OPTIMIZING DIABETIC FOOT CARE THROUGH MACHINE LEARNING AND IMAGE PROCESSING

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Dissertation submitted in partial fulfillment of the requirements for the Bachelor of Science (Hons) Degree in Information Technology Specializing in Data Science

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DECLARATION

I declare that this is my own work and this dissertation1 does not incorporate without acknowledgment, 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 acknowledgment is made in the text.

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ABSTRACT

In recent years, there has been a notable surge in the prevalence of diabetes, leading to a concomitant increase in complications such as diabetic foot ulcers and neuropathic damage. The implementation of customized diabetic insoles has emerged as a pivotal strategy in mitigating these complications by effectively redistributing high-pressure points, a practice commonly referred to as pressure offloading, and providing essential support. Nonetheless, the conventional manual customization process for these insoles is not only time-intensive but also subjective, frequently resulting in erroneous outcomes. This research endeavors to introduce "DiabiSole," a pioneering web-based application engineered to automate several critical aspects of this process. DiabiSole expedites the identification and measurement of calluses and heightened pressure, the identification of regions on the foot exhibiting pressure offloading regions, and the prediction of callus severity. To accomplish these objectives, three distinct datasets were harnessed. A sole image dataset for callus area detection and quantification, a scanned foot image dataset for detecting heightened-pressure areas, and a dataset with callus and pressure area measurements to predict severity. The two distinct U-Net models employed for callus and heightened-pressure area identification achieved commendable accuracies of 93% and 98%, respectively. Measurements of relevant areas were facilitated through the utilization of the OpenCV library, while Pixel Distribution Analysis was incorporated to accentuate areas necessitating pressure offloading. Wound criticality prediction employed a Gaussian Naive Bayes model, reaching a remarkable 99.21% accuracy. In summary, "DiabiSole" revolutionizes personalized insole creation for diabetic foot ulcers in Sri Lanka. This innovative system enhances patient outcomes, reduces ulceration, and minimizes the need for amputations.

Keywords – Callus, pressure offloading, web application, wound criticality

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LIST OF ABBREVIATIONS

Abbreviation	Description
IP	Image Processing
ML	Machine Learning
DL	Deep Learning
AI	Artificial Intelligence
UI	User Interface
DFU	Diabetic Foot Ulcer
LBP	Local Binary Pattern
GLCM	Grey Level Co-occurrence Matrix
LEA	Lower Extremity Amputations
CHS	Chronic Health Status
ROC	Receiver Operating Characteristic
AUC	Area Under Curve

LIST OF APPENDICES

1 INTRODUCTION

1.1 Background

Diabetic Foot Ulcer (DFU) is a chronic wound prevalent among individuals with diabetes, typically presenting as ulcers on the plantar surface, specifically the forefoot, toes, or dorsal foot region. These ulcers exhibit variability in size and depth and often manifest with clinical indicators such as exudate, edema, and erythema. In severe instances, DFUs can culminate in grave complications, notably osteomyelitis (bone infection) or gangrene (tissue necrosis).

Sri Lanka has witnessed an alarming surge in lower limb amputations, with DFUs accounting for more than 50% of these cases [1], [2]. To gauge the severity of DFUs, clinicians frequently employ Wagner's classification system, which assigns a numerical stage from 0 to 5 [3], considering ulcer depth, tissue involvement, and the presence of osteomyelitis. The stages encompass the absence of open lesions - Stage 0, superficial ulcers/calluses - Stage 1, deep ulcers - Stage 2, osteitis - Stage 3, partial foot gangrene - Stage 4, and complete foot gangrene - Stage 5 [3].

Below is a visual representation of a foot in different DFU stages which is taken referring to [3].

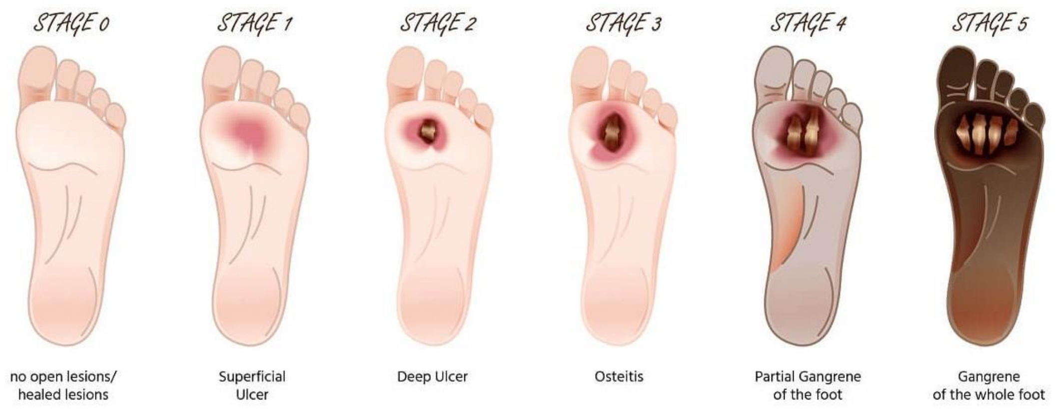

Figure 1.1: Visual representation of Diabetic Ulcer Stages

Preventing ulcers' progression is imperative, particularly in ‘Stage 1’ and ‘Stage 2’, to avert amputations. ‘Stage 1’ ulcers can often be managed with customized footwear, while ‘Stage 2’ requires measures like pressure relief, sharp debridement, and proper dressings [2]. Pressure offloading (redistributing high-pressure) shoes are vital for managing ‘Stage 2’ DFUs, aiming to alleviate pressure on the affected area to prevent further harm. Accurate knowledge of pressure distribution during standing and walking is crucial for devising effective offloading strategies.

Traditionally, clinicians assessed pressure distribution manually using pressure mapping devices, which involved pressure-sensitive film placed on the foot, followed by manual analysis. Alternatively, static scanners offered a more efficient method for similar measurements. Dynamic scanners, on the other hand, provided real-time imaging of pressure distribution during movement, enabling precise identification of heightened-pressure areas contributing to DFU development.

Customizing diabetic footwear predominantly entails tailoring the insole. Existing practices in Sri Lanka involve using materials such as plaster of Paris to create a foot impression, subsequently modifying it based on clinical evaluation, and fabricating a static insole [4]. Alternatively, manual hole creation within the insole is attempted at the site of calluses, supplemented with an overlay to prevent contact between the callus and the hole edges. These procedures, however, are protracted, vulnerable to wound site misidentification, and may pose challenges for individuals with sensory deficits [5], [6].

Furthermore, the prediction of DFU criticality is a critical consideration when implementing pressure offloading strategies. According to [7], High pressure is a key factor in DFU occurrences. Nonetheless, subsequent research has indicated that risk factors, including the presence of calluses, exhibit greater predictability regarding the occurrence of future ulcers [8]. Moreover, it has been observed that relying solely on high pressure as a predictive tool for ulceration yields limited effectiveness [9]. In light of these observations, there arises a clear need for a comprehensive DFU criticality prediction system that incorporates both the callus area and the elevated pressure area as pivotal features when customizing pressure offloading insoles. Although various wound criticality scoring or prediction systems have been developed for evaluating DFUs, there is a noticeable lack of systems that encompass the prediction of callus criticality while concurrently considering both DFU area and pressure distribution.

Addressing these limitations, this research initiative endeavors to devise a web-based application capable of precise identification of callus regions, measurement of their dimensions, provision of visualizations for targeted pressure relief within the insole, and the prediction of callus criticality. By rectifying deficiencies inherent in conventional approaches, this application aspires to augment pressure mitigation for DFUs and high-pressure regions, enhancing overall patient care and therapeutic outcomes.

1.2 Literature Survey

The UTrack framework for segmenting and measuring dermatological ulcers through telemedicine [10].

The research presented in reference [10] introduces "UTrack," a telemedicine-driven framework tailored for the segmentation and quantitative assessment of dermatological ulcers. This innovative approach comprises a smartphone application coupled with a measurement technique reliant on a simple ruler to quantify ulcer dimensions accurately. Furthermore, it facilitates a longitudinal storage, visualization, and sharing of chronic dermatological ulcer analyses. It is important to underscore that this solution is readily accessible and user-friendly, compatible with standard mobile devices equipped with conventional cameras. Notably, it is exceptionally inclusive, serving patients, caregivers, and healthcare professionals without necessitating specialized equipment like internet connectivity, specific sensors, or advanced cameras. The system efficiently utilizes the ruler-based measurement approach to precisely determine wound dimensions.

The authors use various features of the wound as given below.

- Wound perimeter: The boundary of the ulcer. The user trace around the ulcer using the smartphone application.
- Wound shape: The overall shape of the ulcer, which can be irregular or asymmetrical.
- Wound color: The color of the ulcer and the surrounding skin. Color features were extracted using Red, Green, Blue (RGB) color space.
- Image quality: The quality of the smartphone image.

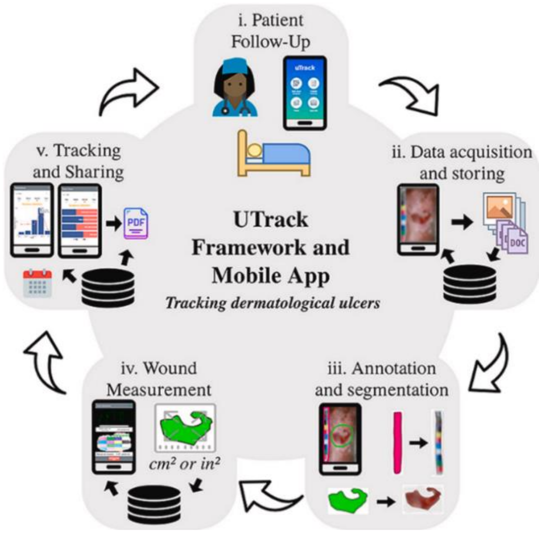

Figure 1.2: Architecture of the Mobile App

Wound area measurement with 3D transformation and smartphone images [11].

The primary aim of the study outlined in reference [11] is to attain a precise and quantitative evaluation of surface wound areas. To achieve this objective, a 3D transformation algorithm is employed, which facilitates the projection of the wound onto a two-dimensional plane, thus enabling accurate measurement of the wound's area. Rooted in photogrammetric principles, this algorithm utilizes user-identified features to reconstruct a three-dimensional model of the wound. Subsequently, the area of the wound is ascertained by incorporating the user-identified perimeter and dimensions within the generated 3D model.

The authors use various features of the wound for measuring the area, which include:

- Wound perimeter: The border between the ulcer and the surrounding healthy tissue, which is identified by tracing around the wound using the smartphone camera.
- Wound shape: The overall shape of the ulcer, which can be irregular or have asymmetrical edges.
- Wound dimensions: The length and width of the ulcer, which are used to calculate the wound area.
- Wound texture: The texture of the ulcer area.
- Wound color: The color of the ulcer area.
- Image quality: The quality of the smartphone image,

The wound extraction and calculation process is shown in Figure 1.5.

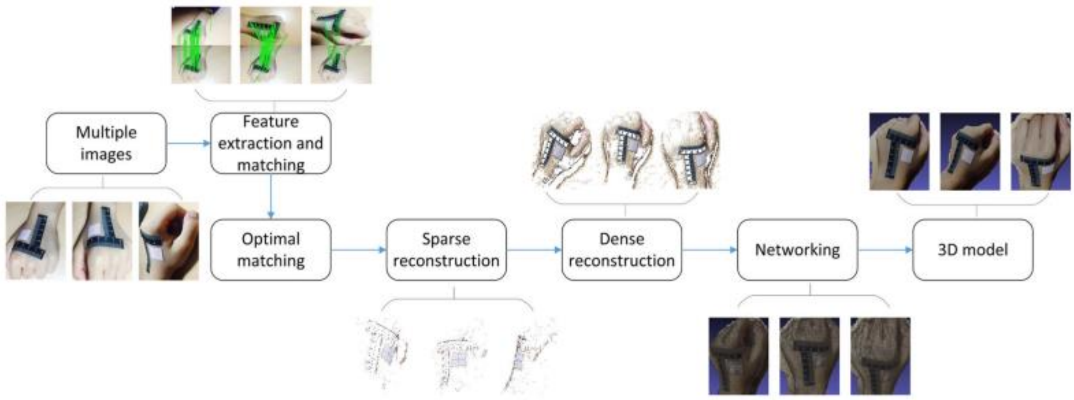

Figure 1.3: The process of 3D reconstruction

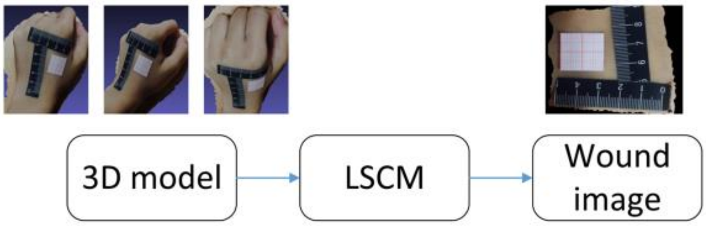

Figure 1.4: The process of 3D unwrapping

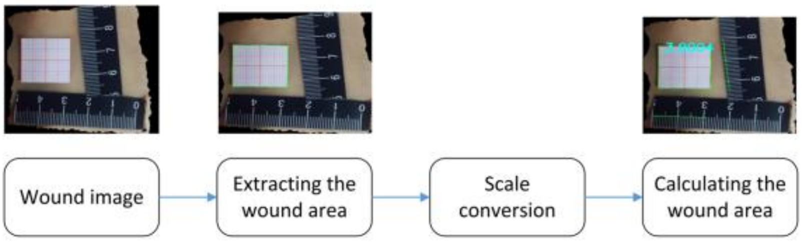

Figure 1.5: Process of calculating the wound area

The effectiveness of this methodology is validated through a rigorous comparison between simulated and actual wounds, confirming its prominent level of accuracy. Importantly, this technique is adaptable to wounds captured by various cameras, regardless of factors such as acquisition angle, distance, or the specific imaging device employed.

Semi-Automatic Ulcer Segmentation and Wound Area Measurement Supporting Telemedicine [12].

The research, as outlined in reference [12], has introduced a semi-automatic system referred to as the "URule" framework, which is dedicated to ulcer segmentation and wound area quantification. This innovative system comprises two principal components: "URule-App," an Android application designed for image annotation, and "URule-Seg," an algorithm tailored for ulcer identification. Healthcare professionals are empowered to annotate images by delineating a bounding box around the ulcer of interest within the user-friendly interface of the "URule-App". Subsequently, the segmentation algorithm, "URule-Seg," employs a fusion of local binary patterns (LBP) and grey-level co-occurrence matrix (GLCM) features to extract textural characteristics from the ulcer region. Following this feature extraction process, a random forest classifier is utilized to categorize each pixel within the image as either ulcer or non-ulcer. Furthermore, the system encompasses a dedicated tool for the precise measurement of ulcer area, employing a straightforward pixel-counting methodology within the bounding box. Notably, the "URule" framework is meticulously designed to facilitate telemedicine applications, enabling healthcare practitioners to remotely monitor the progression of chronic wounds over time, thereby enhancing patient care and clinical decision-making.

The authors use various features of the wound for measuring the area, which include:

- Wound boundary: The border between the ulcer and the surrounding healthy skin tissue, which may be irregular or have different textures.
- Wound shape: The overall shape of the ulcer, which can be irregular or have asymmetrical edges. Used based on the circularity and convexity of the wound region.
- Edge information: Edge detection was used to identify the edges of the wound and to segment the wound from the surrounding healthy tissue.
- Wound texture: The texture of the ulcer and surrounding tissue. Used based on local binary patterns (LBP).
- Wound color: Feature is used to separate the wound region from the surrounding healthy tissue. Used color features based on the RGB color space.
- Image quality: The quality of the smartphone image, which can affect the accuracy of wound area measurement.

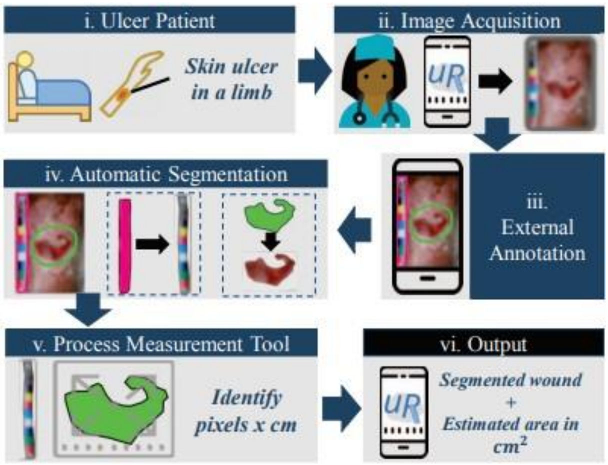

Figure 1.6: Usage of the used framework

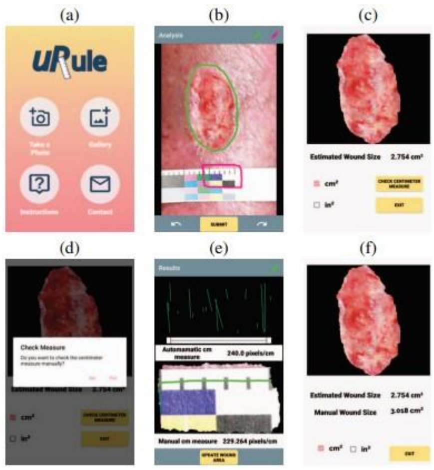

Figure 1.7: User interfaces

A new diabetic foot risk assessment tool: DIAFORA [13].

In 2016, the “Diabetic Foot Risk Assessment (DIAFORA)” tool was developed in Portugal, comprising eight distinct variables. The variables are commonly used clinical factors for diabetic foot risk assessment, such as the presence of neuropathy, foot deformities, peripheral arterial disease, and previous foot complications. Additionally, it considered factors like the extent of diabetic foot ulcers, infection, gangrene, and bone involvement. This classification system serves a dual purpose, as it can be divided into two sections, each serving a different objective. The initial four variables, related to foot conditions, are primarily utilized for predicting the onset of foot ulcers. Meanwhile, the comprehensive version, encompassing all eight variables, is employed to forecast the likelihood of Lower Extremity Amputations (LEA) in individuals already diagnosed with DFUs.

DIAFORA employs a point-based system to categorize individuals into different risk groups, as outlined in Figure 1.8. There has been no external validation or assessment of the tool's reliability.

Foot related			DFU related		
Variables	Definition	Points	Variables	Definition	Points
DPN	Inability to feel SWM at ≥1 of 4 points (hallux pulp, first, third and fifth MTT heads)	4	Multiple DFU	Presence of ≥1 DFU	4
Foot deformity	Foot alteration increasing pressure in ≥1 sites of the foot	1	Infection	Purulent discharge with another two local signs (warmth, erythema, lymphangitis, lymphadenopathy, oedema or pain)	4
PAD	≤1 palpable pedal pulse (posterior tibial and dorsalis pedis arteries)	7	Gangrene	Presence of necrosis (dry or wet)	10
Previous DFU or LEA	History of previous DFU or LEA	3	Bone involvement	Bone exposure identified through visual inspection, touch with sterile probe and/or bone affection identified through X-ray	7
Risk groups					
Less than 15 points	Low risk of LEA	Between 15 and 25 points	Medium risk of LEA	More than 25 points	High risk of LEA

Figure 1.8: Rules for prediction

Diabetic neuropathic foot ulcers: predicting which ones will not heal [14].

Margolis et al. introduced various models based on data gathered from 150 wound care facilities operated by a single organization in the United States. These models aimed to predict the healing outcomes of neuropathic ulcers within a 20-week timeframe. The most straightforward model in their analysis incorporated factors such as a wound duration exceeding 2 months, wound size greater than 2 cm^2, and a Chronic Health Status (CHS) wound grade of 3 or higher. Each of these components contributed 1 point to the scoring system.

This scoring system demonstrated a noteworthy performance, achieving an area under the receiver operating characteristic (AUROC) curve of 0.8 for predicting non-healing outcomes, which encompassed lower extremity amputations (LEA) and death, within the 20-week period during an internal validation study. Notably, the research revealed that 35% of uncomplicated neuropathic Diabetic Foot Ulcers (DFUs) did not heal by the 20-week mark, highlighting the importance of these predictive models. However, there is a lack of published information regarding the reliability assessment of this model in the existing literature.

Comparison of existing systems:

Table 1.1: Comparison of existing systems

	01	02	03	04	05	**DIABISOLE**
Identification of DFUs	✓	✓	✓	✗	✗	✓
Measure DFU areas	✓	✓	✓	✗	✗	✓
Image processing techniques	✓	✗	✓	✗	✗	✓
Assess DFU criticality	✗	✗	✗	✓	✓	✓
Use **both wound area and high-pressure area** for criticality prediction.	✗	✗	✗	✗	✗	✓

01- The UTrack framework for segmenting and measuring dermatological ulcers through telemedicine [10]

02 - Wound area measurement with 3D transformation and smartphone images [11]

03 - Semi-Automatic Ulcer Segmentation and Wound Area Measurement Supporting Telemedicine [12]

04 - A new diabetic foot risk assessment tool: DIAFORA [13]

05- Diabetic neuropathic foot ulcers: predicting which ones will not heal [14]

1.3 Research Gap

The research gap identified in the research problem encompasses the absence of an integrated and efficient solution for addressing the prevention and management of DFUs through a comprehensive approach, including DFU criticality prediction.

The existing methods for preventing and managing DFUs are fragmented and outdated. Traditional techniques in Sri Lanka involve manual customization of insoles, relying on materials like plaster of Paris, which is time-consuming and error prone. These methods do not consider both DFU identification and pressure relief, which are critical aspects of DFU management.

Moreover, while some technologies exist for tracking and relieving high-pressure areas on foot, there is a notable absence of a holistic approach that encompasses DFU identification, precise measurement of DFU and pressure areas, and DFU criticality prediction. This gap means that current approaches may not effectively prevent and manage DFUs, leading to suboptimal patient care and treatment outcomes.

The addition of DFU criticality prediction is of paramount importance in addressing this research gap. The prediction involves assessing the severity of DFU which considers both DFU area and high-pressure areas as pivotal features. By incorporating this aspect into the system, healthcare professionals can make more informed decisions about the urgency and type of interventions required for individual patients. This predictive capability can significantly enhance patient outcomes by allowing for early and targeted interventions, reducing the risk of complications and amputations.

Additionally, this web application acknowledges the challenges faced by individuals with vision impairments or foot numbness, which are not adequately addressed by existing methods and technologies. This further underscores the need for an innovative solution that can accommodate a wider range of patient’s needs and provide personalized and precise care.

In summary, the research gap not only revolves around the absence of a comprehensive and automated system that combines wound identification, precise measurement, and pressure relief but also highlights the critical need for wound criticality prediction. Such a system, by addressing these gaps, would enhance patient outcomes, reduce the occurrence of ulcers, and help prevent the need for amputations in diabetic individuals, revolutionizing DFU management.

1.4 Research Problem

Diabetic foot callus is a common complication of diabetes, which occurs due to repetitive pressure and shear forces on the skin of the foot. If left untreated, diabetic foot callus can progress to ulceration, infection, and ultimately amputation [4],[15]. Pressure offloading is an essential component of the treatment plan for diabetic foot callus, as it redistributes pressure away from the affected area, reduces the risk of further damage, and promotes healing.

Custom-made diabetic shoes and insoles are often used to provide pressure offloading for diabetic foot callus. However, the effectiveness of these interventions depends on the accurate identification and measurement of the callus. If the size of the callus is not precisely identified, the offloading may not effectively redistribute pressure away from the affected area, leading to further damage and development of the condition.

Additionally, the conventional approach practiced at the Diabetic Foot and Wound Care Clinic of King's Hospital in Sri Lanka, involving manual observation, measurement, and hand-cutting of insole holes to alleviate pressure on calluses, may not be optimal. This method is susceptible to inaccuracies and misidentifications. Determining the exact sizes of insole holes is challenging, leading to suboptimal pressure redistribution and reduced intervention efficacy. Furthermore, DFU criticality prediction is a valuable factor to consider when offloading pressure.

Therefore, there is a need for an innovative and effective approach that combines callus and high-pressure area identification and measurement through image processing, pressure offloading area identification, and DFU criticality prediction to optimize pressure redistribution and improve the effectiveness of pressure offloading interventions for diabetic foot callus.

1.5 Background Research

Visiting to meet the stakeholders related to this system is necessary to get a clear idea about the existing insole customization methods and the importance of developing a system for customizing the insole of a diabetic shoe to offload the pressure on calluses and high-pressure areas on foot. To achieve this, we have visited several places that we identified as our stakeholders. The main places are shown below,

- Beta Diabetic Footwear Solutions – The main shoe production company (DSI) where the basic diabetic shoe is produced and distributed to the places where customization of the shoe takes place.
- Dr. Namarathne from Diabetic Footcare and Rehabilitation Center – A private hospital that treats patients who have diabetic feet. The primary method to offload pressure on DFUs is using Gauze Bandage Rolls on low-pressure areas to remove the high pressure on DFUs and instruct them to wear diabetic shoes.
- Ragama Rehabilitation Hospital – The main method to offload pressure on DFUs are, after wrapping the whole foot from bandages, use Plaster of Paris to build a mold of the foot and create a customize insole by hand using the mold.
- Exceed Prosthetics and Orthotics Foot balance Lanka Pvt Ltd – Use the same method as Ragama Rehabilitation Hospital to offload pressure on DFUs.
- Diabetic Foot and Wound Care Clinic of Kings Hospital – The primary method to offload pressure on DFUs is to cut holes in the insole where the callus is located to reduce pressure on the affected area and add another thin layer on top of the insole to avoid the collision between the edges of callus and hole to remove unnecessary pressure on the callus.

After meeting the stakeholders, we have come to a few conclusions,

1) All the above-mentioned pressure offloading methods are entirely manual.
2) As a result, it consumes a considerable amount of time to customize an insole.
3) The risk of misidentifications and inaccuracies is high.
4) Prosthetist and Orthotist surgeons seemed to be interested in the idea of automating the pressure offloading process and the DFU criticality prediction feature.

Therefore, we decided to automate the pressure offloading method used in “Diabetic Foot and Wound Care Clinic of Kings Hospital” which is to cut holes in the insole where the calluses are located. We have identified two main users of our system as Prosthetist and Orthotist surgeon and Orthopedic shoe Technician.

Below,

- Figure 1.51 displays the Pressure Offloading Method at Ragama Rehabilitation Hospital,
- Figure 1.52 displays the Pressure Offloading Method at Exceed Prosthetics and Orthotics Foot balance Lanka Pvt Ltd,

- Figure 1.53 displays the treatment method of Dr. Namarathne from Diabetic Footcare and Rehabilitation Center,
- Figure 1.54 displays the Pressure Offloading Method at Diabetic Foot and Wound Care Clinic of Kings hospital (using dynamic scanner and a customized insole by cutting hole).

Figure 1.51: mold of a patient and a customized insole

Figure 1.52: creation of a customized insole

Figure 1.53: treating a patient

Figure 1.54: dynamic scanner and custom insole by cutting hole

2 OBJECTIVES

2.1 Main Objective

Measure the identified wound areas to get the hole sizes in the insole and predict DFU criticality.

There are mainly six stages of a DFUs. Customizations to reduce the pressure (pressure offloading) on the DFUs in insoles are mostly done in the second stage where the DFU is called as a Callus. Main objective here is to measure the callus area to get the hole size to be cut in the insole according to callus measurements.

As mentioned previously, the prediction of DFU criticality is a key factor to consider when customizing the insole to offload high-pressure. Such a system is essential for doctors to make more informed decisions about the urgency and type of interventions required for individual patients. This predictive capability can significantly enhance patient outcomes by allowing for early and targeted interventions, ultimately reducing the risk of complications and amputations.

The main objective here is to measure the callus area sizes and to predict the criticality of the DFU in an accurate manner. Our developed application is designed in a user-friendly way to maximize the user experience.

2.2 Specific Objectives

2.2.1 Measure the precise size of the identified callus area.

Referring to [6], customizations to the insoles are done in DFU stage two where the formed ulcer also known as a callus, is only can be seen superficially. We are planning to automate the pressure offloading method of cutting holes in the insole. To achieve this, first we need to identify the calluses accurately and modify the initial real foot image dataset by displaying circles around the detected callus areas. "Identify wound areas by analyzing the real sole images" Component has completed this task. In this component, the measurements of the calluses are given using the OpenCV library Python as pixel area measurements. Later, the callus area measurements are used to predict the DFU criticality.

2.2.2 Predict the DFU criticality.

As mentioned earlier, predicting the DFU criticality assists doctors to take more accurate decisions which further increase the efficiency of the insole customization process. In the system, user has to input the DFU area measurements, high-pressure area measurements and area locations separately and the trained ‘Gaussian Naive Bayes’ model will display the DFU criticality as ‘severe’ or ‘not severe.’

2.2.3 View the callus area measurements and DFU status history.

After the user input the diabetic patient’s sole image, the application will identify and measure the DFU area and save the measurements in the database. Similarly, after the user has input the DFU and high pressure area measurements and locations, the application will obtain the other required parameters from patient registration history, predict the criticality and save the status in the database. Later, the user can view the results by using the relevant interface.

3 METHODOLOGY

3.1 Methodology

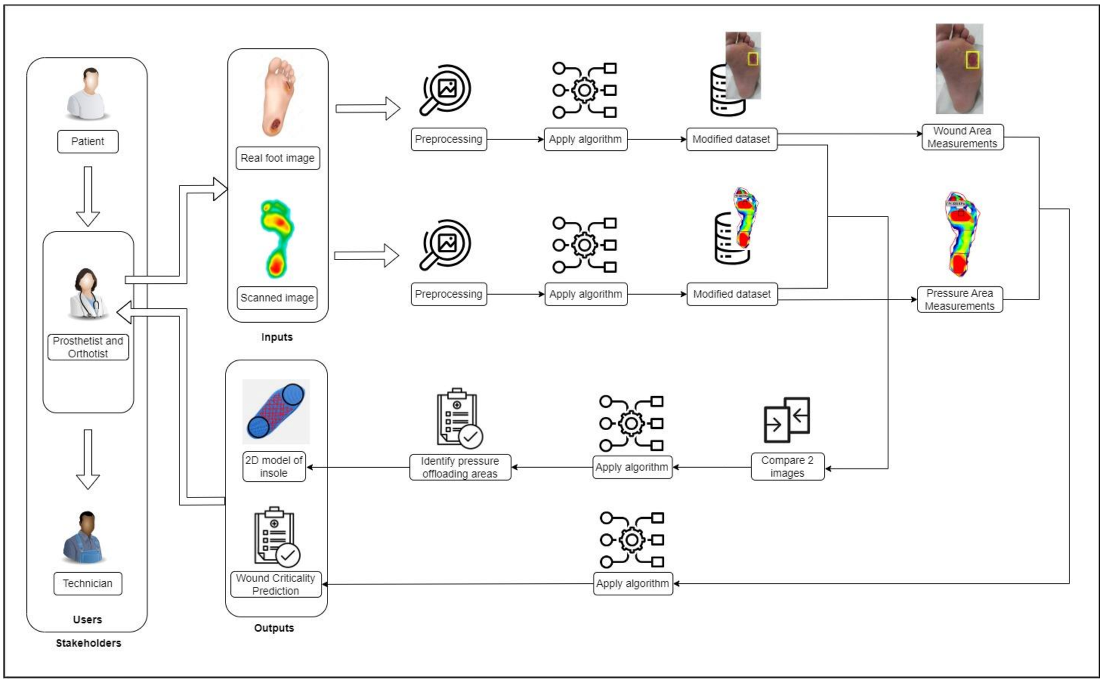

Figure 3.1: System high level diagram

All four sub-functions integral to this research are depicted in Figure 3.1 above. To construct the web application, we have harnessed PHP in conjunction with the Laravel framework. This web application relies on a MySQL database to securely store user data and test records. Furthermore, we have established a Python-based API, developed using Flask, as a pivotal component to seamlessly interconnect all the essential processes.

The web application's structure revolves around four principal functions: DFU area detection and measurement, high-pressure area detection and measurement, identification of offloading areas, and wound severity detection, culminating in the final system's implementation. Prosthetic and Orthotic surgeons and Orthopedic shoe technicians are the primary users of the system. The workflow commences with the submission of a Diabetic patient’s sole image containing DFUs and a scanned image depicting the sole's pressure distribution. These images undergo preprocessing and enable the system to identify the DFU and high-pressure areas and measure their sizes using deep learning models. Subsequently, through a comparison between the identified DFU regions and high-pressure areas, the system proposes new locations for pressure offloading on the foot. Lastly, employing an analysis of callus areas and high-pressure area measurements and locations, the system gauges the severity level of the wounds as ‘severe’ or ‘not severe.’ The user can view a 2D insole model, highlighting DFU areas and high-pressure regions in red, while pressure offloading areas are delineated in blue. Additionally, the system generates a comprehensive DFU severity report.

The component overview diagram for measuring the DFU areas and predicting DFU criticality is shown in Figure 3.2.

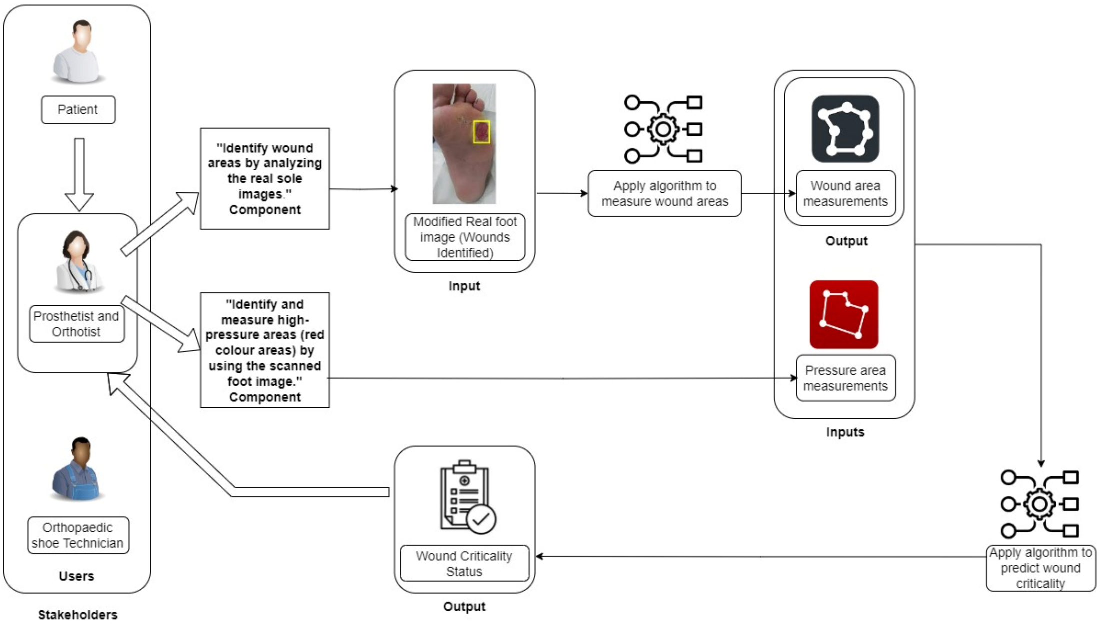

Figure 3.2: High level diagram of individual function

(High level diagram of “Measure the identified wound areas to get the hole sizes in the insole and predict DFU criticality” component)

3.1.1 Measure and display the size of callus area.

In the context of diabetic patient foot image analysis, the task involves measuring the area of calluses, which are highlighted with a green circular marker. To accomplish this, the initial step involves verifying the accuracy of detecting the green circle through the application of thresholding techniques, with blue color contours serving as a reference. Following successful circle detection, area measurements are subsequently obtained using the OpenCV library, as illustrated in Figure 3.3 below.

Figure 3.3: Obtaining callus area measurements

To obtain callus area measurements in the web application, the user initiates the process by providing the system with the pertinent sole image of the diabetic patient. Subsequently, the system autonomously identifies the callus area using OpenCV library and diligently records the measurements in pixels, along with a timestamp, in the MYSQL database. These recorded measurements can be conveniently accessed by the user at a later time by perusing the patient's checkup history, as illustrated in Figure 3.4.

Furthermore, user can filter the patients’ callus area measurement details by the NIC number or checkup date of the patient which is an enhancement of the user-friendliness and usability of the application.

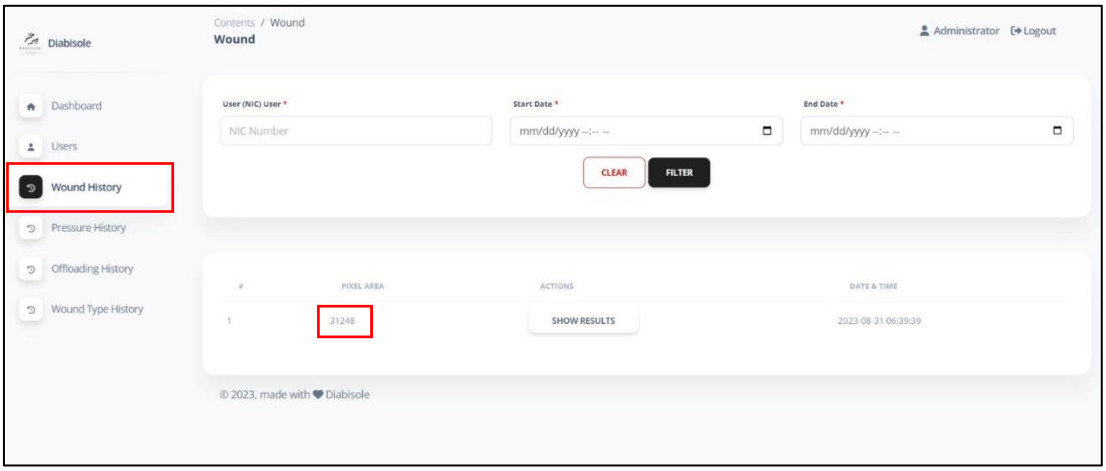

Figure 3.4: UI for callus area measurement history

3.1.2 Predict and display DFU criticality.

After an extensive literature review, the chosen primary **features** for model development were age and gender of the patient, location of callus and high-pressure areas (both are in the same location – 1, else – 0), callus area measurements and high-pressure area measurements. The dataset required for model training was obtained from Dr. Namarathne, comprising records from 1902 patients. Dr. Namarathne assisted in generating the 'DFU severity' column, which serves as the class label for model training.

severity	disease_pixel_count	pressure_pixel_count	location	age	gender
1	19896	30368	1	54	M
0	3105	4046	0	42	F
0	3348	4952	0	61	M
0	2344	5650	0	51	M
1	20158	28504	0	55	M
1	20000	29518	1	49	F
0	2693	5957	0	38	M
0	2246	3887	0	53	F
1	20059	31842	1	47	F

Figure 3.5: Dataset

Initially, the dataset was pre-processed to handle missing and duplicated values. After the feature engineering to preprocess data is completed, a classification model was constructed. Five machine learning models were considered: 'Decision Tree,' 'Random Forest,' 'XGBoost Classifier,' 'Gaussian Naive Bayes,' and 'K-Nearest Neighbor Classifier.' The ‘Gaussian Naive Bayes’ model, with the highest accuracy, was selected for training the model. The pickle file of the trained model was then employed to get the predictions for DFU criticality. Figure 3.5 illustrates the steps to build the prediction model.

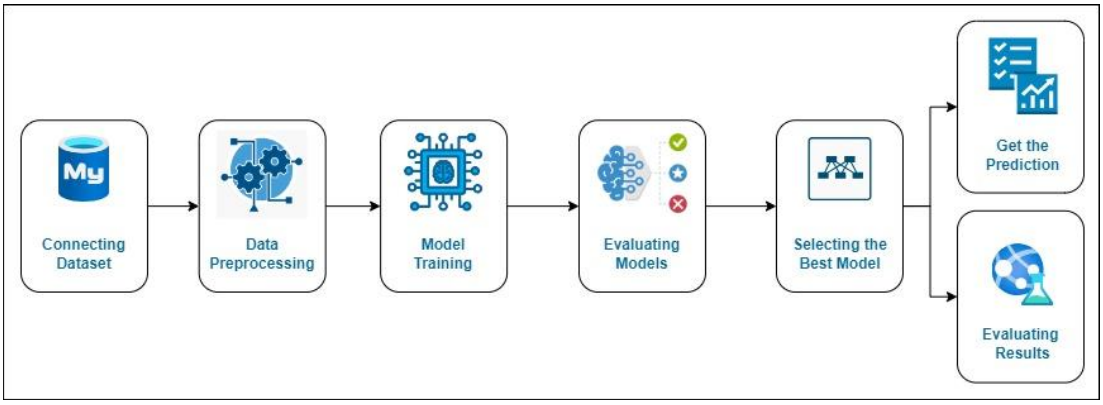

Figure 3.6: Prediction model building steps

To obtain predictions regarding the criticality of DFUs for a given patient in the web application, the user is required to provide input data encompassing callus and high-pressure area measurements and the location in the prompted interface. Subsequently, the system obtains the age and gender of the patient from patient's registration history and leverages the trained 'Gaussian Naive Bayes' model to predict the DFU's criticality, categorizing it as either 'severe' or 'not severe'.

This criticality status is then stored in the MySQL database, accompanied by a timestamp for reference. Much akin to the aforementioned procedure, users have the capability to access and review the DFU criticality status of all patients within their checkup history as illustrated in Figure 3.7.

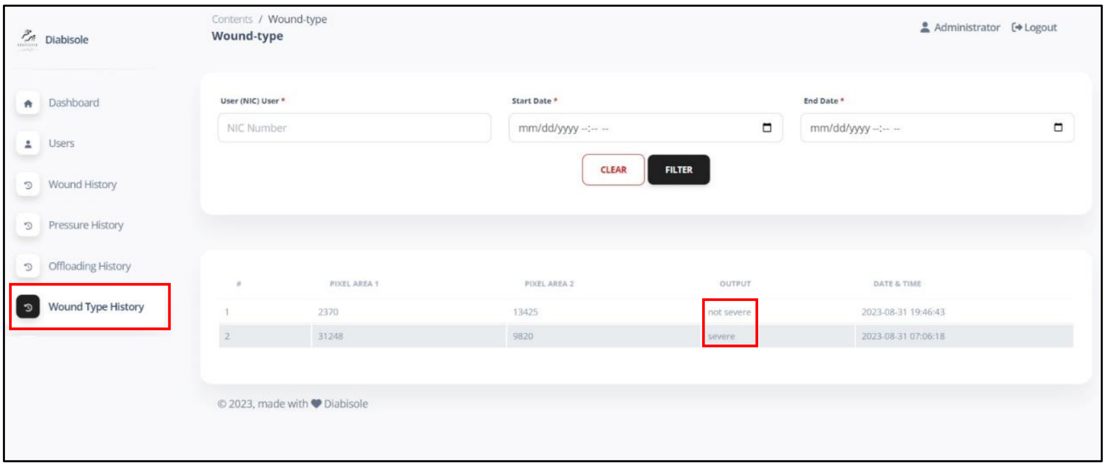

Figure 3.7: UI for DFU criticality status history

Figure 3.8 illustrates the application procedure steps which were discussed above.

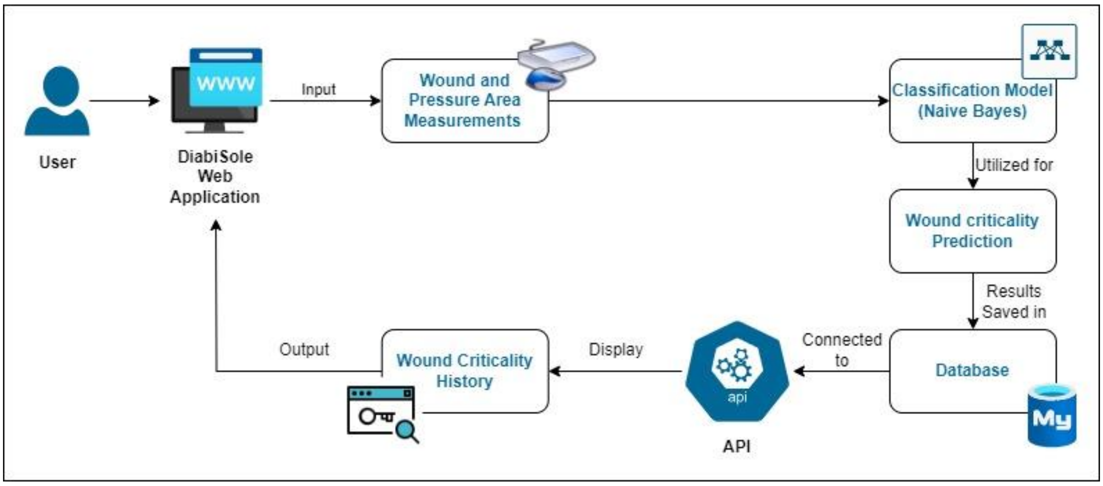

Figure 3.8: Application procedure steps

3.2 Commercialization Aspects of Product

The developed web application "DIABISOLE" is designed to help prosthetic and orthotic surgeons when treating the diabetic patients who are at the initial stages of DFUs and to help orthopedic shoe technicians who are customizing the insoles of diabetic shoes. Since the awareness about cutting holes in the insole to offload pressure on calluses method is at an exceptionally low level, hardly any solution or research were conducted in this field. Considering these facts, in the market, for our system has a high market value.

We hope to provide this system as a free service for Kings Hospital, Colombo since we got the research idea and relevant guidelines from there. Also, it will be given as a free service for the hospitals who cannot afford to pay the subscription fee. Any other prosthetic and orthotic surgeon or orthopedic shoe technician who uses this application will be required to register for a month-wise or annual-wise subscription plan as shown in Figure 3.9.

Additionally, we hope to use social media such as Facebook, LinkedIn also YouTube for the commercialization to increase awareness of the proposed solution.

Figure 3.9: Diabisole Commercialization Plan

3.3 Testing and Implementation

To guarantee comprehensive quality control, both functional and non-functional testing procedures were conducted at various stages throughout the development and testing of the web application.

Table 3.1: Use Case 1 for measuring identified callus area

Test Case ID	WM001
Test Case Scenario	Measure the identified callus area of a sole image with one DFU.
Test Input Data	Upload a sole image with a DFU.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient's relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to upload a sole image for DFU detection. 4. Click on the "Upload Sole Image" button. 5. Wait for the application to process and prompt the identified callus area. 6. Click on the "Measure Area" button to get the callus area measurements in pixels. 7. Check the displayed result to see if the application accurately measures the identified callus area.
Expected Outcome	The application accurately measures the identified callus area.
Actual Outcome	The application accurately measures the identified callus area.
Test Result	Pass

Table 3.2: Use Case 2 for measuring identified callus area

Test Case ID	WM002
Test Case Scenario	Measure the identified callus area of a sole image with multiple DFUs.
Test Input Data	Upload a sole image with multiple DFUs.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient's relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to upload a sole image for DFU detection. 4. Click on the "Upload Sole Image" button. 5. Wait for the application to process and prompt the identified callus areas. 6. Click on the "Measure Area" button to get the callus area measurements in pixels. 7. Check the displayed result to see if the application accurately measures the identified callus areas.
Expected Outcome	The application accurately measures all the identified callus areas.
Actual Outcome	The application accurately measures all the identified callus areas.
Test Result	Pass

Table 3.3: Use Case 3 for measuring identified callus area

Test Case ID	WM003
Test Case Scenario	Measure the identified callus area of a sole image with no DFUs.
Test Input Data	Upload a sole image with no DFUs.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient's relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to upload a sole image for DFU detection. 4. Click on the "Upload Sole Image" button. 5. Wait for the application to process and prompt the identified callus area. 6. Click on the "Measure Area" button to get the callus area measurements in pixels. 7. Check the displayed result to see if the application accurately measures the identified callus area.
Expected Outcome	The application prompts pixel area as 0.
Actual Outcome	The application prompts pixel area as 0.
Test Result	Pass

Table 3.4: Use Case 1 for callus criticality prediction

Test Case ID	WCP001
Test Case Scenario	Acquire the DFU criticality prediction for valid pixel areas. (Measurements should only contain numeric values)
Test Input Data	Input valid pixel areas for both callus and high-pressure area measurements.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient's relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to predict DFU criticality. 4. Input valid callus and high-pressure area measurements. 5. Click on the "Predict" button to get the DFU criticality prediction. 6. Check the displayed result to see if the prediction is accurate.
Expected Outcome	The application prompts the DFU criticality status whether 'severe' or 'not severe.'
Actual Outcome	The application prompts the DFU criticality status whether 'severe' or 'not severe.'
Test Result	Pass

Table 3.5: Use Case 2 for callus criticality prediction

Test Case ID	WCP002
Test Case Scenario	Acquire the DFU criticality prediction for invalid pixel areas. (Measurements should contain other characters as well)
Test Input Data	Input invalid pixel areas for one or both callus and high-pressure area measurements.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient's relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to predict DFU criticality. 4. Input invalid callus and high-pressure area measurements. 5. Click on the "Predict" button to get the DFU criticality prediction. 6. Check the displayed result to see if the prediction is accurate.
Expected Outcome	The application prompts a message as 'Invalid Measurements. Please enter valid measurements.' and re-directed to input measurements again.
Actual Outcome	The application prompts a message as 'Invalid Measurements. Please enter valid measurements.' and re-directed to input measurements again.
Test Result	Pass

4 RESULTS & DISCUSSION

4.1 Results

The web application was developed utilizing the PHP Laravel framework, and it was integrated with MySQL as the designated database technology for the management and storage of application data records. In pursuit of identifying the most optimal classification model for predicting DFU criticality, a comprehensive evaluation was conducted, employing five machine learning models, namely, 'Decision Tree,' 'Random Forest,' 'XGBoost Classifier,' 'Gaussian Naive Bayes,' and 'K-Nearest Neighbor Classifier.' The performance metrics, including accuracies and classification reports, were rigorously compared among these models.

Remarkably, ‘Gaussian Naive Bayes’ emerged as the model of choice due to its high accuracy, 99.21%, and the production of a confusion matrix characterized by superior precision. The accuracies and comprehensive classification reports of all five models are presented below.

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred))
```

```
Accuracy: 0.989501312335958
```

```
# Classification Report
print(classification_report(y_test, y_pred, target_names=["0", "1"]))
cf_matrix= confusion_matrix(y_test, y_pred)
print(cf_matrix)
```

```
              precision    recall  f1-score   support

           0       0.99      0.99      0.99       171
           1       0.99      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[169   2]
 [  2 208]]
```

Figure 4.1: Decision Tree Model Results

```python
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred1))
```

```
Accuracy: 0.989501312335958
```

```python
# Classification Report
print(classification_report(y_test, y_pred1, target_names=["0", "1"]))
cf_matrix1= confusion_matrix(y_test, y_pred1)
print(cf_matrix1)
```

```
              precision    recall  f1-score   support

           0       0.98      0.99      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[170   1]
 [  3 207]]
```

Figure 4.2: Random Forest Model Results

```python
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred3))
```

```
Accuracy: 0.9868766404199475
```

```python
# Classification Report
print(classification_report(y_test, y_pred3, target_names=["0", "1"]))
cf_matrix3= confusion_matrix(y_test, y_pred3)
print(cf_matrix3)
```

```
              precision    recall  f1-score   support

           0       0.99      0.98      0.99       171
           1       0.99      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[168   3]
 [  2 208]]
```

Figure 4.3: XGB Classifier Model Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred3))
```

```
Accuracy: 0.9921259842519685
```

```
# Classification Report
print(classification_report(y_test, y_pred3, target_names=["0", "1"]))
cf_matrix3= confusion_matrix(y_test, y_pred3)
print(cf_matrix3)
```

```
              precision    recall  f1-score   support

           0       0.98      1.00      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[171   0]
 [  3 207]]
```

Figure 4.4: KNN Classifier Model Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred2))
```

```
Accuracy: 0.9921259842519685
```

```
# Classification Report
print(classification_report(y_test, y_pred1, target_names=["0", "1"]))
cf_matrix1= confusion_matrix(y_test, y_pred1)
print(cf_matrix1)
```

```
              precision    recall  f1-score   support

           0       0.98      0.99      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[170   1]
 [  3 207]]
```

Figure 4.5: Naive Bayes Model Results

The selected 'Gaussian Naive Bayes' model exhibited an impressive ROC (Receiver Operating Characteristic) Area Under the Curve (AUC) value of 0.98939 as shown in Figure 4.1.6, indicative of its robust predictive capabilities.

```
# ROC_AreaUnderCurve_Score
y_score = clf.predict_proba(X_test)[:,1]
false_positive_rate, true_positive_rate, threshold = roc_curve(y_test, y_score)
print('ROC_AUC_score for GaussianNaiveBayes: ', roc_auc_score(y_test, y_score))

ROC_AUC_score for GaussianNaiveBayes:  0.9893901420217209
```

Figure 4.6: ROC_AUC_Score of the selected model

Furthermore, Figure 4.1.7 visually illustrates the optimal positive rate graph associated with this model.

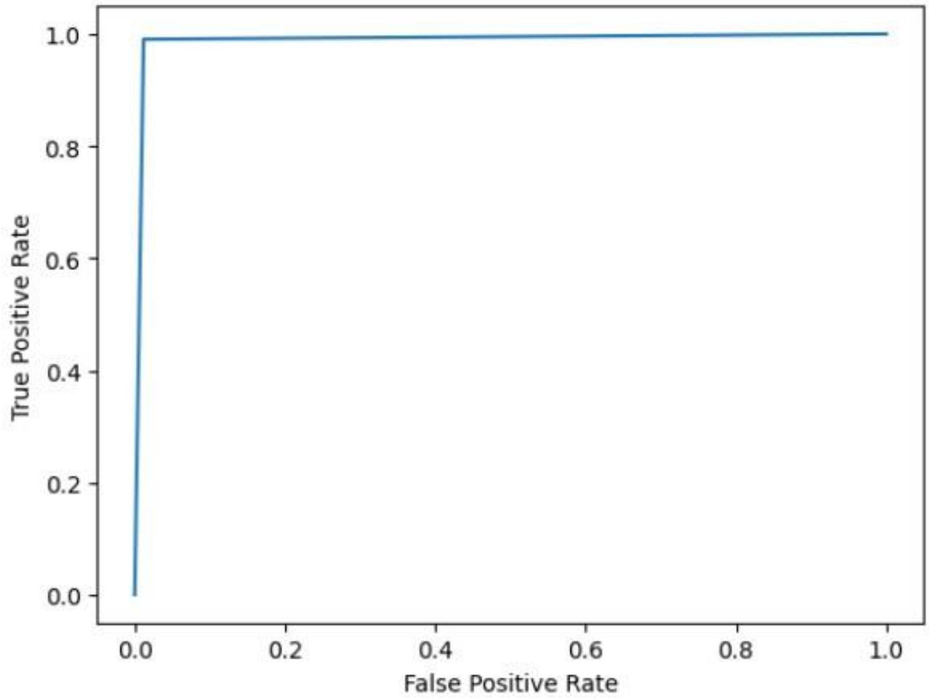

Figure 4.7: Positive rate graph of the selected model

In summary, the outcomes derived from the implementation of the classification model within the "DiabiSole" web application underscore its capacity to enhance the precision and efficacy of predicting DFU criticality. As a result, it has the potential to enhance the efficiency of the insole offloading process.

4.2 Research Findings

The implemented system has demonstrated a pivotal advancement in the realm of DFU management. The development of the "DiabiSole" web-based application signifies a crucial breakthrough, as it automates the identification and measurement of callus areas on foot, a critical element for designing effective pressure offloading insoles. The accurate callus area measurements not only streamline the time-consuming manual customization process but also significantly enhances precision when tailoring insoles to the unique needs of individual patients. This innovation addresses a longstanding challenge in DFU management.

Furthermore, the study's introduction of a novel approach to DFU criticality prediction, considering both callus and high-pressure area distribution, represents a pioneering advancement in this field. The Gaussian Naive Bayes model's exceptional accuracy, 99.21% with an ROC Area Under Curve value of 0.98939, ensures a highly precise prediction of DFU criticality. This multifaceted approach provides a more comprehensive assessment of DFUs, addressing an existing gap in current prediction systems. This predictive capability is of paramount importance, as it empowers healthcare professionals to identify and intervene in high-risk situations promptly, reducing the incidence of amputations, improving patient outcomes, and lessening the overall burden on healthcare systems.

In summary, "DiabiSole" represents a groundbreaking tool that not only enhances patient care and treatment outcomes but also has the potential to transform the landscape of DFU management, providing a comprehensive and personalized approach to this critical healthcare challenge.

4.3 Discussion

The "DiabiSole" web application comprises four primary components: callus area identification for determining hole sizes in the insole, high-pressure area identification and measurement, pressure offloading area detection, and callus criticality prediction. Rigorous testing, encompassing both functional and non-functional aspects, confirmed the application's robust performance. Importantly, our research revealed a notable gap in the existing literature, with no prior solutions addressing the automation of the manual insole customization process involving the strategic placement of holes to alleviate pressure. To enhance user experience, we designed intuitive and user-friendly interfaces for smoother navigation.

The capabilities of "DiabiSole" application can be expanded by incorporating the generation of 3D models for custom insoles, tailoring each design to the unique needs of individual patients. By doing so, the users of this application will be able to visualize the final customized insole before the actual customization process takes place. This advancement promises to further elevate the application's capacity to deliver personalized solutions for the management of diabetic foot ulcers. These advancements hold great promise for significantly improving diabetic foot ulcer management, translating into enhanced patient outcomes.

5 CONCLUSION

In conclusion, the "DiabiSole" web application represents a pioneering step forward in the field of diabetic foot ulcer (DFU) management. This comprehensive research project has successfully addressed the critical need for automating the manual insole customization process, which involves identifying callus areas, determining hole sizes for pressure relief, and predicting DFU criticality. Through rigorous testing, both functionally and non-functionally, the application has proven its robust performance and user-friendliness, offering a valuable tool for healthcare professionals and patients in Sri Lanka and potentially beyond.

One of the key contributions of this research is the identification of a significant gap in the existing literature, highlighting the absence of prior solutions that comprehensively address the strategic placement of holes in insoles to alleviate pressure, a crucial aspect of DFU management. By bridging this gap, "DiabiSole" has the potential to revolutionize the way diabetic insoles are customized, reducing the risk of complications and amputations and significantly improving patient outcomes.

“DiabiSole” represents a remarkable achievement in the intersection of healthcare and technology, offering an innovative solution to a pressing medical issue. As we continue to refine and expand its capabilities, we are optimistic that "DiabiSole" will continue to play a pivotal role in improving diabetic foot ulcer management, reducing the burden of ulcers, and leading to better overall patient outcomes in the realm of diabetic care.

6 BUDGET & BUDGET JUSTIFICATION

Table 6.1: Budget plan per month

Component	Amount (Rs.)
Travelling fee for the data gathering	2500.00
Internet charges (the development and technical information learning)	3000.00
Stationary	2000.00
Total	**7500.00**

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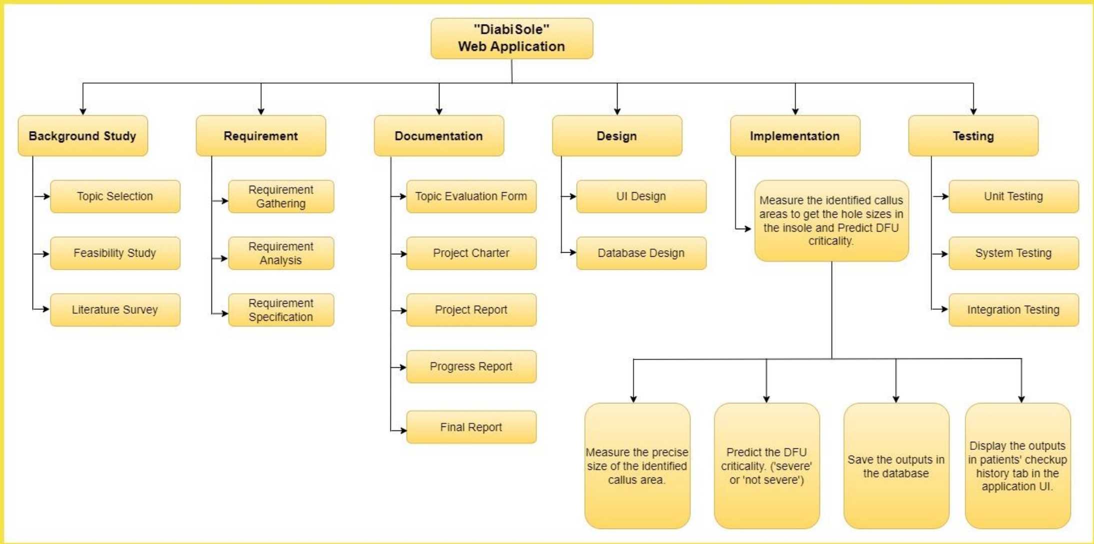
APPENDICES

Appendix – A: Application logo



Appendix – B: Work breakdown 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]4^{th} year students at Sri Lanka Institute of Information Technology under supervision of Ms. Jenny Krishara.

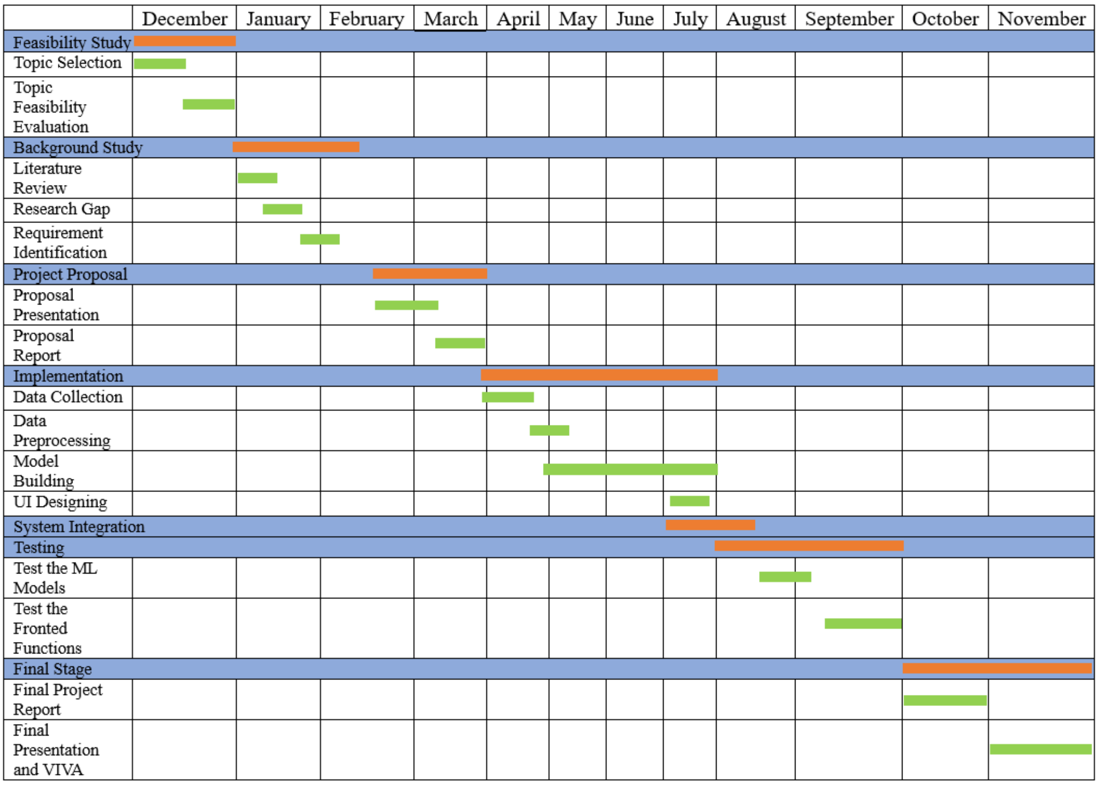
This is to certify that for the above-mentioned research project, I will be providing the medical consultation for all the medical related aspects in this project. I hereby confirm that as an external supervisor of the project, I will be offering my consultation and all the datasets that they require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

Thank you.

Piumika

Dr. Piumika De Silva

Appendix – C: External supervisor (Consultant Doctor) letter



Appendix – D: Gantt chart

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.

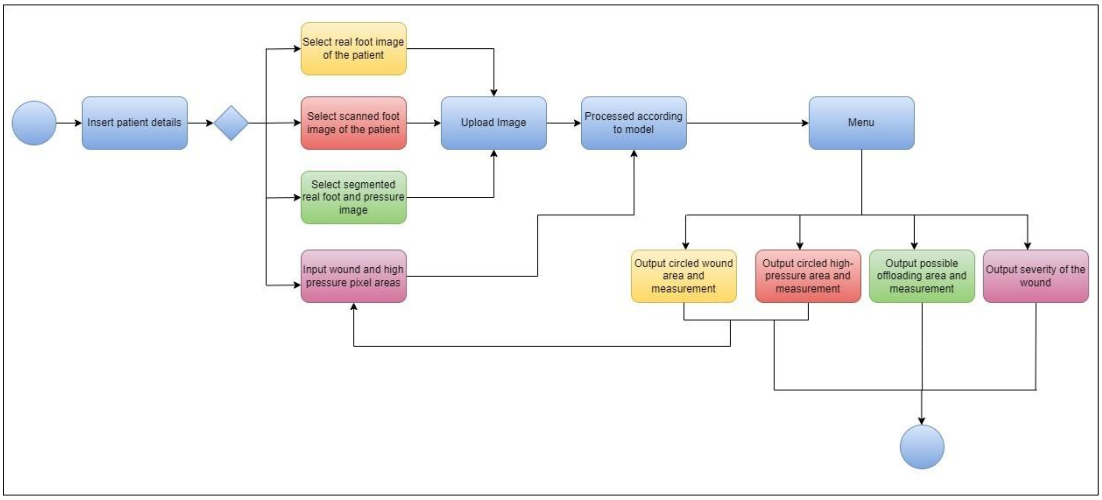
……………………………………………

Dr. Piumika De Silva

Kings Hospital

Colombo 05

Appendix – E: External supervisor’s Recommendation letter



Appendix – F: Application flow diagram