DIABISOLE: OPTIMIZING DIABETIC FOOT CARE THROUGH MACHINE LEARNING AND IMAGE PROCESSING.

Project ID: 23-170

Project Final (draft) Report

Dahanayake U.S. – IT20043650

BSc (Hons) Degree in Information Technology (specialization in Data Science)

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DECLARATION

I declare that this is my own work and this proposal does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any other university or Institute of higher learning and to the best of my knowledge and belief it does not contain any material previously published or written by another person except where the acknowledgement is made in the text.

Name	Student ID	Signature
Dahanayake U.S.	IT20043650	UShani

The above candidate is carrying out research for the undergraduate Dissertation under my supervision.

Jenny -- 2023/04/06 ---------------------------------

Signature of the Supervisor Date

-- ---------------------------------

Signature of the Co-Supervisor Date

ACKNOWLEDGEMENT

I sincerely thank everyone who assisted me in continuing my fourth-year research project. First and foremost, I want to express my deep gratitude to Ms. Jenny Krishara, who oversaw our research project and gave us the direction and inspiration we needed to continue this project successfully. I am also appreciative of the CDAP panel for their assistance in our project work. I would also like to thank our co-supervisor, Ms. Ishara Weerathunga, for her insightful suggestions on achieving our task more effectively. Additionally, I thank Ms. Piumika De Silva, our external supervisor, for providing us with the knowledge we needed to start our research project.

I also thank the other group members that assisted me, including our research project leader, Ariyasinghe P.A.D.N.I. Finally, I sincerely thank my parents and friends for their assistance in making this endeavour successful.

ABSTRACT

Diabetes is a chronic disease affecting millions worldwide, and diabetic foot ulcers (DFUs) are one of its most serious complications. The existing manual method of customising insoles for DFU patients is time-consuming and costly, creating a pressing need for a faster, more accurate, and cost-effective solution. To address these challenges, we introduce "DiabiSole", a machine learning and image processing-based system designed to optimise diabetic foot care by accurately identifying wound locations and high-pressure areas. "DiabiSole" creates custom 2D insole models with visual indications for offloading and hole-cutting areas, providing critical data for treatment decisions. The core of this system is the U-Net architecture, which allows for the precise identification of wound regions and the creation of new data sets with prominently highlighted wound areas for accurate treatment decisions. "DiabiSole" achieves a remarkable 95% accuracy rate in localising diabetic foot wounds, demonstrating its precision and reliability. This exceptional accuracy displays the model's potential to serve as a reliable tool for wound identification and localisation, paving the way for improved patient care. This system aims to assist doctors and technicians in accurately identifying wound locations and creating customised insoles for patients with DFUs. It promises to enhance patient outcomes and prevent long-term complications associated with DFUs by reducing inaccuracies and the time required for customisation. Therefore, this system can potentially enhance diabetic foot care in the country significantly.

Keywords: Diabetic foot ulcers, Semantic Segmentation, Machine learning, Image processing

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LIST OF ABBREVIATIONS

Abbreviation	Description
DFU	Diabetic Foot Ulcer
ML	Machine Learning
IP	Image Processing
NN	Neural Network

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1 INTRODUCTION

1.1 Background

Diabetes is a significant global health challenge, affecting an estimated 463 million adults worldwide in 2019 [1]. One of the most severe complications of diabetes is Diabetic Foot Ulcers (DFUs), non-healing or poorly healing sores that develop on the feet or lower legs of people with diabetes. It is estimated that 15-25% of diabetic patients will develop a DFU at some point in their lifetime [2]. DFUs are often caused by a combination of factors, including poor circulation, nerve damage, and impaired wound healing. In diabetic patients, high blood sugar levels can cause damage to blood vessels and nerves, reducing blood flow to the feet and impairing the body's ability to feel pain and injury. As a result, minor injuries or blisters on the feet may go unnoticed and become infected, leading to the development of DFUs.

DFUs are challenging to heal and can lead to infections and other serious complications, making them a leading cause of lower limb amputations in diabetes patients. In fact, more than 1 million patients lose part of their leg every year due to the failure to recognize and treat DFU appropriately [3]. Patients with DFU need periodic checkups, expensive medication, and hygienic care to prevent these consequences. This causes a massive financial burden on patients and their families, especially in developing countries where treatment costs can be equivalent to 5.7 years of annual income [4]. Sri Lanka is no exception. According to a recent study in Sri Lanka, the percentage of people with diabetes in urban areas has increased significantly over the last thirty years, with an estimated 27.6% of the urban population affected [6]. This is a concerning trend because many of these patients have foot complications, with up to 50% of those with type 1 and 2 diabetes developing DFUs [7], [8].

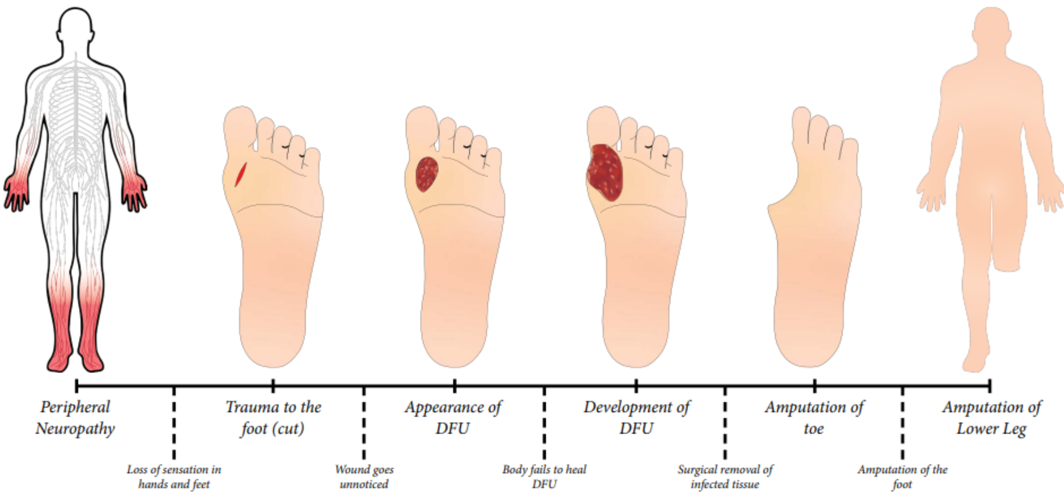

Figure 1.1: Timeline of DFU development leading to lower leg amputation.

Source: Digital Design for Diabetes [5]

There are several types of DFUs, each with its own characteristics and treatment requirements. The most common types of DFUs are,

- Neuropathic ulcers, which are caused by nerve damage and frequently appear on pressure points.
- Ischemic ulcers, which are caused by poor circulation and can appear on the toes or heels.
- Neuro-ischemic ulcers, which are caused by a combination of nerve damage and poor circulation and can be especially difficult to heal.

Table 1.1: Typical features of DFUs

Feature	**Neuropathic**	**Ischaemic**	**Neuro-ischaemic**
Sensation	Reduced or absent sensation in the affected area.	Normal sensation but may experience pain at rest.	Reduced or absent sensation in the affected area.
Typical location	Weight-bearing areas of the foot, such as metatarsal heads, the heel and over the dorsum of clawed toes.	Tips of toes, nail edges and between the toes and lateral borders of the foot.	Margins of the foot and toes.
Wound appearance	Usually round, smooth edges, with little to no drainage, callused edges or surrounding skin.	Usually irregularly shaped, with a punched-out appearance, dry and pale skin, and minimal drainage.	Usually round or irregularly shaped, with deep tissue loss and signs of infection, such as drainage or foul odour.
Treatment	Offloading pressure with special footwear or inserts, control of underlying diabetes or other contributing factors.	Revascularization, debridement of necrotic tissue, and wound dressings.	Combination of offloading pressure, revascularization, and wound care.
Prevalence	35%	15%	15%

Source: Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers

DFUs can be classified into different stages based on their severity. One commonly used system is the Wagner classification, which has six stages from 0 to 5. Stage 0 indicates a high-risk foot with no open wounds, while stage 5 indicates gangrene or necrosis of the foot requiring amputation. Customized footwear is often recommended for patients with stage 2 or higher DFUs, especially those with moderate to high risk of developing further foot complications.

Offloading and pressure redistribution can be achieved using specialized footwear, which helps to relieve pressure on the affected area and accelerate healing. Customized footwear can be tailored to patients' foot shape, size, and specific ulcer location, providing a more effective and comfortable fit than standard off-the-shelf options. They reduce the risk of injury and infection while improving patients' comfort and mobility by providing proper foot support, cushioning, and protection [9]. They also have removable insoles that can be customized to provide extra foot support. Customized insoles can address foot issues such as arch support, pressure relief, and shock absorption [10]. They are made manually by taking a plaster of Paris mould of the patient's foot and then making the insole according to the mould. The process requires a high level of skill and attention to detail because even small mistakes can lead to discomfort or pain in the patient's wound and also can cause it to worsen. Especially when cutting holes in insoles on wound areas, technicians must be precise with the placement, as improper placement can harm the wound. Furthermore, the process is time-consuming, taking several hours to complete [11].

Therefore, there is a need to address these challenges and develop more precise and accurate customized insoles, making them more accessible to patients. By reducing the chances of discomfort or pain in the patient's wound and minimizing the time and cost associated with creating customized insoles, patients can receive the necessary care and support to manage DFUs effectively.

Figure 1.2: Diabetic shoes currently available in the Sri Lankan market.

Figure 1.3: Diabetic shoes with manually customized insoles.

1.2 Literature Survey

Robust Methods for Detecting and Localizing Diabetic Foot Ulcers in Real Time on Mobile Devices [12].

This application seeks to facilitate the real-time identification and pinpointing of Diabetic Foot Ulcers (DFUs) on mobile devices. Currently, DFU screening is typically carried out by podiatrists, but automated solutions present a faster and more efficient alternative. This application offers healthcare professionals a portable and effective tool for instant DFU detection, enabling timely interventions and improved condition management.

In their research, the team collected a dataset comprising 1775 images of feet with DFUs. Two medical experts defined the DFU regions of interest using annotation software to establish ground truths. They evaluated various traditional machine learning and deep learning models for DFU localization and determined that the Faster R-CNN with InceptionV2 model, employing a two-tier transfer learning approach, achieved a mean average precision of 91.8%.

Figure 1.4: Three common tasks for inspection of abnormalities on a DFU

Figure 1.5: Real-time localization using smartphone

Deep Learning Methods for Real-time Detection and Analysis of Wagner Ulcer Classification System [13].

The research introduces a system designed to promptly identify and pinpoint Wagner ulcers on the feet of diabetic patients in real-time. The primary objective of this system is to ease the burden on podiatrists while delivering timely and pertinent information to individuals with Diabetic Foot Ulcers (DFU).

To enhance its accuracy and reliability, the study proposes the utilization of a dataset consisting of 2688 diabetic foot images, each with annotations. These enhancements involve refining the YOLOv3 model. The system can promptly classify and locate Wagner ulcers on diabetic feet using the YOLOv3 algorithm, along with the incorporation of image fusion, label smoothing, and variable learning rate mode technologies.

The upgraded algorithm has been implemented on an Android smartphone to enable real-time detection and analysis of Wagner ulcers on diabetic feet. Based on the experimental results, the improved YOLOv3 algorithm achieves an impressive mean Average Precision (mAP) score of 91.95%, surpassing the performance of other models like SSD and Faster R-CNN.

The study underscores the potential of this system to offer an effective healthcare solution for analyzing DFU tissue and monitoring healing progress, ultimately reducing the workload of professional podiatrists.

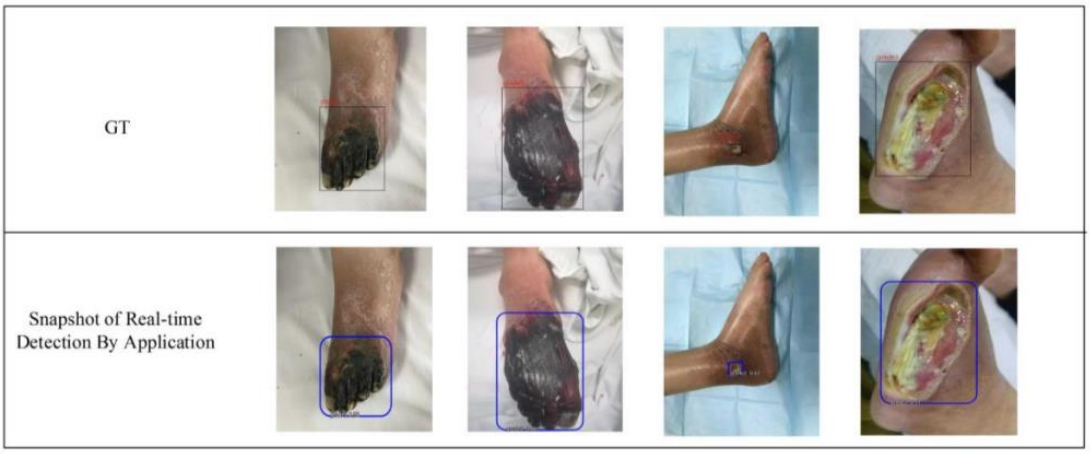

Figure 1.6: Ground truth vs real time detection.

Fully Convolutional Networks for Diabetic Foot Ulcer Segmentation [14].

The current method for treating diabetic foot ulcers (DFUs) relies on the watchfulness of both patients and clinicians, but it has its limitations. This research introduces a novel deep learning approach aimed at automatically detecting and precisely delineating DFUs and the adjacent skin areas.

The study proposes a two-step transfer learning process, utilizing extensive datasets, to train Fully Convolutional Networks (FCNs) for the automatic segmentation of ulcers and their surrounding skin. This technology can be valuable for healthcare professionals in tracking ulcer progress. The performance of these FCN models is assessed through 5-fold cross-validation, and the results are presented in terms of the Dice Similarity Coefficient. The proposed FCN models achieved a Dice Similarity Coefficient of 0.794 for the ulcer region, 0.851 for the surrounding skin region, and 0.899 for the combined regions.

Furthermore, this deep learning approach could extend its utility to segmenting various other skin lesions, such as moles, freckles, blemishes, pimples, wound types, and infections like chickenpox or shingles.

Figure 1.7: Delineating the different regions of the wound.

A New Mobile Application for Standardizing Diabetic Foot Images [15].

The research paper outlines the creation of a novel mobile application called "FootSnap," designed to standardize photographs of diabetic feet. This application was specifically developed for use on the iPad and is capable of producing images of the plantar foot surface, along with an outline of the foot referred to as the "ghost image." To assess its performance, the app underwent testing involving 30 diabetic feet and 30 non-diabetic control feet. These evaluations were conducted on two separate occasions by two different operators. The results demonstrated strong consistency both within and between operators, as indicated by Jaccard similarity index (JSI) values ranging from 0.89 to 0.91 for diabetic feet and 0.930 to 0.94 for control feet.

Utilizing FootSnap for the standardization of plantar foot photographs holds promise for future applications involving advanced computer vision algorithms applied to these images. These algorithms could be valuable for monitoring changes in diabetic foot conditions, such as ulcer development. The study also acknowledges certain limitations of the app, with ongoing research expected to assess its sensitivity and specificity in imaging diabetic foot ulcers.

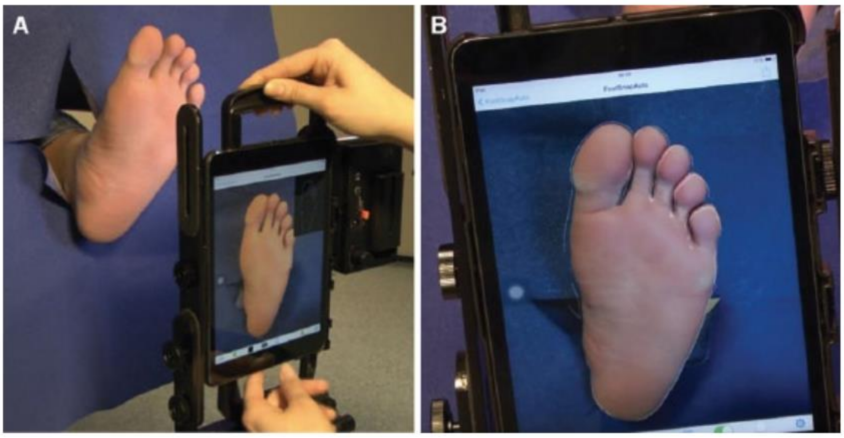

Figure 1.8: (A) Illustration of the experimental setup for using FootSnap. (B) An image being captured by the operator using the ghost image facility (white outline around the foot) within FootSnap.

Development of 3D-Printed Orthopedic Insoles for Patients with Diabetes and Evaluation with Electronic Pressure Sensors [16].

The study discusses the use of 3D printing technology to develop customized orthopaedic insoles for diabetes patients to redistribute plantar pressures and prevent foot injuries. The study discovered that customized insoles influence plantar pressure distribution, particularly in people with flat feet or high-arched foot deformities and that average peak pressures while wearing 3D-printed insoles were not significantly different from standard insoles.

The study proposed using the same techniques to determine which regions of the insole in the 3D model can be modified to create pressure-relieving insoles. The study concluded that three-dimensional printed insoles have the potential to help with diabetes management but that more material testing is needed before they can be used in healthcare facilities.

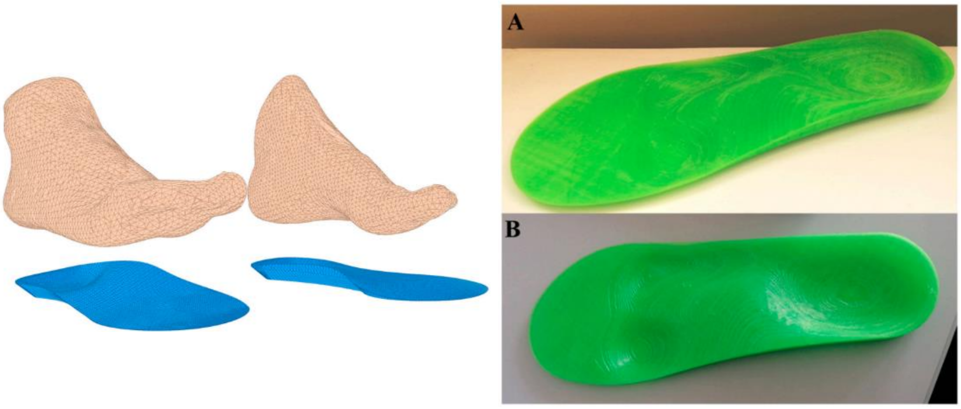

Figure 1.9: 3D Insole Customization

Comparison between existing systems and proposed system

Table 1.2: Comparison between existing systems and proposed system

	Robust Methods for Detecting and Localizing Diabetic Foot Ulcers in Real Time on Mobile Devices	Deep Learning Methods for Real-time Detection and Analysis of Wagner Ulcer Classification System	Fully Convolutional Networks for Diabetic Foot Ulcer Segmentation	A New Mobile Application for Standardizing Diabetic Foot Images	DiabiSole
Wound location identification	✓	✓	✓	✗	✓
Display indications around identified wound areas	✓	✗	✗	✗	✓
New dataset generation	✗	✗	✗	✗	✓
2D insole model generation	✗	✗	✗	✗	✓
Image processing techniques	✓	✓	✓	✓	✓

1.3 Research Gap

DFUs are a significant health concern worldwide, and their accurate and timely diagnosis is crucial to avoid complications. In recent years, computer-aided approaches have emerged as a valuable tool for DFU diagnosis, providing more accurate and reliable diagnoses and improving DFU management and treatment [17]. However, despite recent advances, there is still a need for more practical applications that can identify wound regions by analysing sole images of patients with DFUs and customising insoles to suit their conditions.

This is especially relevant in Sri Lanka, where DFU identification technology is limited, and to our knowledge, no wound detection systems are currently in use. In Sri Lanka, there is a minimal discussion about insole customisation as a method of diabetic relief. The main reason is that people with diabetes are unaware of these products' existence and advantages, and the high costs associated with purchasing them further limit their accessibility [7]. The existing manual method of insole customisation is time-consuming and requires a high level of skill, making it impractical for widespread use.

While numerous studies have focused on DFU detection and localisation, most studies have focused only on identifying wound locations, with limited attention given to customising insoles to relieve pressure on those areas. One significant gap in the current research is the need for a new dataset generation with identified areas highlighted. The new dataset could improve the accuracy and reliability of evaluating computer-aided approaches for identifying wound locations and customising insoles to relieve pressure. In addition, they do not use the identified wound areas on customising insoles to relieve pressure on those wound areas. Furthermore, there is a lack of research on customising insoles considering wound locations, high-pressure areas, and pressure-loading areas, which is critical for accurate and effective relief. There is a need for further research to address these gaps and develop practical applications that can customise insoles to relieve pressure on the identified wound locations effectively.

To address these gaps, we propose the "DiabiSole" application to optimise diabetic foot care using ML and IP. Our application aims to assist doctors in accurately identifying wound locations and technicians in making custom insoles more accurately, and cost-effectively. By analysing sole images of patients with DFUs, the application will identify the exact location of the wound, enabling the technician to precisely place holes in the insole, ensuring that the insole provides relief in the areas where it is most needed.

1.4 Research Problem

DFUs are a serious complication of diabetes that can cause painful wounds and severe complications if not treated properly. Pressure offloading is a common treatment approach to prevent further damage to the affected area, which can be achieved through various methods, such as cutting holes in the insole and creating a custom insole with raised areas. It is critical to accurately identify the exact location of the wound for suitable pressure offloading. In the current practice, identifying the exact location of wounds on the feet is done through visual observation, which can be subjective and prone to errors [18]. This leads to further complications and delays in treatment. Therefore, developing a more accurate and reliable method to identify the location of wounds is crucial for the effective treatment and management of DFU. Applying ML and IP techniques can improve wound identification and pressure offloading accuracy.

The proposed solution “DiabiSole”, aims to optimize diabetic foot care using ML and IP techniques to identify wound locations accurately and to show indications around identified wound locations. A large dataset of sole images can be used to train the system to learn the features and patterns associated with diabetic foot ulcers. The system will use advanced image processing techniques such as segmentation, edge detection, and feature extraction to precisely locate wounds on the sole. A new dataset will be generated using the identified wound locations. The dataset will include indications around the wound areas, which will be utilized to determine the size of the hole to be cut to reduce pressure on the wound. Additionally, the dataset will be used to identify new pressure offloading areas.

Furthermore, the system can detect high-pressure areas that may lead to future wounds and generate a 2D image of the insole displaying necessary adjustments as well as detect the severity of existing wounds. This can enable healthcare professionals to develop personalized insoles for each patient that provide relief in the areas where it is most needed. The proposed method has several advantages over the current practice and is expected to significantly improve the accuracy of wound identification, reducing the risk of further complications. Patients would no longer have to undergo the time-consuming process of plaster casting their feet, and the accuracy of the custom insole would be significantly improved. As the prevalence of diabetes and its associated complications continues to increase, developing technologies like “DiabiSole” is critical for improving patient outcomes and preventing long-term complications.

1.5 Background Research

To gain a better understanding of diabetic foot wounds and the importance of developing a program to customize insoles, we conducted visits to several clinics for diabetic patients and places that make custom diabetic shoes. Our first visit was to Diabetic Foot Care and Rehabilitation Centre Nawala (Figure 1.10), where we met with a specialist in diabetic foot wounds. Here, we learned about diabetic foot wounds, their stages, how treatments are done, and the importance of diabetic foot care in managing and healing foot wounds. We also understood about using diabetic shoes as a part of the treatment plan for patients.

We also visited the Sri Lanka School of Prosthetics and Orthotics (Figure 1.11). We met with a Prosthetist and Orthotist who explained and showed us the steps of manual custom insole production using a plaster of Paris mould. We learned about the difficulties in the procedure and what improvements they needed in the industry to benefit production.

During our visits to Beta Diabetic Footwear Solutions, a subsidiary of DSI, and Exceed Lanka Pvt Ltd (Figure 1.12), we gained insights from orthopaedic shoe technicians regarding the customization of insoles for off-the-shelf diabetic shoes available in the market, as well as the market for diabetic footwear.

At the Diabetic Foot and Wound Care Clinic at Kings Hospital Colombo (Figure 1.13), we discovered a dynamic scanner that can detect the pressure distribution of patients' feet to understand high-pressure areas. We plan to use the scanner report image to identify high-pressure areas at risk of ulceration and perform pressure offloading of those areas.

We have drawn several conclusions from these visits that will aid our research.

- Firstly, we discovered that most patients do not use diabetic footwear due to its high prices and difficulties in customizing the shoes.
- Secondly, we found a need for improved communication between doctors and technicians who make the shoes to correctly state which modifications are needed when customizing.
- Thirdly, we learned that manual insole customization has accuracy issues when not properly taken, and patients may need to repeat the process.
- Lastly, we observed interest among them in the idea of developing an application to automate customizing insole production.

Figure 1.10: Diabetic Foot Care & Rehabilitation Centre Nawala.

Figure 1.11: Sri Lanka School of Prosthetics and Orthotics.

Figure 1.12: Exceed Lanka Pvt Ltd

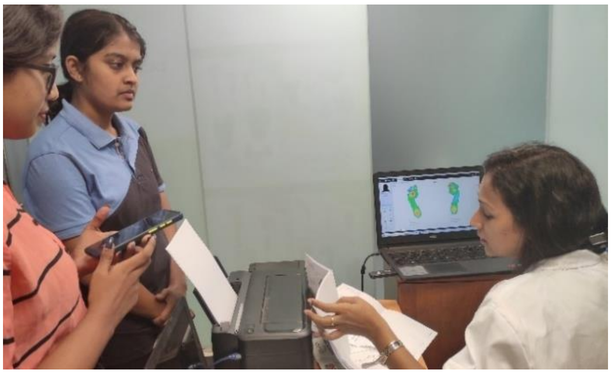

Figure 1.13: Diabetic Foot and Wound Care Clinic at Kings Hospital Colombo.

1.6 OBJECTIVES

1.6.1 Main Objective

Analyze the images of the soles of patients with DFU to locate the wound locations.

The main objective of this system is to identify wound areas on the soles of the feet by analyzing sole images. DFUs take a long time to heal and may become infected, leading to further complications. Customized insoles are worn inside diabetic shoes to lower the risk of developing new ulcers and relieve pressure on existing ulcers [9]. These insoles are customized by making holes where the wounds are. Before doing so, the wound regions must first be precisely defined. The current practice of identifying the location of wounds on the feet is done through visual observation, which can be subjective and prone to errors. Therefore, the main objective of this system is to use ML techniques to analyze sole images and identify the exact location of diabetic foot ulcers.

1.6.2 Specific Objectives

To gather a dataset of images of real soles with wounds.

Collecting a diverse set of images representing a wide range of wound types, sizes, and locations is critical. This will aid in training the ML model to identify a variety of wound patterns accurately. The main challenges involved with this task are a long time in collection and expert labelling of the DFU images, the high similarity between the normal (healthy skin) and abnormal (DFU) skin, lighting conditions and the patient's ethnicity. The quality and quantity of images collected for this dataset are critical to the overall system's success.

To train an ML model to detect wound locations.

Feeding a large dataset of labelled images to an ML model involves annotating each image to highlight the location of the wound. After that, the model is trained to recognize data patterns and accurately identify and locate wounds. To effectively train the model, a large amount of data is required. After training, the model can analyze new images and accurately identify and locate wounds.

To generate a new dataset with identified wound areas.

This involves displaying indications around the identified wound areas and creating a new dataset that is used to calculate the area of the hole to cut on the insole to relieve pressure on the wound.

To generate a 2D model of the insole and a severity report on the findings.

This involves generating a 2D insole model, indicating pressure-offloading areas and areas that need pressure relief. Generating a report with severity of wounds, holes area and high-pressure area measurements.

2 METHODOLOGY

2.1 Methodology

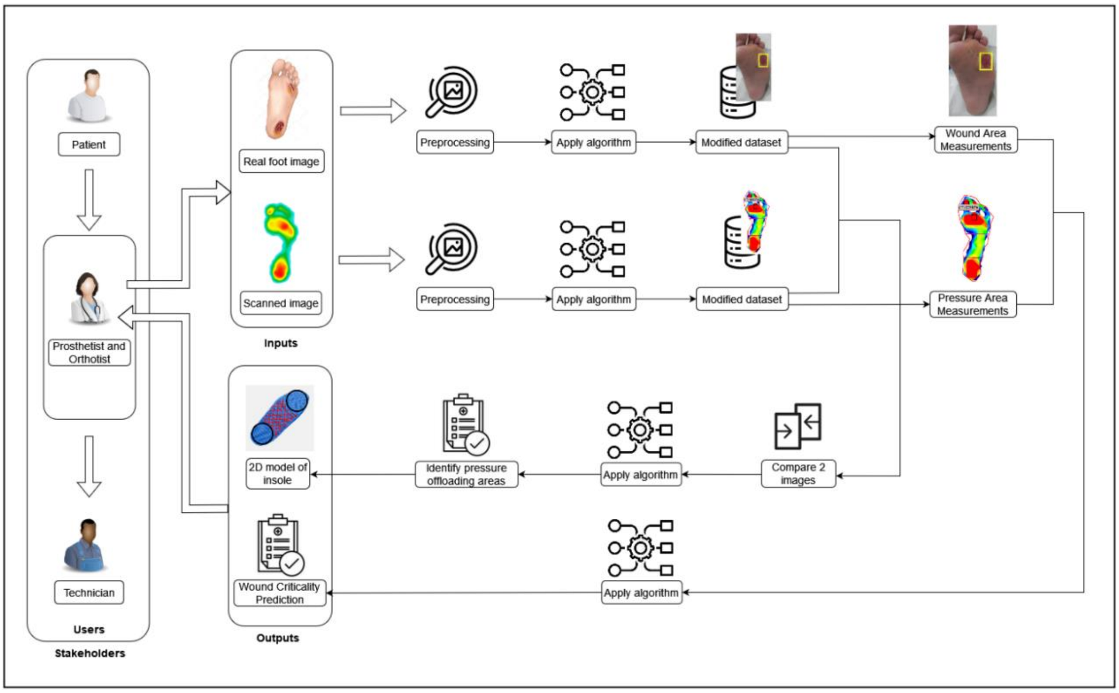

Figure 2.1: System High-Level Diagram

All four sub-functions of the research are shown in the above figure 2.1. To accomplish this, a comprehensive web application has been developed using PHP and the Laravel framework. The web application uses an SQLite database to securely store user information and test results. Additionally, a Python-based API, built with Flask, plays a vital role in interconnecting all processes. The final system is built around four key functions: wound area detection and measurement, high-pressure area detection and measurement, offloading area identification, and wound severity detection.

This solution's workflow begins with the submission of two key inputs: an image of the sole with wounds and a scanned image of the pressure distribution across the sole. These images are pre-processed, and then using deep learning algorithms the system identifies and delineates wounds, measures wound sizes, locates areas of high-pressure, and measure their sizes. The system then compares identified wound locations with high-pressure locations to suggest new places for optimal pressure offloading points on the foot. Finally, by analysing wound sizes and high-pressure area sizes the system will assess the severity level of the wounds. Ultimately, the system produces two valuable outputs: a 2D model of the insole marked with recommended pressure offloading areas, and a detailed report detailing the criticality of the wounds.

These outputs are valuable insights for doctors, assisting them in making informed decisions and, as a result, improving patient care. The component overview diagram for identifying wound areas by analyzing the real sole images is shown in Figure 2.2.

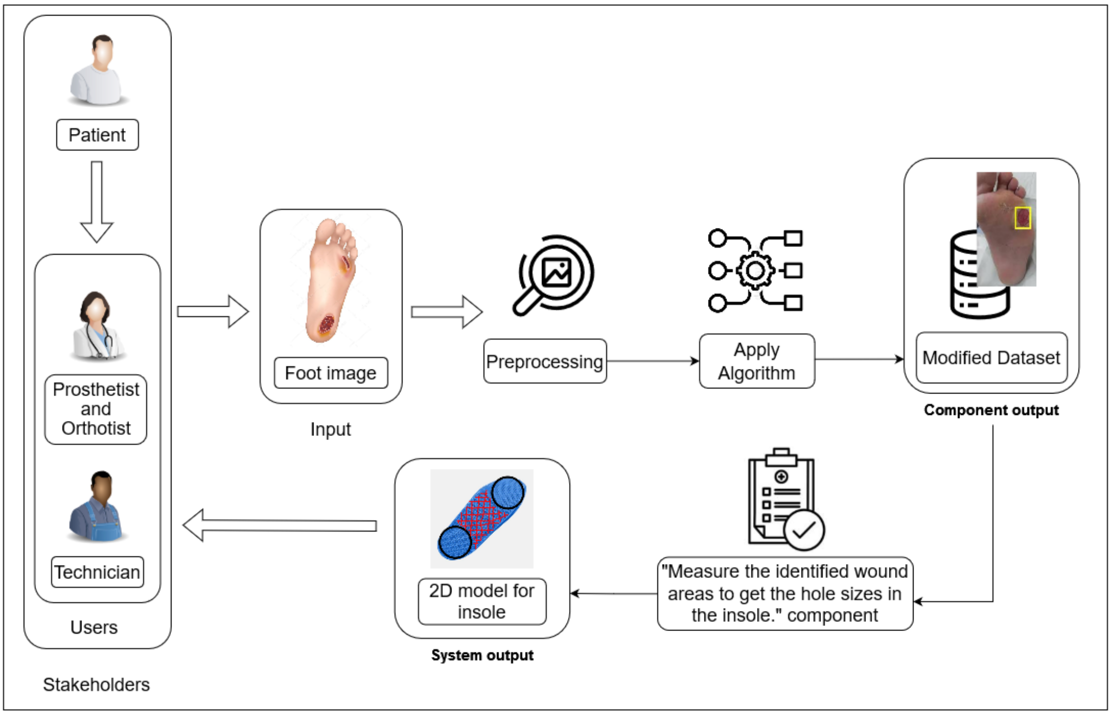

Figure 2.2: High-level diagram of individual function (Identify wound areas by analyzing the real sole images)

2.1.1 Data Collection and Annotation

In order to identify and precisely localize wound regions, the applied methodology involves using images of patients' feet with DFUs obtained from clinics. The initial challenge was that only a small number of pictures showing DFU were readily available. To address this limitation, the Augmenter library was used to apply a variety of augmentation operations, including Gaussian distortion, brightness, contrast, colour adjustments, rotations, flips, distortions, and zooming. The approach can simulate a wide range of real-world scenarios by diversifying the dataset with these augmentations, enhancing the versatility of the model.

The next step is to skillfully annotate the dataset to precisely define wound regions on the sole images. The LabelMe image annotator tool facilitates this annotation process by enabling accurate annotation of the diabetic foot wound, the patient's sole, and background regions in distinct colours. With pixel-level annotations, the wound areas are clearly identified. Figure 2.3 shows an annotated image with wound areas in green, the foot in red, and the background in black. This method improves the granularity of the annotation process as well as the accuracy of the resulting model's localization.

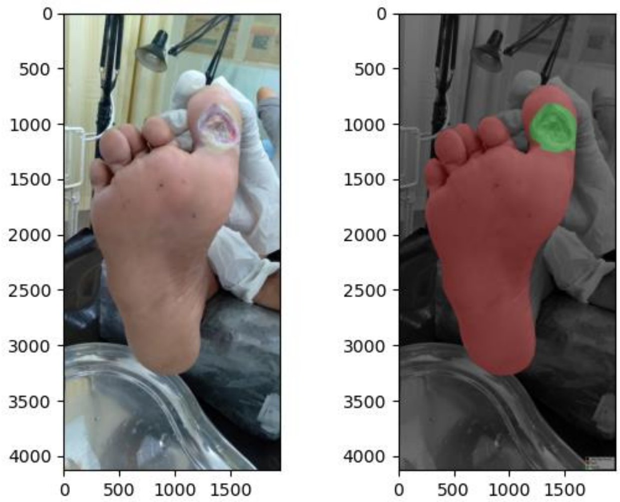

Figure 2.3: Annotated wound image

2.1.2 Deep Learning Model Implementation

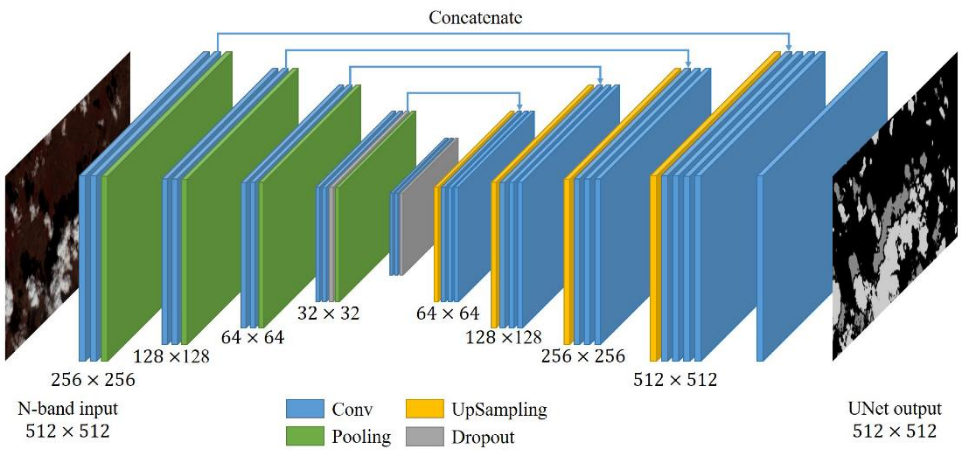

Figure 2.4: U-net architecture of wound detection

The application utilizes a U-Net architecture, a well-known convolutional neural network (CNN) design frequently used for medical image segmentation tasks, to identify DFU wound areas in real sole images of diabetic patients. The U-Net model, implemented using TensorFlow and Keras, was chosen for its effectiveness in semantic image segmentation tasks. This architecture is composed of an encoder and decoder, strategically capturing high-level and low-level image features. The encoder employs multiple convolutional layers with dropout and max-pooling operations to progressively distill critical image features. In contrast, the decoder employs transpose convolutional layers to upscale features and combine them with encoder features using skip connections. A softmax activation function is applied in the output layer to classify each pixel as background, foot, or wound.

Training the model involves a systematic split of the annotated dataset into training and validation subsets, with the validation set comprising 20% of the data. Essential parameters, including loss function (Categorical Cross-Entropy), optimizer (Adam with a learning rate schedule), and evaluation metrics (accuracy, recall, and precision), are configured. The model then starts an iterative training process over a predetermined number of epochs, gradually improving its ability to locate wounds. Furthermore, sample weights are used to address any issues with class imbalance. By using an early stopping mechanism, we can avoid overfitting and keep the model with the best validation loss.

Once the model effectively segments wounds by classifying each pixel as background, foot, or wound, the wounds become clearly visible on the mask. Following the identification of wounds, the procedure involves encircling these areas with precise circles superimposed on the foot image. These localized images, now with highlighted wound regions, are saved for doctors' use. To enhance user-friendliness, an interface has been implemented, allowing doctors to select images containing DFUs. The model processes the chosen image and presents it on the web application, complete with marked wound areas and pixel count information. This method simplifies DFU wound assessment by providing healthcare professionals with a tool for accurate and visually enhanced wound identification and documentation, thereby improving DFU management. Figure 2.5 shows the application's procedure steps.

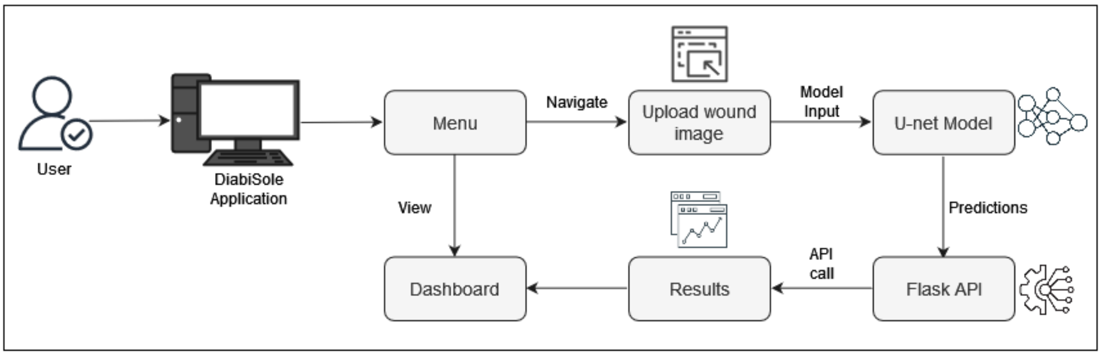

Figure 2.5: Processing steps of the application

2.1.3 Web Application Development

The developed web application is an innovative DFU management solution with a user-friendly interface designed to meet the needs of healthcare professionals. The user interface of the application was created with clarity and effectiveness in mind. It provides a detailed 2D model of the insole, with different visual indications for offloading and hole-cutting areas, as well as accurate area measurements in pixels, providing critical data for treatment decisions to healthcare professionals.

Upon logging into the application, doctors have the option to add a new patient record if the patient is not already in the system, ensuring a comprehensive and organized patient database. The key feature of the application is its ability to process and analyze sole images of patients with DFU. Once the patient is selected, doctors can effortlessly upload a sole image featuring the DFU condition as shown in Figure 2.5. The application processes the uploaded image to identify the wound areas swiftly and accurately. It not only identifies the wound areas with remarkable accuracy but also highlights them with clearly circled markings as shown in Figure 2.6. Additionally, the pixel area of each wound is calculated, allowing doctors to accurately determine the severity and progression of the ulcers.

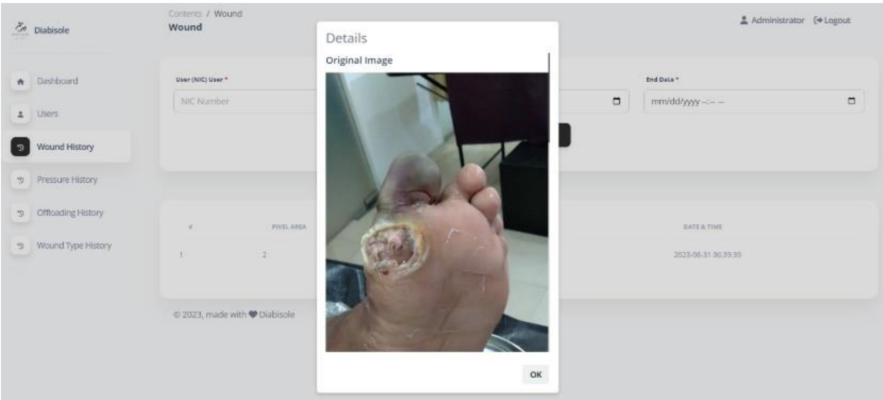

Figure 2.6: Upload foot image

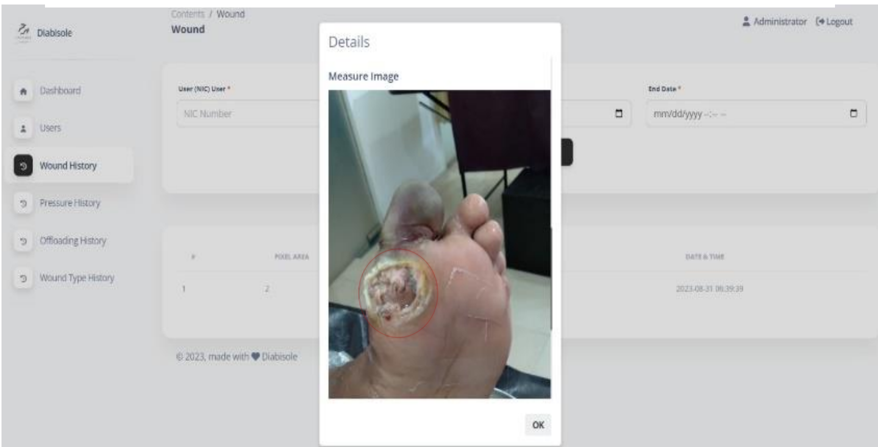

Figure 2.7: Foot image with wound areas highlighted

Following this, doctors can upload a scanned foot image, which will result in the automatic detection and highlighting of high-pressure areas, as well as their precise pixel measurements. By comparing these two sets of data, the application identifies areas that are neither wounds nor high-pressure regions. These areas, often referred to as pressure off-loading areas, represent the portions of the sole where pressure should be distributed to prevent further injury or the worsening of existing ulcers. The application then generates an image of the sole, with off-loading and non-offloading areas clearly highlighted in different colors.

This web app enables healthcare professionals to make highly informed decisions in the management of DFU patients by simplifying the complex task of identifying and analyzing DFU wounds, high-pressure areas, and pressure off-loading zones. Its user-friendly interface and comprehensive capabilities promise to significantly improve patient care, resulting in better outcomes and an overall better quality of life for DFU patients.

2.2 Commercialization Aspect of Product

To address the pressing demand for cost-effective insole customization, it is important to recognize the shortcomings of current methods, which are both time-consuming and prohibitively expensive, making them unsuitable for widespread adoption. Our innovative solution to this challenge is "DiabiSole," a solution designed to assist both prosthetic and orthotic surgeons in the early treatment of diabetic patients with DFUs, as well as orthopedic shoe technicians in the personalized customization of diabetic shoe insoles. It is worth noting that awareness of the technique involving the creation of perforations in insoles to relieve pressure on calluses is still low, with little research or solutions available in this field. Given these circumstances, we believe our proposed solution has large market potential.

It is a service provided solely to assist orthotists, prosthetists and orthopaedic shoe technicians who customise the insoles of diabetic shoes. We aim to offer this system to Kings Hospital in Colombo as a complimentary service, as we have obtained the required data from them. Additionally, we plan to provide this service for free to hospitals that do not have the financial means to pay the subscription fee. However, other orthotists, prosthetists and orthopaedic shoe technicians who wish to use our application will be required to register and choose a subscription plan, either monthly or annually as shown in figure 2.7.

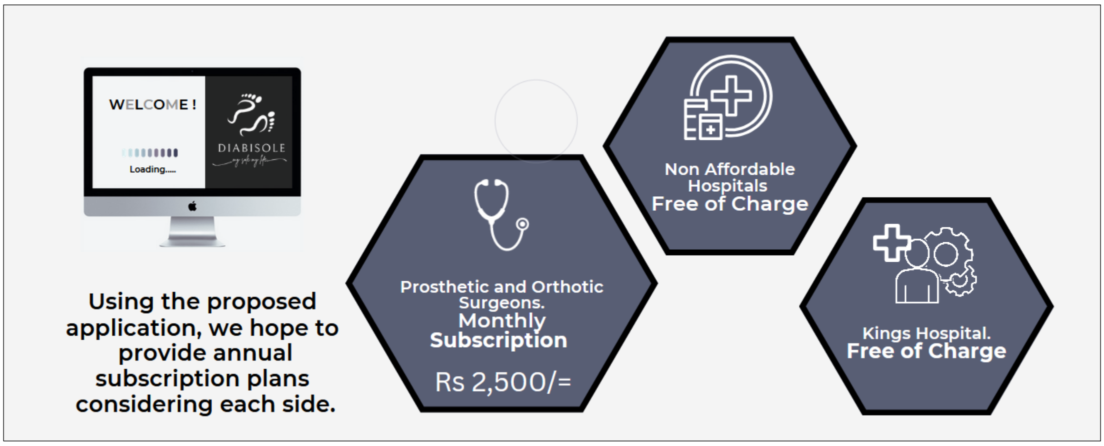

Figure 2.8: DiabiSole commercialization plan

Aside from that, we intend to use popular social media platforms such as Instagram, Facebook, and YouTube to promote the application and its features. Also, we are planning to conduct awareness for diabetic patients on specialized diabetic shoes and customization of diabetic shoe insoles.

2.3 Testing and Implementation

To ensure both functional and non-functional quality control of the implemented web application, a number of tests have been carried out in both the implementation and testing phases.

Table 2.1: Wound detection test case (in a clear sole image)

Test case ID	WC001
Test Case Scenario	Detect DFU wound in a clear sole image.
Test Input Data	Upload a sole image with a clear DFU wound.
Test Procedure	1. Log in to the web application using valid credentials. 2. On the dashboard, select an existing patient from the patient database, or if the patient is not in the system, click on the "Add New Patient" button and provide the required patient information. 3. After selecting or adding the patient, upload a sole image for DFU detection. 4. Use the file upload dialogue to select and upload a sole image that contains a clear DFU wound. 5. Click on the "Show Results" button to view the uploaded wound image along with the circled wound areas.
Expected Outcome	The application accurately identifies and highlights the DFU wound area with a clearly circled marking.
Actual Outcome	The application accurately identifies and highlights the DFU wound area.
Test Result	Pass

Table 2.2: Wound detection test case (in a sole image with multiple wounds)

Test case ID	WC001
Test Case Scenario	Detect DFU wound in a sole image with multiple wounds.
Test Input Data	Upload a sole image with multiple DFU wounds.
Test Procedure	1. Log in to the web application using valid credentials. 2. On the dashboard, select an existing patient from the patient database, or if the patient is not in the system, click on the "Add New Patient" button and provide the required patient information. 3. After selecting or adding the patient, upload a sole image for DFU detection. 4. Use the file upload dialogue to select and upload a sole image with multiple wounds. 5. Click on the "Show Results" button to view the uploaded wound image along with the circled wound areas.
Expected Outcome	The application accurately identifies and highlights all DFU wound areas.
Actual Outcome	The application accurately identifies and highlights all DFU wound areas.
Test Result	Pass

Table 2.3: Wound detection test case (in a sole image with noise)

Test case ID	WC001
Test Case Scenario	Detect DFU wound in a sole image with noise.
Test Input Data	Upload a sole image with noise.
Test Procedure	1. Log in to the web application using valid credentials. 2. On the dashboard, select an existing patient from the patient database, or if the patient is not in the system, click on the "Add New Patient" button and provide the required patient information. 3. After selecting or adding the patient, upload a sole image for DFU detection. 4. Use the file upload dialogue to select and upload a sole image with noise. 5. Click on the "Show Results" button to view the uploaded wound image along with the circled wound areas.
Expected Outcome	The application accurately identifies and highlights the DFU wound area while ignoring noise.
Actual Outcome	The application accurately identifies and highlights the DFU wound area while ignoring noise.
Test Result	Pass

Table 2.4: Wound detection test case (in a sole image with varying lighting conditions)

Test case ID	WC001
Test Case Scenario	Detect DFU wound in a sole image with varying lighting conditions.
Test Input Data	Upload a sole image with varying lighting conditions.
Test Procedure	1. Log in to the web application using valid credentials. 2. On the dashboard, select an existing patient from the patient database, or if the patient is not in the system, click on the "Add New Patient" button and provide the required patient information. 3. After selecting or adding the patient, upload a sole image for DFU detection. 4. Use the file upload dialogue to select and upload a sole image with noise. 5. Click on the "Show Results" button to view the uploaded wound image along with the circled wound areas.
Expected Outcome	The application accurately identifies and highlights the DFU wound area, even with varying lighting conditions.
Actual Outcome	The application accurately identifies and highlights the DFU wound area, even with varying lighting conditions.
Test Result	Pass

3 RESULTS AND DISCUSSION

3.1 Results

The implementation of the web application, utilizing PHP and the Laravel framework, along with an SQLite database for data storage and a Flask-based Python web framework for the U-Net model's API endpoint, yielded promising results.

The trained U-Net model showcased its proficiency by achieving an outstanding accuracy rate of 95% in the localization of diabetic foot wounds, as evidenced in Figure 3.1. This impressive accuracy highlights the model's capacity for precise and reliable identification and localization of these critical wound areas.

```
Epoch 490/500
12/12 [==============================] - 44s 4s/step - loss: 0.0174 - accuracy: 0.9917 - recall: 0.9917 - precision: 0.9918 - val_loss: 0.3442 - val_accuracy: 0.9508 - val_recall: 0.9507 - val_precision: 0.9510
Epoch 491/500
12/12 [==============================] - 43s 4s/step - loss: 0.0173 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3286 - val_accuracy: 0.9509 - val_recall: 0.9507 - val_precision: 0.9510
Epoch 492/500
12/12 [==============================] - 40s 3s/step - loss: 0.0172 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3404 - val_accuracy: 0.9500 - val_recall: 0.9499 - val_precision: 0.9502
Epoch 493/500
12/12 [==============================] - 42s 4s/step - loss: 0.0178 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3177 - val_accuracy: 0.9528 - val_recall: 0.9527 - val_precision: 0.9530
Epoch 494/500
12/12 [==============================] - 43s 4s/step - loss: 0.0178 - accuracy: 0.9916 - recall: 0.9915 - precision: 0.9917 - val_loss: 0.3146 - val_accuracy: 0.9529 - val_recall: 0.9528 - val_precision: 0.9532
Epoch 495/500
12/12 [==============================] - 42s 4s/step - loss: 0.0167 - accuracy: 0.9918 - recall: 0.9918 - precision: 0.9919 - val_loss: 0.3266 - val_accuracy: 0.9513 - val_recall: 0.9512 - val_precision: 0.9516
Epoch 496/500
12/12 [==============================] - 41s 3s/step - loss: 0.0169 - accuracy: 0.9919 - recall: 0.9918 - precision: 0.9919 - val_loss: 0.3492 - val_accuracy: 0.9497 - val_recall: 0.9496 - val_precision: 0.9499
Epoch 497/500
12/12 [==============================] - 39s 3s/step - loss: 0.0164 - accuracy: 0.9922 - recall: 0.9921 - precision: 0.9922 - val_loss: 0.3487 - val_accuracy: 0.9509 - val_recall: 0.9508 - val_precision: 0.9510
Epoch 498/500
12/12 [==============================] - 39s 3s/step - loss: 0.0168 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3559 - val_accuracy: 0.9488 - val_recall: 0.9487 - val_precision: 0.9490
Epoch 499/500
12/12 [==============================] - 41s 3s/step - loss: 0.0176 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3252 - val_accuracy: 0.9517 - val_recall: 0.9515 - val_precision: 0.9519
Epoch 500/500
12/12 [==============================] - 41s 3s/step - loss: 0.0175 - accuracy: 0.9917 - recall: 0.9917 - precision: 0.9918 - val_loss: 0.3304 - val_accuracy: 0.9500 - val_recall: 0.9499 - val_precision: 0.9502
Final Validation Accuracy: 95.00%
```

Figure 3.1: U-net model accuracy

Figure 3.2 provides a detailed view of the model's performance by presenting an extensive set of graphs illustrating key metrics such as accuracy, loss, recall, and precision. These metrics provide a quantitative evaluation of the model's performance, highlighting its remarkable consistency and precision in identifying diabetic foot wounds. Furthermore, Figure 3.3 goes a step further in showing the model's capabilities by including input images, manually annotated ground truth, and prediction masks generated by the model. Comparison between ground truth and prediction masks emphasizes the model's exceptional accuracy and proficiency in identifying and delineating diabetic foot wounds.

In Figure 3.4, shows the original image with clearly drawn circles, highlighting the model's ability in identifying regions of interest within the images. This visual representation serves as compelling evidence of the model's accuracy in localizing diabetic foot wounds.

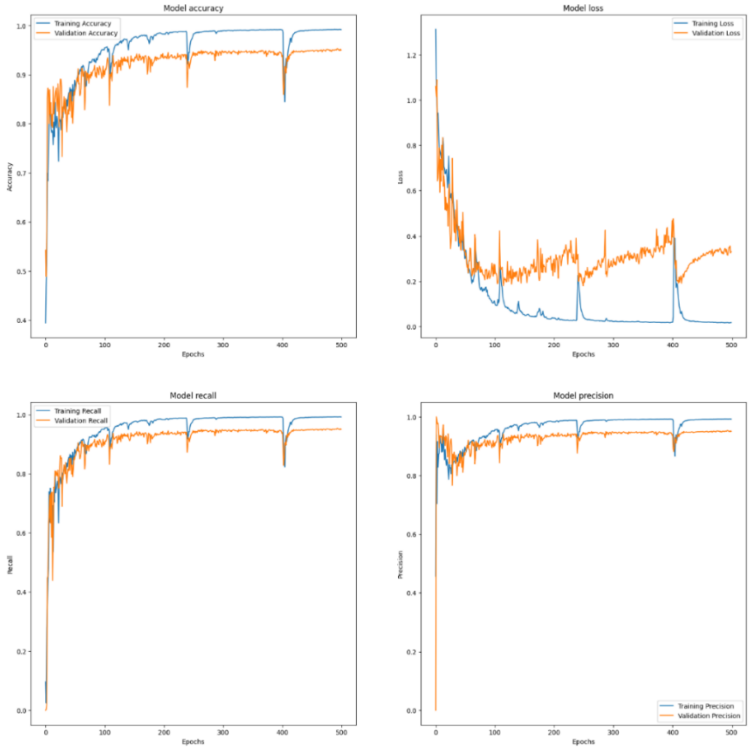

Figure 3.2: U-net model accuracy, loss, precision and recall graphs

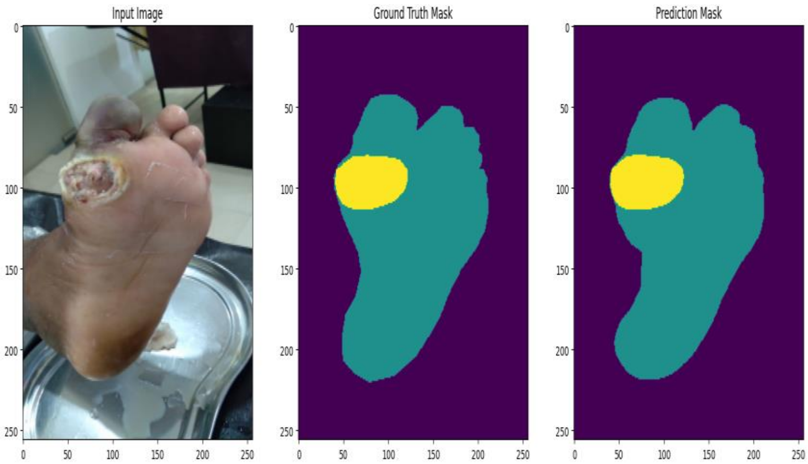

Figure 3.3: Input image, Ground truth and Prediction mask

Figure 3.4: Model output

The trained U-Net model summary, shown in Figure 3.4, depicts the model's architecture, highlighting its layers and emphasizing its effectiveness in semantic segmentation tasks. This model architecture is critical in achieving the outstanding accuracy demonstrated by our results.

Overall, the results of the implementation and evaluation of the "DiabiSole" web application highlight its potential to significantly improve the accuracy and efficiency of wound identification, thereby significantly improving diabetic foot ulcer management.

```
Model: "wound_classification"
____________________________________________________________________________________________
 Layer (type)                   Output Shape         Param #     Connected to
============================================================================================
 input (InputLayer)             [(None, 256, 256, 3  0           []
                                )]

 conv2d (Conv2D)                (None, 256, 256, 32  896         ['input[0][0]']
                                )

 dropout (Dropout)              (None, 256, 256, 32  0           ['conv2d[0][0]']
                                )

 conv2d_1 (Conv2D)              (None, 256, 256, 32  9248        ['dropout[0][0]']
                                )

 max_pooling2d (MaxPooling2D)   (None, 128, 128, 32  0           ['conv2d_1[0][0]']
                                )

 conv2d_2 (Conv2D)              (None, 128, 128, 64  18496       ['max_pooling2d[0][0]']
                                )

 dropout_1 (Dropout)            (None, 128, 128, 64  0           ['conv2d_2[0][0]']
                                )

 conv2d_3 (Conv2D)              (None, 128, 128, 64  36928       ['dropout_1[0][0]']
                                )

 max_pooling2d_1 (MaxPooling2D)  (None, 64, 64, 64)  0           ['conv2d_3[0][0]']

 conv2d_4 (Conv2D)              (None, 64, 64, 128)  73856       ['max_pooling2d_1[0][0]']

 dropout_2 (Dropout)            (None, 64, 64, 128)  0           ['conv2d_4[0][0]']

 conv2d_5 (Conv2D)              (None, 64, 64, 128)  147584      ['dropout_2[0][0]']

 max_pooling2d_2 (MaxPooling2D)  (None, 32, 32, 128)  0          ['conv2d_5[0][0]']

 conv2d_6 (Conv2D)              (None, 32, 32, 128)  147584      ['max_pooling2d_2[0][0]']

 dropout_3 (Dropout)            (None, 32, 32, 128)  0           ['conv2d_6[0][0]']

 conv2d_7 (Conv2D)              (None, 32, 32, 128)  147584      ['dropout_3[0][0]']

 up_sampling2d (UpSampling2D)   (None, 64, 64, 128)  0           ['conv2d_7[0][0]']

 concatenate (Concatenate)      (None, 64, 64, 256)  0           ['up_sampling2d[0][0]',
                                                                  'conv2d_5[0][0]']

 conv2d_8 (Conv2D)              (None, 64, 64, 64)   147520      ['concatenate[0][0]']

 dropout_4 (Dropout)            (None, 64, 64, 64)   0           ['conv2d_8[0][0]']

 conv2d_9 (Conv2D)              (None, 64, 64, 64)   36928       ['dropout_4[0][0]']

 up_sampling2d_1 (UpSampling2D)  (None, 128, 128, 64  0          ['conv2d_9[0][0]']
                                )

 concatenate_1 (Concatenate)    (None, 128, 128, 12  0           ['up_sampling2d_1[0][0]',
                                8)                                'conv2d_3[0][0]']

 conv2d_10 (Conv2D)             (None, 128, 128, 64  73792       ['concatenate_1[0][0]']
                                )

 dropout_5 (Dropout)            (None, 128, 128, 64  0           ['conv2d_10[0][0]']
                                )

 conv2d_11 (Conv2D)             (None, 128, 128, 64  36928       ['dropout_5[0][0]']
                                )

 up_sampling2d_2 (UpSampling2D)  (None, 256, 256, 64  0          ['conv2d_11[0][0]']
                                )

 concatenate_2 (Concatenate)    (None, 256, 256, 96  0           ['up_sampling2d_2[0][0]',
                                )                                 'conv2d_1[0][0]']

 conv2d_12 (Conv2D)             (None, 256, 256, 32  27680       ['concatenate_2[0][0]']
                                )

 dropout_6 (Dropout)            (None, 256, 256, 32  0           ['conv2d_12[0][0]']
                                )

 conv2d_13 (Conv2D)             (None, 256, 256, 32  9248        ['dropout_6[0][0]']
                                )

 conv2d_14 (Conv2D)             (None, 256, 256, 3)  99          ['conv2d_13[0][0]']

 reshape (Reshape)              (None, 65536, 3)     0           ['conv2d_14[0][0]']

 softmax (Softmax)              (None, 65536, 3)     0           ['reshape[0][0]']

============================================================================================
Total params: 914,371
Trainable params: 914,371
Non-trainable params: 0
____________________________________________________________________________________________
```

Figure 3.5: U-net model summary

3.2 Research Findings

The implementation of the "DiabiSole" solution has demonstrated a remarkable improvement in the accuracy of wound identification on the soles of diabetic patients. In Sri Lanka, the existing practice relies on subjective visual observation, which can lead to errors and treatment delays. Utilizing advanced image processing methods such as segmentation, edge detection, and feature extraction, our system reliably and precisely located wound areas, surpassing traditional visual observation methods that are often subjective and error prone. With a validation accuracy rate of 95%, the trained U-Net model consistently and precisely identifies the locations of diabetic foot wounds. This result underscores the model's proficiency in tackling the intricate task of wound localization, a critical aspect of DFU management. This improved accuracy lowers the risk of complications and treatment delays, ultimately improving patient care.

Beyond quantitative metrics, the research also offered visual evidence of the U-Net model's capabilities. Original wound images were accurately presented, with circles drawn around identified wound areas, helping in determining the appropriate hole sizes to be cut in insoles for effective pressure offloading. This visual representation offers tangible proof of the model's precision in localizing diabetic foot wounds. It allows for a good understanding of the model's effectiveness and its capacity to make precise identifications. Additionally, this dataset contributes to identifying new pressure offloading areas, optimizing the pressure relief provided to patients. As a result, our solution streamlines and optimizes the creation of personalized insoles, offering targeted relief to areas in need and improving overall DFU management.

When used in clinical settings, the "DiabiSole" system can seamlessly replace manual wound visualization techniques with notable benefits in terms of scalability and accessibility. With such ease of integration, a larger patient population in a variety of healthcare facilities can benefit from accurate wound identification. Additionally, there is a significant opportunity for cost savings through the automation of time-consuming and skill-intensive tasks related to insole customization, making the system cost-effective and extremely useful for broad adoption.

3.3 Discussion

The implementation of the "DiabiSole" web application represents a significant milestone in addressing the complexities of DFU management. This application is structured around four key components, wound area detection and measurement, high-pressure area detection and measurement, identification of offloading areas, and wound severity detection. These components collectively offer a comprehensive solution for the effective management of DFUs in diabetic patients, a novel approach not previously seen in research or practical applications.

Accurate wound detection and measurement improve treatment precision, potentially reducing complications and treatment delays. High-pressure area detection and measurement provide insights into areas that are prone to future wounds, allowing proactive measures to be taken to prevent complications. Identifying offloading areas improves pressure relief for patients, increasing their comfort and overall well-being. Furthermore, wound severity detection assists healthcare professionals in tailoring treatment plans to each patient's specific needs, aligning with the overarching goal of improving patient outcomes.

Looking ahead, our future work includes expanding the capabilities of the "DiabiSole" application to generate 3D models of customized insoles, considering unique modifications for each patient. This advancement will further enhance the application's ability to provide tailored solutions for DFU management. Additionally, we plan to train the system on a larger dataset to increase its accuracy, ensuring that it continues to deliver the highest level of support to healthcare professionals and patients alike. These advancements in the "DiabiSole" application have the potential to have a significant impact on the field of diabetic foot ulcer management, ultimately leading to better patient outcomes.

4 CONCLUSION

This research addresses an important gap in the management of diabetic foot ulcers (DFUs) and diabetic care in Sri Lanka. We began with the recognition of a significant research gap in the field, where the existing methods identifying DFUs and creating custom insoles were lacking in both accuracy and accessibility. Our innovative 'DiabiSole' application takes a significant step forward, with the potential to revolutionize diabetic foot care by accurately identifying wound locations and assisting doctors in creating personalized insoles for DFU patients.

While our research has yielded promising results and represents a significant advancement, we do recognize some limitations in the current version of 'DiabiSole.' It currently provides results in a 2D format and focuses primarily on wound identification and pressure offloading. Because of this limitation, a complete visualization of the fully customized insole is not possible. Our future work aims to expand 'DiabiSole' by incorporating a web-based 3D model of the custom insole. This advancement will allow both patients and healthcare providers to visualize the insole prior to customization, resulting in a more comprehensive and user-friendly solution.

In essence, our research journey has made a significant contribution to the lives of diabetic patients, particularly those with DFUs in Sri Lanka, by introducing an innovative solution. We remain dedicated to the ongoing development of 'DiabiSole,' with the ultimate goal of improving patient outcomes, preventing complications, and making diabetic foot care more accessible and effective for all.

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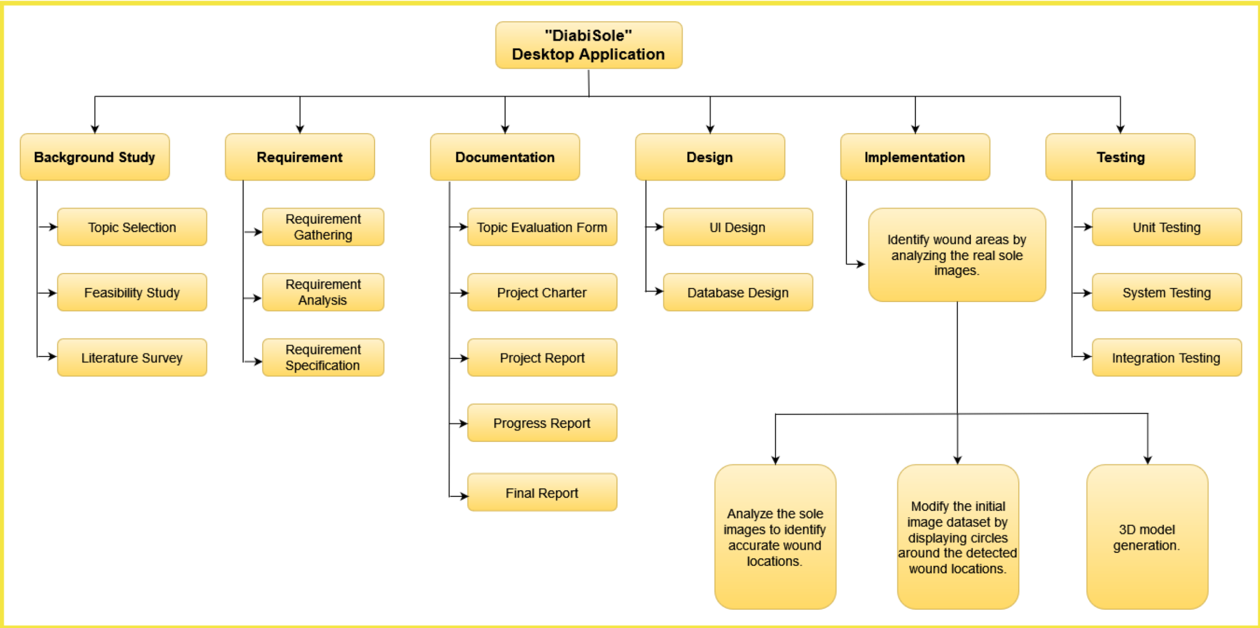
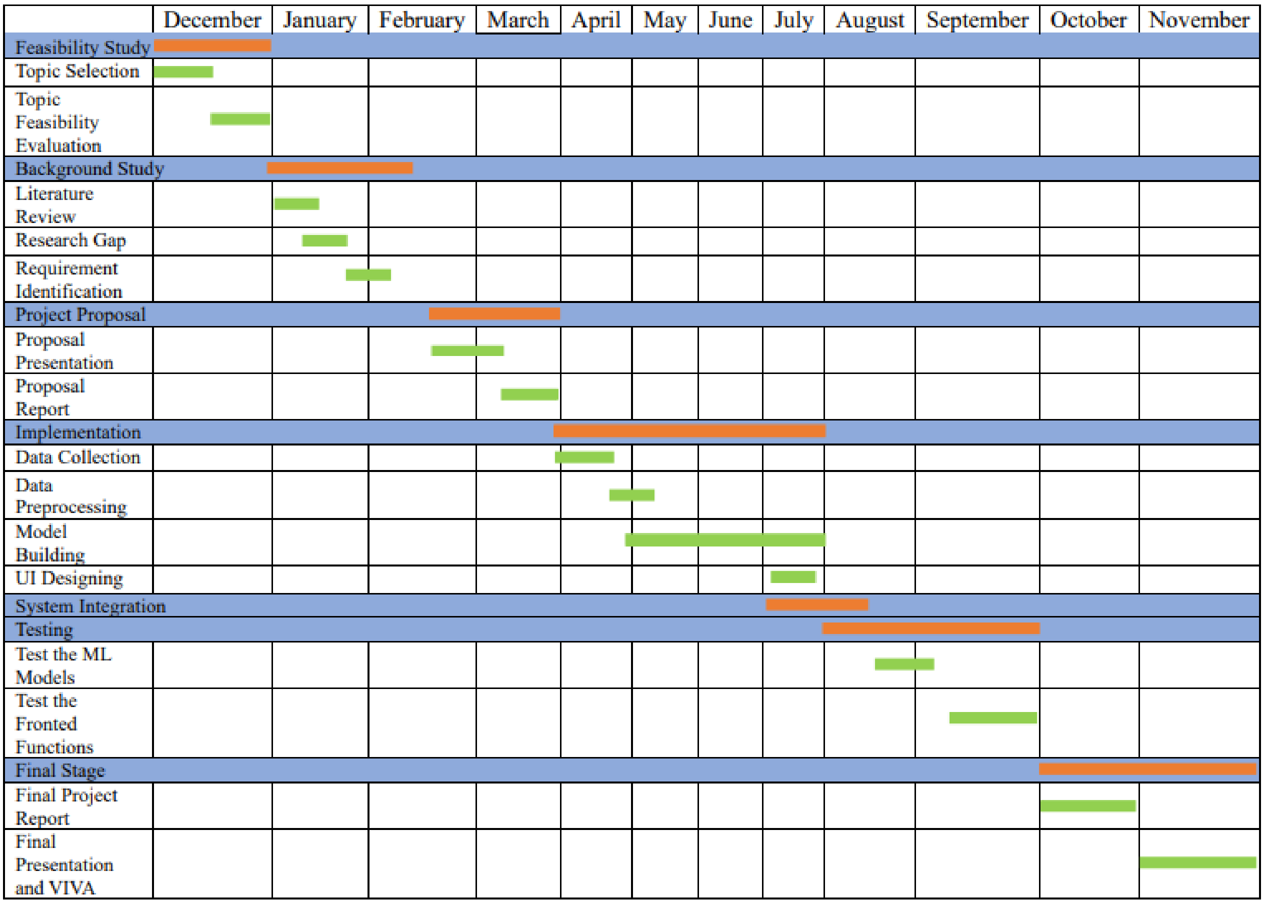
6 APPENDICES

Appendix - A: Application logo



Appendix - B: Work breakdown chart



Appendix - C: Gantt chart

To whom it may concern, 15 March 2023

"DiabiSole – Optimizing Diabetic Foot Care through Machine Learning and Image Processing" research project which is conducted by the Ariyasinghe P.A.D.N.I. [IT20033828], Dahanayake U.S. [IT20043650], Samarasinghe S.A.K.S. [IT20206246] and Samarakoon S.M.D.H. [IT20457952]4th year students at Sri Lanka Institute of Information Technology under supervision of Ms. Jenny Krishara.

This is to certify that for the above-mentioned research project, I will be providing the medical consultation for all the medical related aspects in this project. I hereby confirm that as an external supervisor of the project, I will be offering my consultation and all the datasets that they require as a medical officer throughout this project.

Thank you.

Dr. Piumika De Silva

Appendix - D: External supervisor letter

To whom it may concern,

I have personally gone through the web application DIABISOLE: Optimizing Diabetic Foot Care Through Machine Learning and Image Processing which is implemented by the students Ariyasinghe P.A.D.N.I., Dahanayake U.S., Samarasinghe S.A.K.S. and Samarakoon S.M.D.H can recommend this web application for podiatrists who are responsible in Diabetic foot care with customizing insoles.

Thank you.

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Dr. Piumika De Silva

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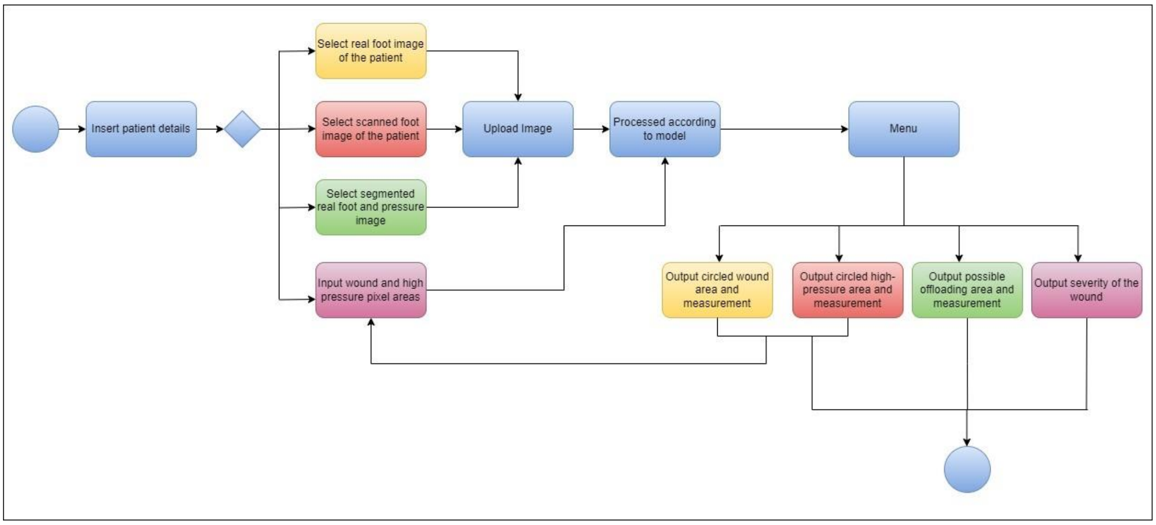
Colombo 05

Appendix - E: Recommendation letter from external medical supervisor letter



Appendix - F: Application Flow Diagram