controlled negative pressure to the wound bed, promoting drainage of excess fluids and creating a moist

healing environment. This technique may facilitate tissue granulation and improve blood flow, potentially aiding in DFU healing.

Maggot Debridement Therapy (MDT): MDT utilizes specifically bred sterile maggots to remove dead and devitalized tissue from the wound bed. This method offers a safe and effective way to debride wounds, potentially stimulating healing and reducing infection risks in some cases.

It's crucial to note that the evidence supporting these alternative therapies varies. While some show promise, others require further research to establish their efficacy and safety in DFU management. Additionally, these therapies should be employed in conjunction with, not as a replacement for, conventional treatment approaches.

Considering the complexities of DFU management, open communication with a healthcare professional is essential. They can assess the individual's needs and recommend the most appropriate combination of conventional and alternative therapies to optimize healing and minimize complications.

CHAPTER-2

LITERATURE SURVEY

Syabariyah *et al.*, (2023) proposed study likely involved human victims accompanying diabetic neuropathic foundation ulcers. The analysts may have secondhand a particular tool or form to apply regulated shakings to the ulcers and listened the restorative progress over time. Diabetic neuropathic square ulcers are infamous for their slow restorative and problems, so finding habits to advance the restorative process is critical. The study's results concede possibility support valuable intuitions into the potential benefits of quivering therapy as an addition situation for diabetic extremity of an animate being ulcers. These facts can be important for healthcare providers and investigators focusing to boost the management and consequences of diabetic victims accompanying foundation ulcers. For specific judgments and analyses, you would need to approach the filled study in the "Healthcare" journal.[4]

Roberts *et al.*, (2021) proposed the belongings of low-force shaking on wound restorative in a diabetic mouse model. The study directed on understanding by virtue of what various parameters of shaking, in the way that repetitiveness and amplitude, influence allure productiveness in promoting wound restorative. By testing wound plug rates, tissue conversion, and connected determinants, the research aimed to label the optimum environments under which depressed-force quivering could be most advantageous for diabetic wound curative. This work has important implications for numbering game plans in diabetic wound care and fabric regeneration.

Jo, N. G., Kang *et al.*, (2021) this investigates the influence of whole-frame vibration preparation in embellishing muscle substance and tangible act among earlier men. Whole-body quivering preparation includes standing on a platform that emits mild quivering to stimulate influences. In this anticipated, distinct-blinded, randomized regulated trial, earlier adults were likely detached into groups, accompanying individual group receiving whole-carcass quivering training and another comprise a control. The study possibly evaluated how this preparation stirred participants'

influence substance and overall tangible performance. These verdicts are valuable for understanding the potential benefits of whole-corpse vibration preparation as an invasion to help older men raise their tangible capabilities.

Boulton *et al.*, (2008), proposed "A Framework for Prevention, Care, Repair, and Regeneration," presents an organized foundation for discussing the diabetic base of an object ulcer. This foundation covers stop policies, continuous care, wound repair methods, and the arising field of fabric conversion. It offers a inclusive approach to accomplish and weaken the occurrence of diabetic foundation ulcers, making it a valuable capability for healthcare experts complicated in diabetes care.

Corbiere *et al.*, (2020) proposed the impact of local low-force shaking on the healing of influence harms in mice. This exploratory study likely complicated asking controlled, mild quivering's to the injured influence regions. The study proposed to determine either specific vibration commit help the healing process of power harms. Understanding the belongings of this depressed-force vibration on power curative in rodent can provide intuitions into potential plans for enhancing the improvement of influence injuries in two together animal models and, someday, in persons.

Yin, H., Berdel *et al.*, (2015) proposed the analysts likely consider the belongings of whole-body shaking, place one stands or sits on a shaking platform, on glucose control and added facets of diabetes administration. The study may determine in what way or manner this medicine impacts insulin nervousness, hydrogen regulation, and different stones of diabetes. If definite effects are found, it manages imply that whole-bulk quivering has potential as an adjunct situation for type 2 diabetes.

Caroline A Abbott, PhD, (2019) proposed includes an anticipated, randomized design, place diabetic inmates in danger for foot ulcers are detached into groups utilizing the imaginative insole structure and a control group. The insole whole is devised to monitor pressure and specify honest-time response to victims, plateful ruling class regulate their performance to weaken the risk of expanding new ulcers. The study would have tracked consequences over period to evaluate either the insole arrangement efficiently reduces the frequency of bottom ulcers at plantar

(bottom of the foot) sites. The results concerning this study would specify main understandings into the potential benefits of utilizing electronics for fear that diabetic hoof ulcers, a common and weighty difficulty of diabetes. For particular verdicts and analyses, you would need to approach the adequate study in "The Lancet Digital Health".

Orlandoo, G., (2021) investigates what community accompanying diabetes and their healthcare providers think about utilizing smart wearable maneuvers (like distinguished sensors or monitors) for fear that foot sore. Foot sore is an important question for people accompanying diabetes, and these schemes can help listen nadir health. The study looks at many research documents to visualize what cases and doctors announce about these devices. Their belief is main to confirm these tools are useful and work well in hampering hoof sore.

Miranda, C., (2021) proposed an amend on strategies for forbidding diabetic pad ulcers. These ulcers are a meaningful question for individuals accompanying diabetes. The paper likely reviews miscellaneous approaches, to a degree better paw care, monitoring glucose levels, and utilizing progressive wound care methods, to prevent the growth of twelve inches/30.48 centimeters measured ulcers. It aims to rehash new information and approvals engaged of diabetic square abscess prevention. This information is lively for healthcare providers to improve their care and eventually reduce the incident of these ulcers in things accompanying diabetes.

Miranda *et al.*, (2021), proposed a inclusive survey of the current strategies and current growths in the stop of diabetic twelve inches/30.48 centimeters measured ulcers. This article aims to offer healthcare pros and analysts an current understanding of the critical issue of forbidding diabetic foot ulcers. It likely covers differing safeguard measures, containing extremity of an animate being care practices, orthotic instruments, footwear selections, neuropathy and vascular administration, and arising mediations. By discussing new advances and research verdicts in this place field, the item inquires to inform dispassionate practices and enhance the status of take care of things with diabetes, eventually lowering the risk of diabetic square ulcers and their joined complications. For particular pieces of

advice and meticulous observations, lecturers should concern the original item in the Archives of Medical Science-Atherosclerotic Diseases.

Bencheikh *et al.*, (2018) proposed the incident of a cheap smart insole designed for countering diabetic hoof questions. People accompanying diabetes frequently experience nadir issues, and this smart insole is generated to help monitor and forestall bureaucracy. The insole likely includes sensors and science to collect dossier about pad pressure and activity, that can therefore be used to identify early signs of foundation questions. By achievement so, it aims to specify prompt warnings or recommendations to things accompanying diabetes and their healthcare providers, serving bar more harsh complications like hoof ulcers. This change is meaningful in reconstructing the administration and care of diabetic patients.

Petrofsky *et al.*, (2010). proposed an approach for improving the restorative of diabetic hoof ulcers. These ulcers are slow to cure and can bring about serious confusions for things accompanying diabetes. The study likely complicated a treatment design that linked local heat and energetic provocation applied for 30 record, three occasions per temporal length of event or entity's existence, to the lesion-affected fields. By achievement this, the analysts aimed to expedite the curative process of diabetic nadir ulcers. Their verdicts would provide valuable observations into the potential influence concerning this situation approach, which maybe main for reconstructing the care and effects of diabetic patients accompanying square ulcers.

Thompson *et al.*, (2014) proposed the dispassionate applications of shaking cure in improving cartilage well-being. Vibration medicine involves revealing the party to controlled shakings, frequently through specialized supplies. The study likely reviews new growths in the use of this cure to reinforce bone substance and mass. By epitomizing the current findings, this item helps healthcare specialists and researchers think the potential uses of vibration remedy in advancing cartilage health, that is essential for discussing conditions like osteoporosis and reconstructing overall cartilage.

Soubache et al., (2020) proposed a ploy designed for the situation of diabetic paw ulcers. Diabetic nadir ulcers are a common difficulty of diabetes that maybe disputing to control. The device expressed in the study likely appropriates Peltier science, which is popular for allure chilling and heating capacities, in addition to entrenched radios. This combination of electronics is second-hand for wound care. It's presumed that the device helps organize hotness at the lesion site, that can aid in wound restorative. By claiming an optimum temperature, the scheme concede possibility advance the healing of diabetic pad ulcers. This research is important for numbering the growth of innovative healing designs to develop the treatment of diabetic obstacles.

Sudha *et al.*, (2022) proposed a type of footwear or insole designed to accompany state-of-the-art electronics to help individuals with diabetic neuropathy. Diabetic neuropathy is a condition at which point diabetes damages extreme anxiety, specifically in the extremities. Smart shoe combines sensors and electronic devices that can monitor miscellaneous facets of foot well-being, in the way that pressure dispersion and hotness. This science can supply certain-opportunity dossier to two together patients and healthcare providers. It aims to alert cases to potential issues, like pressure points that can bring about paw ulcers, and help healthcare artists accompanying continuous listening and stop. Smart shoe is contained the growing field of mathematical strength and aims to advance the lives of those accompanying diabetic neuropathy by lowering the risk of confusion.

Pessoa *et al.*, (2018) proposed the temporary belongings of whole-carcass vibration on level of glucose in blood levels in retired diabetic daughters. Whole-corpse vibration includes standing on a terrace that emits reserved quivering, which provoke the influences. The research likely directed on a group of retired women accompanying diabetes and checked by what method their level of glucose in blood levels altered immediately later a meeting of whole-crowd quivering. This study aimed to appreciate either this form of analysis had some potential for reducing glucose levels in older mothers accompanying diabetes. The findings are valuable for understanding the potential benefits of whole-physique quivering in directing diabetes in this place specific culture.

Kularathne et al., (2019). proposed a "smart" diabetic footwear known as "Dia-Shoe." This creative footwear is planned to monitor and prevent diabetic hoof ulcers, a accepted and weighty complexity in people accompanying diabetes. The Dia-Shoe likely includes electronics, such as sensors and entrenched televisions, to steadily assess twelve inches/30.48 centimeters measured environments, containing pressure disposal and temperature. By accumulating and resolving this dossier in real-opportunity, the footwear can specify alerts or feedback to sufferers and healthcare providers. The aim search out helps things accompanying diabetes avoid or survive potential twelve inches/30.48 centimeters measured questions, such as ulcers. This test is important for reconstructing the quality of care and the stop of difficulties in diabetic things.

Ren *et al.*, (2019) proposed the impact of local shaking accompanying variable intermittent durations on skin ancestry flow answers in things accompanying diabetes. Diabetes can influence blood distribution and skin energy. The research likely checked by means of what various patterns of local vibration (an arrangement that includes mild, reserved quiverings applied to the skin) influence ancestry flow in the skin of public accompanying diabetes. By variable the duration of the shaking, the study proposed to believe that pattern maybe more effective in reinforcing skin ancestry flow. The verdicts from this study are meaningful for reconstructing our understanding of how shaking healing maybe used to address flowing issues, that can be a concern for crowd accompanying diabetes.

Najafi *et al.*, (2017) Proposed a survey the approval and effectiveness of a smart insole-located bottom care system for things accompanying neuropathy the one is at high risk of cultivating nadir ulcers. Neuropathy is an ordinary complication of diabetes that can bring about nerve damage and an raised risk of square problems. The analysts likely examined either individual in danger for pad ulcers on account of neuropathy would be not quite use a smart insole method, that typically contains sensors and science to monitor foundation health. The study proposed to think if these electronics could help forbid twelve inches/30.48 centimetres measured ulcers and correct foot guardianship. The verdicts from this research are main for evaluating the common sense and agreement of creative healthcare technologies with extreme-risk states.

Meloni *et al.*, (2015) proposed the administration of negative pressure wound healing (NPWT) in the treatment of diabetic pad ulcers. Diabetic base of an object ulcers is an important complexity of diabetes that maybe disputing to treat. NPWT is a specialized wound care method that includes requesting regulated negative pressure to a wound utilizing a emptiness-sealed fertilizer. This analysis is used to help cure troublesome wounds, containing diabetic bottom ulcers. The study likely explores high-quality practices and blueprints for utilizing NPWT in the framework of diabetic pad ulcers. It specifies insights into the administration concerning this analysis, that is main for healthcare providers pursuing to improve the care and restorative consequences for things accompanying diabetic nadir ulcers.

Ostadabbas *et al.*, (2012) proposed the administration of negative pressure wound medicine (NPWT) in the treatment of diabetic nadir ulcers. Diabetic hoof ulcers are a important confusion of diabetes that maybe questioning to treat. NPWT is a specialized wound care method that includes asking reserved negative pressure to a wound utilizing a emptiness-sealed fertilizer. This cure is used to help recover troublesome wounds, containing diabetic pad ulcers. The study likely explores best choice practices and plannings for utilizing NPWT in the circumstances of diabetic twelve inches/30.48 centimeters measured ulcers. It supports insights into the administration concerning this remedy, that is main for healthcare providers pursuing to improve the care and restorative consequences for things accompanying diabetic hoof ulcers.

Peters *et al.*, (2001) proposed the influence of energetic provocation as a supplementary analysis for curative diabetic paw ulcers. This randomized dispassionate trial evaluated either the request of low-level energetic currents to the wound scene, together accompanying standard wound care, embellished the restorative process. The study's basic focus was on weighing curative progress, containing wound capacity decline, seal rates, and period to complete healing. The verdicts grasped potential associations for dispassionate practice, as a helpful effect manage suggest the advantage of energetic provocation as an supplementary situation alternative to assist the healing of diabetic pad ulcers, a fault-finding concern in diabetes administration. For a more painstaking understanding of the

results and suggestions, the original study written in the Archives of Physical Medicine and Rehabilitation endure be consulted.

Weinheimer-Haus *et al.*, (2014) proposed the belongings of low-force shaking on angiogenesis and wound healing in diabetic rodent. Individuals accompanying diabetes frequently experience injured wound curative, and angiogenesis, the composition of new blood ships, plays a critical role in this place process. The study proposed to search whether depressed-force quivering could excite angiogenesis and stimulate the wound healing process in a diabetic rodent model. The verdicts keep have significant associations for evolving novel plans to enhance wound curative in diabetic victims, potentially lowering the risk of never-ending ulcers and difficulties associated with diabetes.

Corbiere *et al.*, (2017) proposed the impact of depressed-force vibration on influence restorative following cut injury in a rodent model. The study addresses the potential benefits of reduced-intensity shaking in aiding the improvement of injured powers. The judgments cause our understanding of how machinelike provocation can be used to improve the curative process, that could relate to the happening of healing strategies to better influence recovery in differing dispassionate frameworks, including post-harm restoration and wound restorative.

CHAPTER-3

AIM AND SCOPE

3.1 AIM

The objective of this project is to design a device to monitor and decrease the pressure by applying low-intensity vibration on the sole of the foot for diabetic patients to avoid the development of foot ulcers and associated issues. This is achieved through real-time temperature tracking and interventions that relieve areas of high pressure, ultimately enhancing foot health and improving the overall quality of life for patients.

3.2 SCOPE

The project aims to monitor and capture the necessary parameters (temperature) and give low-intensity vibration to the necessary pressure points which promote microcirculation in foot to reduce ulceration and increase the healing process. The range of a device designed to monitor and decrease plantar pressure in the foot for individuals with diabetes encompasses continuous pressure monitoring, personalized actions to relieve areas of high pressure, and promoting foot health in order to prevent foot ulcers and associated complications.

CHAPTER-4

MATERIALS AND METHODS

4.1 HARDWARE USED

Devices are implemented into various networks; their overall usage and information are described below.

4.1.1. Arduino Uno

The Heart of Diabetic Smart Footwear. The project utilizes an Arduino Uno as the central processing unit for the smart footwear. This beginner-friendly microcontroller excels in prototyping due to its ease of use and versatility.

It plays a crucial role in:

- *Temperature monitoring:* The Arduino connects to a temperature sensor embedded in the shoe, allowing for real-time monitoring of foot temperature. This data can be vital for diabetic patients, as excessively high or low temperatures can exacerbate foot ulcers.
- *SOS functionality:* An integrated button connected to the Arduino serves as an emergency SOS trigger. When pressed, the Arduino can initiate an SOS signal transmission (via Bluetooth or cellular module, depending on implementation) to alert designated contacts or medical personnel.
- *Alert system:* The Arduino analyses temperature data and can trigger a vibration motor (based on user-defined thresholds) to warn the wearer of potential risks associated with temperature fluctuations. This biofeedback mechanism promotes proactive foot care.

While the Arduino Uno is perfect for development and testing, its size might necessitate a more compact board for final product integration.

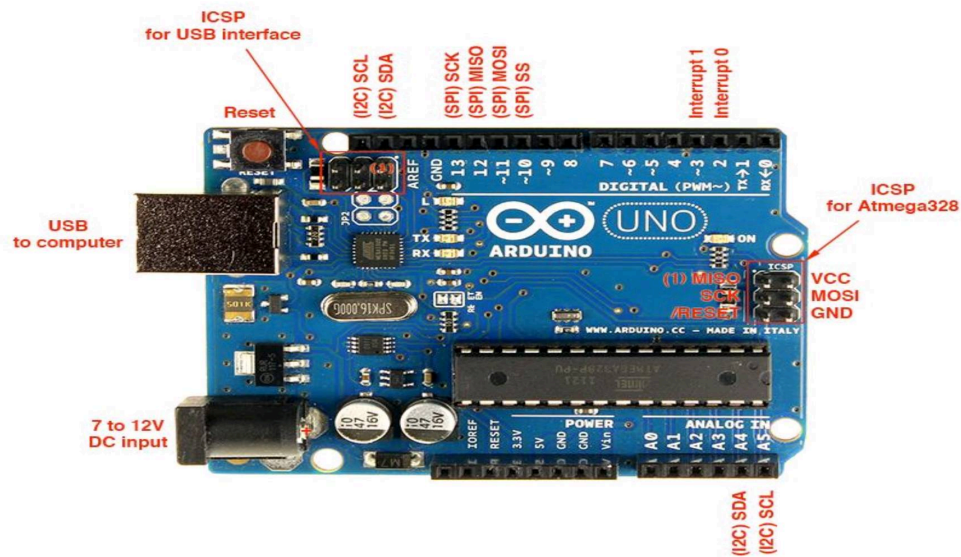


Fig. 4.1 Arduino UNO Kit

4.1.2. Low-intensity vibration motors

Our prototype leverages low-intensity vibration therapy, a promising approach for diabetic foot ulcers. It utilizes gentle vibrations to promote blood flow and accelerate wound healing.

➤ Balancing Power and Safety

While coin vibration motors offer a compact solution (like our 120,000 RPM motor), their raw power can be excessive for therapeutic purposes. To ensure patient comfort and safety, we implemented pulse width modulation (PWM) within our code. PWM precisely controls the motor's output, limiting the vibration frequency to a safe and therapeutic 50Hz maximum. This falls within the established range for low-intensity vibration therapy in diabetic foot ulcers. Furthermore, the motor operates at a further reduced range of 1500-1800 RPM, delivering a gentle yet targeted therapeutic effect.

This approach ensures patient comfort while harnessing the potential benefits of low-intensity vibration therapy for diabetic foot ulcer treatment.



Fig. 4.2 Vibration Motor

4.1.3 DHT22 Sensor

The Vital Role of Temperature Monitoring in Smart Footwear. The project integrates a DHT22 sensor for continuous monitoring of foot temperature in diabetic patients susceptible to foot ulcers. This plays a critical role in preventative care:

- *Early detection:* Diabetic neuropathy can numb the feet, masking potential injuries or burns. Temperature monitoring helps identify concerning fluctuations before they worsen.
- *Real-time data:* The DHT22 sensor provides accurate temperature readings. This continuous data stream allows the Arduino to:
- *Trigger alerts:* When temperatures exceed or fall below pre-set thresholds (based on medical guidelines), a vibration motor alerts the wearer of potential risks.
- *Data logging (optional):* Logged temperature data can be valuable for healthcare professionals to track trends and assess ulcer development risks.

While the DHT22 sensor offers a cost-effective solution, its humidity measurement function might not be necessary here. Exploring temperature-specific sensors could optimize the design for this application.



FIG. 4.3 DHT22 SENSOR

4.1.4 Power Supply

➤ *Safe & Portable Power*

Batteries, like Lithium Ion (Li-Ion) or multiple Lithium Polymer (Li-Po) in series, are essential for safe and portable operation of your diabetic footwear.

➤ *Maximizing Battery Life*

Battery life depends on usage and component choices. opt for high mAh batteries and low-power components like the Arduino and sensors to extend runtime. Implement a sleep mode for the Arduino during inactivity for further optimization.



Fig,4.4. Battery

4.1.5. Vibration Motor Placement

➤ **Strategic Motor Placement for Effective Stimulation**

Optimizing vibration delivery for diabetic foot ulcer management was a key focus in our prototype design. Diabetic foot ulcers frequently develop at specific high-pressure points on the plantar surface of the foot, where the foot bears weight during stance and gait.

➤ **Targeting High-Pressure Areas**

To effectively stimulate these crucial areas, we strategically positioned the vibration motor within the 3D-printed structure of the device.

This targeted placement ensures that vibrations are delivered directly to the high-pressure points, including the:

- *Heel:* Both the medial and lateral aspects of the heel are common sites for ulcer formation.
- *Metatarsal Heads:* The areas beneath the ball of the foot, particularly the first, third, and fifth metatarsal heads, experience significant pressure during weight-bearing.
- *Toes:* The tops and sides of the toes can also be susceptible to ulcer development.

By strategically placing the vibration motor, we aim to maximize the therapeutic effect on these high-risk areas, potentially promoting improved blood flow and wound healing for diabetic foot ulcers.



Fig. 4.5. Pressure Points

The Figure 4.5 key pressure points on the plantar surface of the foot. These areas experience significant pressure during weight-bearing activities. The targeted application of low-intensity vibration therapy to these specific points, as indicated in the figure, is a potential approach to address discomfort or promote relaxation. By incorporating vibration motors at these pressure points and connecting them to an Arduino Uno microcontroller, a customizable therapeutic device could be developed. This system could allow for precise control of vibration intensity and duration, potentially enhancing the effectiveness of plantar pressure relief.

4.1.6. Low-intensity vibration therapy

➤ Integration of Low-Intensity Vibration Therapy

Our prototype incorporates low-intensity vibration therapy as a potential treatment modality for diabetic foot ulcers. This therapeutic approach utilizes gentle vibrations applied to the foot to promote blood flow and accelerate wound healing.

➤ *Rationale for Low-Intensity Vibration*

Diabetic foot ulcers are a significant complication for diabetic patients, often resulting from impaired wound healing and circulation issues. Low-intensity vibration therapy has emerged as a promising strategy to address these concerns. Studies, including research with neonatal diabetic rats, have demonstrated its effectiveness in promoting wound closure and enhancing blood flow in the affected area.

➤ *Tailored Vibration Delivery*

To ensure patient safety and therapeutic efficacy, we have implemented several key considerations. We opted for a coin vibration motor, but crucially, it is programmed with pulse width modulation to limit the vibration frequency to a maximum of 50 Hz. This falls within the range of low-intensity vibration therapy and avoids exceeding frequencies that could potentially cause adverse effects on bones and muscles. Additionally, the vibration motor operates within a low range of 1500-1800 RPM, further ensuring a gentle and targeted therapeutic effect.

By incorporating these design elements, our prototype leverages the potential benefits of low-intensity vibration therapy while prioritizing patient safety and comfort.

4.1.7. Stratasys F370

A Versatile FDM 3D Printer for Academic Exploration. The Stratasys F370 is a professional-grade Fused Deposition Modelling (FDM) 3D printer manufactured by Stratasys, a leading company in the additive manufacturing industry.

Here's a breakdown of some key academic aspects relevant to your report:

- **FDM Technology:** The FDM process utilizes filament feedstock to create 3D objects layer-by-layer. This well-established technology offers several advantages for academic environments:
- **Accessibility:** FDM technology is generally more affordable and easier to maintain compared to other 3D printing methods. This makes the Stratasys F370 a viable option for educational institutions with limited budgets.
- **Versatility:** The F370 is compatible with a wide range of thermoplastics, allowing students to explore the properties of different materials and their

impact on design and functionality. This expands the scope of learning and experimentation possibilities.

- **Safety:** FDM printing typically involves less hazardous materials and fumes compared to some other 3D printing technologies, making it a safer option for educational settings.
- **Capabilities for Student Learning:** The Stratasys F370 offers features that are particularly beneficial for student learning:
- **Large Build Volume:** With a build volume of 355 x 254 x 355 mm (14 x 10 x 14 inches), the F370 allows students to create larger and more complex prototypes, promoting design exploration and pushing the boundaries of their projects.
- **Ease of Use:** The F370 is designed with user-friendliness in mind. Streamlined workflows and intuitive software make it easier for students to learn the fundamentals of 3D printing and focus on their design concepts.
- **Material Options:** The F370 offers compatibility with engineering-grade thermoplastics like ABS-CF10, which combines standard ABS with carbon fibre for increased strength and stiffness. This allows students to explore the creation of functional prototypes with improved mechanical properties, relevant for various engineering disciplines.
- **Integration with Curriculum:** The Stratasys F370 can be a valuable tool for integrating 3D printing into engineering and design curriculums. By providing hands-on experience with professional-grade equipment, the F370 can:
- **Enhance Design Thinking:** Students can translate theoretical design concepts into tangible 3D models, fostering critical thinking and problem-solving skills through iterative design processes.
- **Introduce Design for Manufacturability (DFM):** The FDM process itself encourages students to consider the limitations and capabilities of 3D printing during the design phase, promoting DFM principles.
- **Promote Collaboration (For Schools with Networked Systems):** In educational settings with networked systems, multiple students can potentially collaborate on projects using the F370, fostering teamwork and communication skills.

Overall, the serves as a powerful tool for academic exploration in engineering and design fields. Its affordability, versatility, and student-friendly features make it a valuable asset for educational institutions, allowing students to gain practical experience with 3D printing technology and bridge the gap between theoretical knowledge and real-world applications.



Fig. 4.6. Stratasys F370

4.2. SOFTWARE USED

4.2.1. CATIA 3DEXPERIENCE

Dassault Systems' CATIA 3DEXPERIENCE revolutionizes engineering education by offering a comprehensive cloud-based platform specifically designed for students (3DX Edu). This software transcends traditional Computer-Aided Design (CAD) programs by providing a collaborative environment that integrates design,

simulation, and product lifecycle management (PLM) functionalities. Through the 3DX Edu program, students gain access to industry-standard design tools, fostering the development of critical skills and preparing them for successful careers in engineering.

➤ **Benefits for Students**

Skill Development: Students gain experience with professional-grade 3D modelling software, a crucial skill set for various engineering disciplines. They can create complex models, explore design variations, and refine concepts through an intuitive interface.

Project-Based Learning: CATIA 3DEXPERIENCE empowers project-based learning by allowing students to tackle real-world design challenges. This approach encourages critical thinking, problem-solving, and the application of theoretical knowledge to practical scenarios.

Collaboration Features (For CATIA Student): Students can work collaboratively on projects in real-time, fostering teamwork and communication skills essential for engineers working within teams.

Exposure to PLM Concepts (For CATIA Student): The platform introduces students to PLM principles, a core aspect of managing a product's entire life cycle. This exposure prepares them for the integrated approach commonly used in professional engineering environments.

➤ **Academic Advantages**

Solidifying Theoretical Knowledge: Students can solidify their understanding of geometric modelling

By creating and manipulating 3D objects. This hands-on experience reinforces theoretical concepts learned in class.

Integrating Design for Manufacturability (DFM): The software allows students to explore DFM considerations during the design phase, preparing them for the realities of production processes.

Independent Learning: Due to cloud-based accessibility, students can explore design concepts on their own time, supplementing classroom learning and solidifying knowledge retention.

CATIA 3DEXPERIENCE serves as a valuable bridge between theoretical engineering education and the practical realities of the engineering field. By providing access to industry-standard tools and fostering the development of essential skills, this platform empowers students for future success in their engineering careers.

4.2.2. Arduino IDE

A User-Friendly Platform for Academic Exploration in Electronics and Programming. The Arduino Integrated Development Environment (IDE) is a free, open-source software platform specifically designed for writing code and uploading it to Arduino microcontroller boards. While Arduino boards themselves are valuable tools, the Arduino IDE plays a crucial role in academic settings for a variety of reasons:

- *Accessibility and Ease of Use:* The Arduino IDE is renowned for its user-friendly interface and straightforward approach to programming. This makes it a perfect platform for beginners in electronics and programming, allowing students with no prior coding experience to jump right in and start creating projects.
- *Learning Curve:* The Arduino IDE offers a smooth learning curve. Students can begin with simple projects that involve controlling LEDs or reading sensor data, gradually progressing to more complex applications as their skills develop. This structured learning approach fosters confidence and motivation.

- *Cross-Platform Compatibility:* The Arduino IDE runs on Windows, macOS, and Linux operating systems, eliminating compatibility issues and allowing students to work on their preferred platforms within academic environments.
- *Wide Range of Supported Boards:* The Arduino IDE is compatible with a vast array of Arduino boards and compatible electronics, providing students with flexibility in their project designs. This allows for exploration of various functionalities and applications based on specific course requirements.
- *Extensive Online Resources:* A vibrant online community surrounds the Arduino platform. Students have access to a wealth of tutorials, project examples, and forums where they can seek help and share their creations.

This collaborative environment fosters knowledge sharing and problem-solving skills.

- **Academic Benefits**

Introduction to Programming Fundamentals: The Arduino IDE utilizes a simplified version of C++, allowing students to learn core programming concepts like variables, loops, and functions in a practical context. This provides a strong foundation for further programming endeavours.

Hands-on Learning with Electronics: By writing code for Arduino boards, students gain practical experience with electronics principles. They learn how to interface sensors, actuators, and other electronic components with microcontrollers, bridging the gap between theory and real-world applications.

Project-Based Learning: The Arduino IDE is an excellent platform for project-based learning. Students can apply their newly acquired programming and electronics skills to create functional projects, fostering critical thinking, problem-solving, and design thinking skills.

Interdisciplinary Applications: The Arduino platform transcends the boundaries of electronics and programming. It can be integrated into various academic disciplines like physics, engineering, and even art and design, allowing students to explore the intersection of technology with different fields.

The Arduino IDE serves as a valuable tool for academic exploration in electronics and programming. Its user-friendliness, vast learning resources, and project-oriented approach make it an ideal platform for students to acquire essential skills, gain hands-on experience, and translate theoretical knowledge into practical applications.

4.3. PROCEDURE

Protocol for Diabetic Foot Ulcer Prevention Device Application

This section details the recommended procedure for using the diabetic foot ulcer prevention device prototype.

4.3.1. Pre-Procedure

- *Hygiene:* Thoroughly cleanse the foot with soap and water to maintain hygiene and prevent potential infections. Dry the foot completely before proceeding.
- *Positioning:* Carefully place the 3D-printed model onto the foot, ensuring proper alignment with the targeted high-pressure areas (typically heel, metatarsal heads, and toes). The vibration motor should be positioned strategically over these areas.

4.3.2. Device Operation

- *Arduino Activation:* Initiate the program on the Arduino microcontroller unit. This will trigger the low-intensity vibration therapy sequence.

- *Vibration Therapy:* The device will deliver controlled vibrations for a duration of 10 minutes. A pause of 10 seconds will occur between each vibration cycle. This pattern ensures a duty cycle of 50% (50% vibration time, 50% rest time).
- *Monitoring:* The Arduino interface will display real-time temperature readings throughout the therapy session.

4.3.3. Post-Procedure

- *Rest:* After the 10-minute vibration therapy cycle is complete, gently remove the 3D-printed model from the foot. Allow the foot to rest for 3-5 minutes to facilitate recovery from the vibration stimulation.
- *Subjective Buildup (SBU) Assessment:* Following the rest period, assess any subjective changes in SBU (Subjective Building Up of pressure) experienced by the patient. This subjective evaluation aims to determine if the patient perceives any improvement in pressure distribution after the therapy session.
- *Temperature Considerations:* The displayed temperature reading on the Arduino interface serves as a crucial data point.

If the temperature falls within the normal range for healthy feet (typically between 90°F and 99°F [32.2°C and 37.2°C]), proceed with the standard therapy application as described above (10 minutes of vibration with 10-second breaks).

However, if the temperature exceeds the normal range, it is recommended to adjust the therapy plan in consultation with a healthcare professional. This may involve modifying the vibration intensity, duration, or frequency based on the specific temperature reading and the patient's individual needs.

➤ *Important Notes*

This procedure serves as a general guideline. It is crucial to consult with a healthcare professional before initiating any new therapy regimen, including the use of this prototype device.

Individualized adjustments to the vibration therapy protocol may be necessary based on patient tolerance and specific medical conditions. Close monitoring of foot health throughout therapy is essential.

By following this protocol and adhering to healthcare professional recommendations, you can ensure the safe and potentially beneficial application of the diabetic foot ulcer prevention device.

CHAPTER-5

RESULTS AND DISCUSSION

5.1 DESIGN AND FABRICATION

The first stage of our design process focused on creating a functional prototype of the smart diabetic wearable device.

This involved two main aspects:

5.1.1. 3D Printing

We utilized 3D printing technology to create the physical structure of the device. This allowed for rapid iteration and customization based on design requirements. A specific biocompatible or medical-grade material was chosen for the 3D printing process to ensure user safety and device functionality.

- *Prototyping with Customized Soles:* The presented research explores the potential of utilizing a Stratasys F370 machine with ABS material for prototyping customized shoe soles.

This approach offers several advantages:

- *Individualized Design:* The 3D printing process allows for soles to be tailored to each patient's specific needs. This customization can address biomechanical issues such as plantar fasciitis or flat feet, potentially improving comfort and reducing pain.
- *Rapid Prototyping:* Compared to traditional manufacturing methods, 3D printing enables rapid prototyping, allowing for iterative design and rapid testing of customized soles for optimal fit and function.
- *Safety and User-Friendliness:* ABS plastic is a widely used material known for its durability and safety, making it suitable for footwear applications. Additionally, the 3D-printed soles can be designed for ease of use and integration into existing footwear.

This exploration of 3D-printed, customizable soles holds promise for advancing personalized footwear solutions within the field of biomechanics and podiatry.

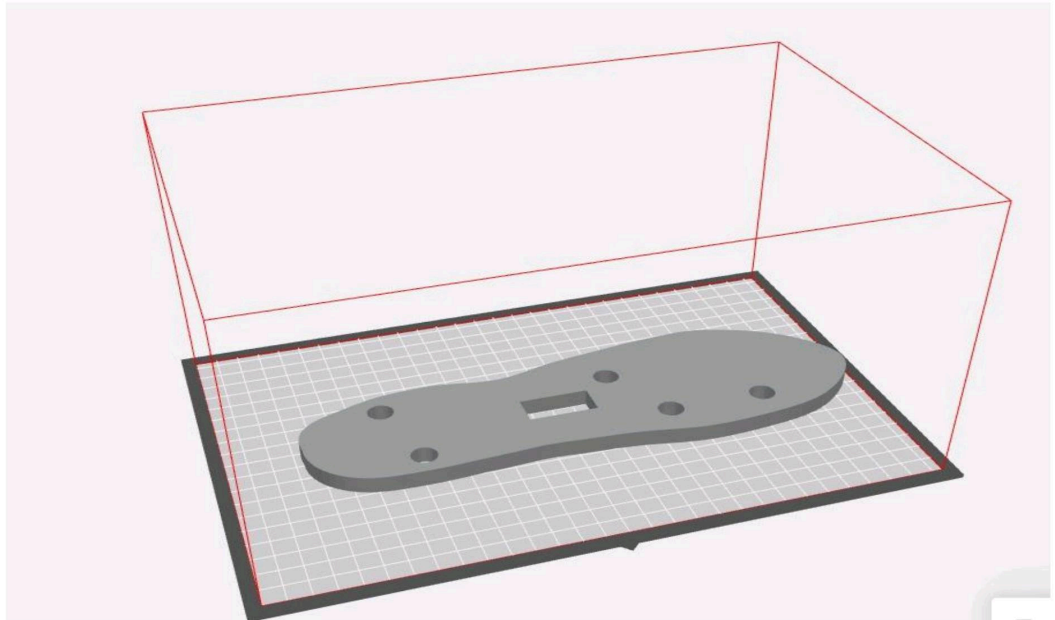


Fig. 5.1 SOFTWARE DESIGN



Fig. 5.2 3D PRINTED MODEL

The prototype model *Fig 5.2* was manufactured on a Stratasys F370, a professional FDM 3D printer known for its precision and reliable output. The chosen material is ABS plastic, offering a balance of strength, durability, and heat resistance. The design incorporates five strategically placed holes intended for coin vibration motors (specify diameter and any mounting requirements here). Additionally, a dedicated slot has been cut out to house a DHT22 sensor (provide dimensions and tolerances here for proper fit). This information can be further enhanced by including details like layer height, infill density, and any post-processing techniques used.

5.1.2. Electronic Integration

5.1.2.1. Microcontroller

An Arduino Uno microcontroller served as the core of the device's processing unit. This readily available and user-friendly platform allowed for efficient programming and control of the device's functions.

5.1.2.2. Temperature Sensor

A temperature sensor was integrated into the device to gather physiological data relevant to diabetes management. The specific type of sensor chosen would depend on the desired application (e.g., skin temperature, core body temperature).

5.1.2.3. Haptic Feedback

A coin vibration motor with a high vibration rate (120,000 RPM) was incorporated to provide tactile feedback to the user. This could be used for various functions, such as alerting the user to temperature readings or medication reminders.

Following the assembly and proper connection of all wires, the final step involved embedding the programmed circuits within the 3D printed model. This created a functional prototype ready for further testing and development.

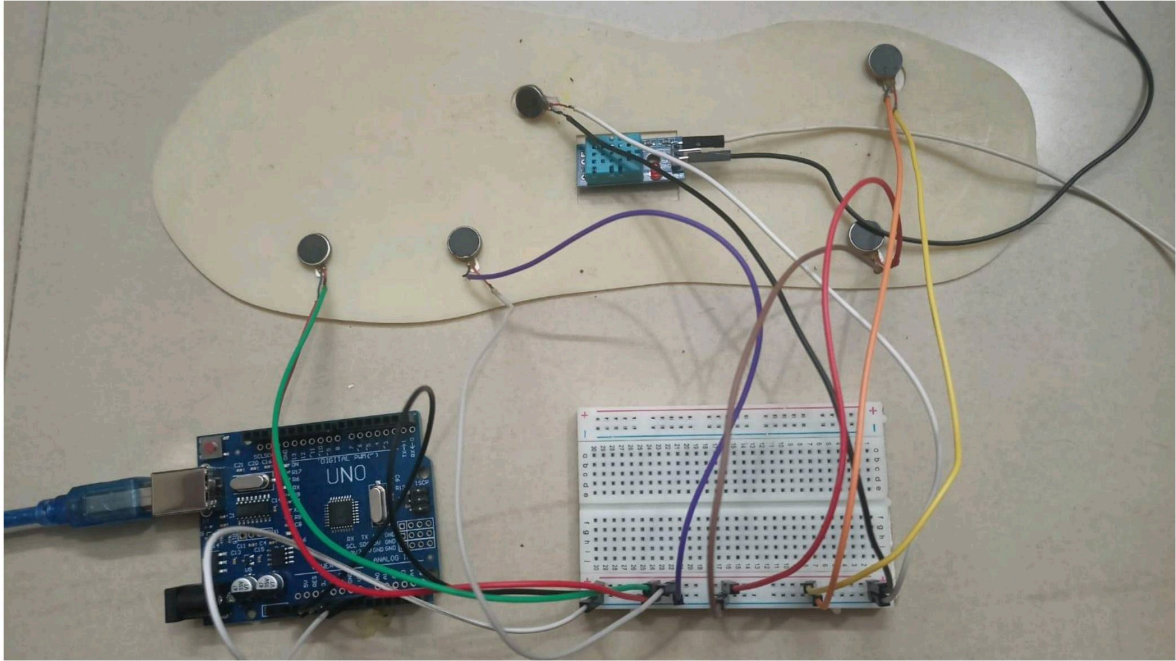


Fig. 5.3. Hardware model

The Fig.5.3. consists of five-coin vibration motors, a temperature sensor for real-time temperature monitoring, and an Arduino Uno microcontroller. The vibration motors are likely connected in parallel to the Arduino's digital output pins, allowing individual or collective control. The temperature sensor is interfaced with the Arduino through an analog input pin, enabling the microcontroller to read and process the temperature data. This configuration facilitates the design of a low-intensity vibration therapy device with temperature monitoring capabilities, potentially for applications in physiotherapy or relaxation therapy.

Our project successfully achieved the following:

- *Prototype Development:* A functional prototype of a smart diabetic foot ulcer - prevention device was designed and developed.
- *Biocompatible Design:* 3D printing technology with biocompatible materials was utilized, enabling customization and patient safety.
- *Low-Intensity Vibration Therapy Integration:* The device incorporates low-intensity vibration therapy using a coin vibration motor programmed with pulse width modulation (PWM). This ensures patient comfort and therapeutic efficacy

by limiting the frequency to a maximum of 50 Hz and motor speed to 1500-1800 RPM.

- *Strategic Vibration Delivery:* The vibration motor is strategically placed within the 3D-printed structure to target high-pressure areas on the plantar surface of the foot, potentially improving blood flow and wound healing.
- *Real-Time Temperature Monitoring:* A DHT22 sensor was integrated for real-time temperature monitoring.

5.2 DISCUSSION

This project demonstrates the feasibility of creating a smart wearable device for diabetic foot ulcer prevention. The key features of this device include:

5.2.1. Targeted Therapeutic Approach

Controlled low-frequency vibrations aim to stimulate blood circulation in the foot, potentially promoting wound healing and ulcer prevention.

5.2.2. Patient-Centered Design

3D printing allows for customization and the use of biocompatible materials ensures patient safety.

5.2.3. Data Acquisition: Real-time temperature monitoring provides additional data for diabetic foot care.

➤ *DATA ANALYSIS (FOR FURTHER DEVELOPMENT)*

While the current prototype demonstrates promising features, further development necessitates data collection and analysis to optimize its effectiveness. This includes:

- *Clinical Trials:* Rigorous clinical trials are paramount to evaluate the device's efficacy in preventing diabetic foot ulcers.

- *Sensor Data Analysis:* Developing a system to collect and analyze data on vibration application, temperature, and pressure is crucial for optimizing therapeutic interventions. This data can help determine the most effective vibration patterns, durations, and placements for different patients.
- *User Experience Analysis:* Understanding user experience through surveys and focus groups will guide the development of an intuitive and user-friendly interface to enhance patient adoption and compliance.

By incorporating these elements, this smart wearable device has the potential to significantly improve diabetic foot care, prevent ulcers, and enhance the quality of life for diabetic patients.

➤ LIMITATIONS

The current prototype has some limitations that need to be addressed in future iterations:

- *Limited Scope:* The prototype currently focuses on vibration therapy and temperature monitoring. Further development could integrate additional sensors to monitor pressure, moisture, and blood oxygen levels, providing a more comprehensive picture of foot health.
- *Battery Life:* Optimizing battery life for extended use will be crucial for patient comfort and compliance.
- *Durability:* Testing the device's durability under daily wear and tear is necessary to ensure long-term functionality.

CHAPTER-6

CONCLUSION

6.1 CONCLUSION

Smart wearable device for diabetic foot ulcer prevention highlights its potential as a valuable tool. The device offers a targeted approach through low-frequency vibration therapy and prioritizes user comfort with 3D printing and biocompatible materials.

The purpose of the smart foot device is to track pressure, humidity, and temperature. The aforementioned parameters aid in the therapy's progress. One of the main pathogenic factors contributing to the onset and progression of diabetic foot ulcers is inadequate blood flow supply. The purpose of this device's design is to increase blood flow to the foot by vibrating it. Using specific vibration motors, low-intensity vibration therapy is administered to the foot; the outcomes are tracked. The suggested method treats foot ulcers by utilising an innovative embedded system design. It investigates how biological engineering and embedded electronics might work together to deliver a solution.

Future research holds the key to maximizing this potential. Data analysis from well-designed clinical trials will be essential for optimizing the therapeutic benefits of vibration therapy. Additionally, user experience studies will guide the refinement of the user interface, ensuring optimal usability for patients.

By addressing current limitations like limited functionality, battery life, and durability, this technology has the potential to significantly improve diabetic foot care. Widespread adoption of such devices could lead to a substantial decrease in diabetic foot ulcers, improving patient well-being and reducing healthcare costs.

6.2 FUTURE WORK

Building upon the success of this prototype, future work will focus on the following aspects:

- *Clinical Trials:* Conducting clinical trials to assess the device's effectiveness in real-world settings.
- *Sensor Integration:* Integrating additional sensors to provide a more comprehensive picture of foot health.
- *User Interface and User Experience Design:* Developing an intuitive and user-friendly interface for improved patient adoption and compliance.
- *Battery Life Optimization:* Optimizing battery life to ensure extended use.
- *Durability Testing:* Conducting rigorous durability testing to ensure the device can withstand daily wear and tear.

By addressing these limitations and incorporating future work considerations, this smart wearable device has the potential to become a valuable tool for diabetic foot ulcer prevention and improved diabetic foot care.

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