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Clinical validation of computer vision and artificial intelligence algorithms for wound measurement and tissue classification in wound care

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ABSTRACT

One of the most important challenges in the management and treatment of complex wounds is the observation and measurement of different indicators that can be observed on the wound over time. This article will present the idea of addressing this challenge with the use of images captured on a mobile device. The aim of this work is to evaluate the use of digitization systems in the field of chronic wound management as tools that support the professional in improving patient care and decision making, as well as to use computer vision and artificial intelligence to improve wound assessment. An approach based on visual recognition and a classification system is proposed; visual recognition using superpixel techniques to determine the region of interest of the wound, as well as calculating its area and a classification system based on convolutional networks to classify its tissues. We found that our proposed approach, Visual Computing methods to detect Wound contour and measurement (with a Median Relative Error of 2.907 and inter-rater reliability of 0.98%) and Tissue Classification CNN with excellent results using Resnet50 with 0.85 of accuracy.

1. Introduction

Skin ulcers are a major cause of morbidity and mortality worldwide [1]. Ulcers are caused by various conditions, such as diabetes mellitus, peripheral neuropathy, immobility, pressure, arteriosclerosis, infections, and venous in-sufficiency [2]. In general, ulcers are lesions that do not undergo an orderly healing process and do not produce functional and anatomical integrity in the expected time (4 weeks–3 months) [3], which is especially relevant in the case of diabetic foot [4]. This is usually due to an underlying pathology that prevents or delays healing. Ulcers have a significant impact on the patient's life, leading to a reduction in the physical, emotional, and social dimensions of life [5]. In addition, the care of these wounds – both chronic ulcers and those related to diabetic foot amputations – requires the expenditure of human and material resources and generates a great economic impact [6,7]. For these reasons, complex wounds such as ulcers are considered a major global problem. Complex and difficult-to-heal wounds include differ-ent types of injuries: pressure ulcers, lower extremity ulcers (arterial, venous, diabetic foot), neo-plastic ulcers, and others. Treatment of complex wounds is often difficult, as the disparity of treatment criteria and the multitude of care products can lead to forgetting the cause. Healthcare professionals are therefore the key to achieving healing and improving the management of material and human resources in the treatment of complex wounds. Organizations have had to modify clinical practice guidelines by incorporating new wound management support mechanisms and adapting these mechanisms for use by healthcare professionals as a support and organizational tool [8–16]. The main goal of these clinical guidelines is to provide professionals with the knowledge to achieve the best possible results in the diagnosis, prevention, and treatment of wounds. Another goal is to encourage the responsible use of organizational resources to improve efficiency in the healing process. In general, clinical practice guidelines are intended to address issues related to preventive or therapeutic intervention in the management of individuals with pressure ulcers or at risk of developing them. These guidelines include details of each of the phases that make up clinical practice in the management of chronic wounds, from prevention to management and healing [9].

Currently, in accordance with the clinical guidelines and recommendations, skin ulcer follow-up is performed through clinical assessment by the healthcare professional, supported by measurement rulers and digital photography (digital devices are used for rapid and efficient collection of photographs). In the wound follow-up process, it is

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important for the healthcare professional to collect graphic evidence by means of one or more photographs, and to use weighted clinical scales to obtain an objective result of the wound severity. If photographic techniques and equipment are used, they must be standardized to ensure an accurate representation of the pressure ulcer condition that can be reliably compared over time (i.e., same perspective, light conditions, etc.) [16]. According to the RESVECH 2.0 scale (widely implemented in Spanish healthcare systems) [17], the most relevant variables to assess the level of severity are: wound area, wound depth classification, types of edges, tissue classification, type of exudate, and signs of infection. The aim of this work is to automate the assessment process with a digital tool and standard smartphone camera, and obtain greater reliability and accu-racy in comparison to traditional methods. Visual Computing and Artificial Intelligence based on neural networks are proposed as a means of detecting and calculating the region of interest and classifying the different tissues of the wound.

2. Current solutions

To determine the size of the wound, some professionals use methods such as planimetry, which involves drawing the outline of the wound with *trans*-parent acetate paper and measuring the surface with a device afterwards [18,19]. Other methods include more traditional elements, such as rulers or reference markers in photography. However, these methods of area measure-ment are inaccurate methods with a high error rate [20–22]. There are alternatives on the market that increase the level of accuracy (e.g., stereo cameras, depth cameras, thermal cameras) [23–25,25–27], but their high costs and difficulty of use by professionals make them challenging to implement in a healthcare system [28]. For this reason, most professionals use methods that simplify the data collection process; for example, using a ruler to measure the two axes of the ellipse containing the wound. However, these simplified methods increase the introduction of accuracy errors [17,20].

To perform tissue classification, there are some studies that have worked on the automatic classification of tissue by means of photography [19,28–30]. However, at present, there is no sufficiently widespread mechanism that allows the professional to detect the presence and percentage of necrotic tissue, or the distribution of other tissues in the wound bed. The professional must visually examine the wound and, based on his or her experience, determine whether or not these tissues exist, as well as their predominance. It should be noted that the existence of necrotic tissue will inevitably require specific clinical action to remove it before the treatment can be applied to heal the wound.

2.1. Classification of existing skin lesion calculation methods

Most skin lesion measurement methods used today are rudimentary (i.e., the ruler, which leads to measurement errors) or are linked to invasive tech-niques (i.e., manual planimetry with transparent acetate, which can be un-comfortable for patients). Hence [31], stresses that, for skin lesion measure-ment, "there is still no clear consensus on which is the best method, which is fast, practical, cheap and simple in routine practice." Therefore, it should be noted that there is no "gold standard" method for skin lesion measurement approved by the medical community.

Concerning the literature review on the safety and performance of this type of method [32], classifies the different methods for measuring skin le-sions into the following three major groups: traditional methods, measuring.

2.1.1. Devices, and software-based computerized methods

The traditional methods are graduated ruler measurement, transparent acetate planimetry, and digital planimetry from photographs.

Square ruler measurement is a convenient, fast measurement system that does not require specialized training and is, therefore, widely integrated into routine clinical practice. However, its reliability is limited, especially when measuring irregularly shaped wounds. In addition, this technique often over-estimates the actual wound size, and accuracy tends to decrease with larger wounds [32,33].

Transparent acetate planimetry allows the calculation of wound size by tracing the wound edges on a transparent sheet, which is then placed on graph paper to calculate the number of square millimetres or centimetres covering the wound surface (square-counting method). This technique is more time-consuming than the ruler-based technique, especially in cases of large wounds. The tracing can also be measured using a precision scale, which is faster than the counting method [33]. Transparent acetate planimetry is considered an inexpensive and convenient technique that requires minimal training. The main limitations of this technique are the difficulty in identifying the edge of a wound and inaccuracy in tracing wounds in the presence of a skin fold. In addition, the reliability of this technique usually decreases as the wound size decreases [32,33].

Commercially available wound planimetry software and applications include [31,32].

- Pictzar CDM and Pictzar PRO®. This software is used to take measurements on digital photographs that include a ruler next to the skin lesion. While they require a ruler in the image, they do not need to know the distance between the camera lens and the subject.
- Wound Matrix®. This telemedicine software is used for measuring the surface of skin lesions. It is primarily intended for companies and organizations.
- WoundWiseIQ®. This software is designed for measuring skin lesions. It is only compatible with the iOS operating system.
- Visitrak is a Class II (FDA) device that determines the wound area from a double-layer transparent tracing sheet on which the wound out-line has been previously drawn. The clean layer is separated from the contaminated layer after the wound is traced and placed on the Visitrak device. Clinicians use the Visitrak pen to trace the wound contour again, and the wound area is estimated from that tracing [32]. Visitrak shows greater accuracy of measurement than the traditional technique of manual planimetry with transparent acetate. However, Visitrak requires contact with the wound surface, which increases the risk of infection, discomfort, and damage to the wound.
- SilhouetteMobile is a Class I (FDA) device that features a laser beam scanner head and camera, which are attached to a personal digital assistant. The laser beams are used to construct laser line curves that represent the topography of the wound surface. The personal digital assistant computes these line curves to create an image of the wound surface in 3D. The wound area is calculated using the wound margin drawn on the image by the physician with a stylus [32].
- AreaMe® is a mobile device software application, not registered as a medical device and marketed since 2013, that calculates the wound area from a photograph of the skin lesion outline using a 1 × 1 cm grid. The wound edges must have been previously outlined manually on a transparent sheet placed over the wound. In addition, the application transfers the data to a clinical database and generates a graph of the change in wound area over time.
- NDKare® application has been developed to address this need and our study evaluates its accuracy and practicality for DFU wound size assessment. The NDKare mobile phone application was evaluated for its accuracy in two- (2D) and three-dimensional (3D) wound measure-ment.
- imitoMeasure®: Digital wound measurement allows exact wound mea-surement without scale.
- WoundVue®: is able to calculate a wound's surface area and volume, as well as objectively classifying the different tissue types within the wound.
- Planimetor®: Planimetric area measurements were carried out using 2 one-dimensional calibration markers placed above and below the wound shape.

- Swift Wound®: app integrated with an infrared camera to measure temperature at the wound site and evaluates its accuracy and reproducibility.

The advantages of 3D imaging technology include non-contact wound measurement, suitability for irregular wound surfaces, and the use of a hand-held instrument. However, this technique is expensive and requires special-ized training.

On the other hand, digital planimetry is one of the current reference methods. However, this measurement system has two main disadvantages: the dependence on the calibration method used and the influence of the orientation of the camera lens with respect to the wound plane. It is important to ensure that the camera lens and the wound plane are strictly perpendicular at the time of measurement [34].

Software-based computerized methods use a digital camera, and special-ized image processing software for wound area measurement [32]. This soft-ware can be used on a computer (e.g., ImageJ software) or can be installed as an application on a mobile device.

2.2. Literature studies on similar applications

In the last few decades, mobile devices have gained a major role as point-of-care support tools in the field of telemedicine due to their accessibility and portability. The cameras of these mobile devices, together with advances in artificial intelligence and increasingly advanced and accurate image process-ing techniques, constitute promising solutions for measuring wound areas in patients with pathologies associated with skin lesions [35].

A study by [34] compares the accuracy and performance between AreaMe and the previously mentioned devices, Visitrak and SilhouetteMobile, using an optical scanner as a reference. Or other applications found in the bibliography like NDKare, WoundVue or Planimator.

Foltynski's study [34] measures the area of 108 wounds using AreaMe, Visitrak, and SilhoueteMobile, evaluates the accuracy by calculating the rel-ative errors and coefficients of variation of each technique with respect to the optical scanner, and compares the results obtained with the three tech-niques. The study concludes that the AreaMe app is more accurate than the Visitrak device but less accurate than SilhouetteMobile. However, this application allows the measurements recorded to be stored in clinical databases, facilitating the monitoring of wound evolution.

A study conducted with 85 patients [36] compares the performance of the imitoMeasure application using photographs taken with the mobile de-vice itself with that of the ImageJ software using photographs taken with a 10-megapixel digital camera. In this case, in addition to examining the performance of the application, Biagioni studies the influence of the quality of the images analyzed on its performance. To evaluate the performance of the mobile application, the study calculates the mean wound area (12.20 +- 10.45 cm2 for imitoApp and 12.67 +- 10.86 cm2 for ImageJ) and the intra-class correlation coefficients (ICC) between the two methods (0.978 for one measurement, and 0.989 for the mean of the measurements). Therefore, the study demonstrates that the imitoMeasure application is a useful, practical, and safe method for measuring wound areas with good accuracy compared to digital photography and the ImageJ processing tool. Furthermore, no incidence, contraindication, or risk of infection, irritability, or allergy (either for patients or users) is reported with the use of the app.

Another recent study [37] presents the NDKare application for measuring diabetic foot ulcers and highlights the importance of wound healing rate as a prognostic indicator of the likelihood of complete wound healing. The study examines the accuracy of 2D and 3D methods of skin lesion measurement by calculating the area, depth, and volume of 115 diabetic ulcer-associated wounds using the NDKare application and comparing its performance to that of the Visitrak planimetry system as the gold standard for 2D measurements, and the WoundVue camera as the reference method for 3D data.

The 2D surface measurements performed with the NDKare application showed excellent agreement with Visitrak and WoundVue measurements (ICC of 0.991 with 95% confidence interval) and between different users (ICC of 0.98 with 95% confidence interval). The NDKare 3D measurements had a good agreement for depth and an acceptable agreement for volume with the WoundVue camera.

The correct performance of the Planimator application intended for skin wound area measurement has been evaluated in several articles in the literature [34,38].

In the study by Foltynski [39], the accuracy and precision of the Plan-imator app were compared with the Visitrak device, the SilhouetteMobile device, the AreaMe app, and with digital planimetry based on calibration with two rulers using images taken by the camera of a mobile device and by a digital camera. The areas of 40 wounds were measured with each device, and the medians of the relative errors in the accuracy tests and the standard deviations of the relative differences in the precision tests were compared. The study concludes that the Planimator application has the same accuracy and precision as digital planimetry measurements with 2-ruler calibration based on images from a digital camera. In addition, this app offers higher accuracy and precision than the Visitrak and SilhouetteMobile devices, the AreaMe app, and digital planimetry based on images from a mobile device's camera.

Furthermore, the 2021 study [38] confirms the good performance of Plani-mator by showing that the app outperforms the commercial SilhouetteMobile and Visitrak devices; the median relative error was 0.32%, 2.09% and 7.69%, respectively. In addition, the standard deviations of the relative difference were 0.52%, 5.83% and 8.92%, respectively.

The study by [40] presents the Swift Wound app integrated with an infrared camera to measure temperature at the wound site and evaluates its accuracy and reproducibility. Accuracy measurements were determined by evaluating the differences in surface measurements of 15 plastic wounds be-tween a digital planimetry device of known accuracy and the Swift Wound app. In addition, to assess the impact of training on the reproducibility of Swift Wound app measurements, three novice evaluators with no wound care training measured the length, width, and area of 12 plastic wounds using the app. ICC values between 0.97 and 1.00 were obtained for the reproducibility of Swift Wound between raters of different levels of wound care training.

Therefore, it is proven that area measurement applications predominate in state-of-the-art. However, 2D methods present certain difficulties in the face of the complexity of anatomical curvatures of the human body or different camera firing angles. The study by [41] proposes a method with 3D transformation to measure the area of skin lesions and solve the challenges of 2D techniques. The article compares the developed 3D method with other widely used market techniques, such as graduated ruler measurement, the Visitrak device, and a 2D method, by analyzing 118 wounds of 54 patients. The 3D transformation method achieves an accuracy of 0.97, a Pearson cor-relation of 0.999, a standardized regression coefficient of 0.895, and an R2 with an adjustment of 0.998. In addition, the use of a mobile device to cap-ture images of the wound without wound contact allows minimization of the risk of infection, thus increasing the safety of the method presented.

[42] explores the reliability and validity of using a mobile device to build 3D models of wounds and simulate and quantitatively evaluate these tis-sues. This study obtained the longest diameter, depth, and volume of 33 wounds from 28 patients using the 3D mobile device application and traditional methods. Reliability was assessed by calculating the ICC and validity by obtaining log differences between manual and mobile device techniques represented in Bland Altmann plots. This study demonstrates that mobile devices can serve as an additional tool for the diagnosis and investigation of wounds by facilitating their treatment through telemedicine.

Ultimately, there is a growing trend of using this application for wound area measurement, reflected in the remarkable presence of prototypes of this type of software in the research described in literature articles. In 2012, a study demonstrated the feasibility of WoundSite software embedded in a mo-bile device to measure wound area without patient contact more quickly, accurately, and reliably than commonly used manual measurement techniques. In addition, a recent study [35], proposes a method of calculating wound area with a mobile device that obtains very similar results to those of the same method implemented on a computer. The article presents a comparative study of the performance of an experimental algorithm analyzing a set of images on a mobile device and on a computer. For this purpose, it calculates the mean absolute error with respect to the results obtained from the algorithm processed on the computer, which it takes as a reference due to its greater computational capacity. The mean absolute error obtained is 4.4% for images of acceptable quality and 21.5% for images with several non-consecutive wound areas.

In all the commercial applications reviewed, great importance is given to the measurement of the area and less to calculating the distribution of the wound tissues.

The bibliographic research drew interesting conclusions about the approach and protocol consider into this study using mobile devices to evaluate wounds characteristics. The excluded publications did not pertain to the area of wounds and did not use photography for evaluation. The advantages and disadvantages of using clinical images taken with mobile devices were observed and the risks that this technology can entail. It was noted that the conditions under which the images were taken were important, such as position, perspective, lighting and sharpness. The type of wound was also identified as a factor to consider. From these studies, the protocol for the current study and the criteria for the inclusion and exclusion of patients can be deduced.

3. Methods

3.1. Proposal

This work introduces a digital method to calculate the area of a wound and to classify tissues in a wound. The method consists of a digital system for the selection of the region of interest (delimiting the wound), an automatic system for measuring area using an external calibrator, and finally a system based on a trained convolutional network for the classification of the tissues of the wound. Fig. 1 shows collecting and process data process that include measurement process and tissue classification process. A mobile application, clinicgram® was used to integrate these processes into clinical practice.

3.1.1. Detection of wounds

The main goal of this mechanism is to detect the edge of the wound in the image. It uses similarity between contiguous pixels. When the image of the wound is captured with a mobile device, the user draws a scraw inside the region of the wound (Fig. 2) to help the system allocate the wound. Fig. 3 shows the process with a test image. After the system detects the contour of the wound, a mask is applied to isolate the region of interest from the intact skin and the background.

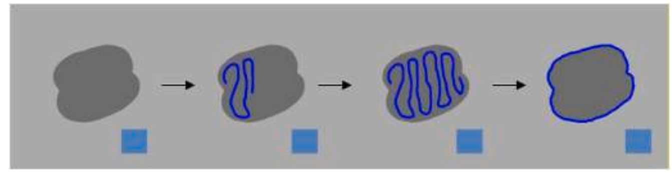


Fig. 2. Example of the system being used to detect a wound, using a test image and the following process: capture the image, scraw inside the region of interest, obtain the mask of the wound.

To determine the wound contour and delimit the Region of Interest (ROI), the system uses a superpixel method [43,44] and a k-means method [28] after trying different techniques (Felzenszwalb [45], Mean shift and Quick shift [46] among others). The superpixel method refers to the procedure of automatically segmenting the wound image into different segments that have consistent meanings, or that have similarity in their properties. On the other hand k-means is an unsupervised classification (clustering) algorithm that groups objects into clusters according to their characteristics. Clustering is performed by minimizing the sum of the distances between each object and the centroid of its group or cluster, usually by its quadratic distance.

In order to detect the contour of the wound, the system applies the algorithms explained above and divides the image into different superpixels. The healthcare professional uses the same mobile application used to capture the image to draw a small segment inside the wound, and relating different superpixels of the wound are obtained to detect the contour.

The SP algorithm will run automatically and unassisted, calculating the different blocks of superpixels. In this section it will be noted that the adjustment of the different operating variables of SP is necessary to obtain an optimum result. N segments: indicate the approximate number of seg-mentation. Compactness: comparison between color and proximity to group pixels in SP. Max iterations: maximum number of iterations of the k-means method. Sigma: Gaussian filter to blur the image. Enforce connectivity: variable that indicates whether the segments are joined or not.

3.1.2. Area's calculation

To calculate the wound area, the ROI obtained in the previous phase is used and the incorporation of a calibrator/marker is required. In our case, the marker is a blue square to contrast with the rest of the image (see Fig. 4). The physical size of this square marker is always 2 cm per side, which will allow us to interpolate with the size of the marker on the image and calculate the actual wound area.

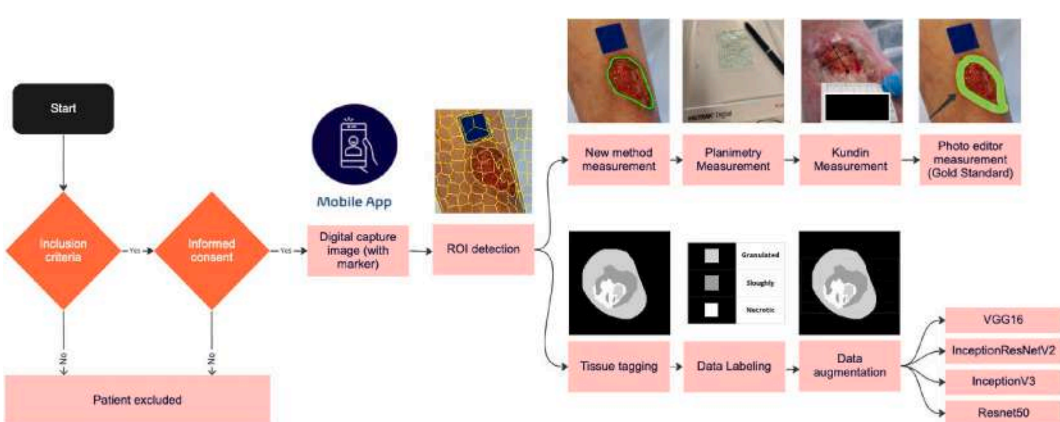


Fig. 1. Proposal method of the study.

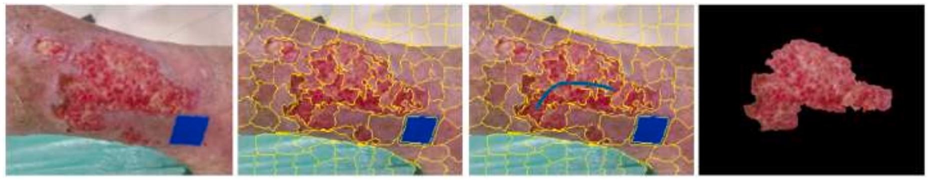


Fig. 3. Example of original image, image with superpixel segmentation, scraw image, detected region of interest.

Fig. 4. Original image of the wound and the marker (left), and the marker detected with yellow outline (right). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

The practitioner places the marker near the wound in a perpendicular position before capturing the image. This process is important because good placement of the marker will determine the result of the measurement. If the marker is oblique, partially covered or distorted by light or shadows the measurement will be invalidated.

The first step (see Fig. 5) is to read the image and convert it from RGB color space to HSV. Then, the image is filtered within a range of colors in which different shades of blue are found and a mask is created with only the pixels within the set range. All the contours of the objects present in the mask are searched for and only those that are square in shape, i.e. twice as long as wide, as is the case of the marker we are using, are selected. Then, an artificial vision function is applied that approximates all the contours to square shapes and, as in the case of the marker where the shape is quite regular, it looks for all the selected regular shapes that have the smallest difference with the real contour by comparing the zones. In this way, if it has detected more than one square shape, it will keep the one with the most rectangle shape; i.e., the area of the object after applying this function and the real area initially detected with mask have the smallest difference.

A marker evaluation system has also been implemented to avoid erroneous measurements. The correct position of the marker is evaluated by detecting its sides and calculating the degree of disproportion and asymmetry. To calculate whether the sides are disproportionate, the evaluation metric is calculated by dividing the smaller detected side by the larger one. A perfectly proportionate shape should have a final value of 1. In the worst case, this value tends to 0. To calculate the horizontal and vertical asymmetry, the degree of inclination of the marker vertices is evaluated. This reading will tend to 0 as long as the marker is completely located on the X and Y axes. Similarly, the value of the asymmetry on one side should be equal to its opposite if the marker is not tilted on the Z-axis. Finally, once the marker has been detected and its proportion and position are evaluated to be correct, the area of the detected wound can be calculated using the ratio obtained for the marker (number of pixels and real measure of 4 cm^2).

3.1.3. *Tissue classification*

One of the most important issues in efficient tissue identification of wound imaging, is the precise segmentation of the tissue regions present in the sample. Complex wounds can have irregular shapes, inaccurate boundaries, and highly heterogeneous colors [47]. In order to create a system that classifies the different tissues of the wound, it was proposed to use a convolutional network. Therefore, different models were trained with a wound dataset (n=726).

This dataset was prepared in such a way that there was a proportional and homogeneous distribution of the tissues.

In order to ensure a good outcome, the images were pre-processed and augmented; they were given a black mask around the region of interest, homogenized in terms of size (200 x 200), and divided into 5 x 5 pixel portions. In order to expand the size of the dataset, augmentation phase is deployed with different transformation applied to the original to make it sizable in applying the deep learning techniques. In our approach, rescale zoom range and horizontal flip was performed.

The data was then divided into training sets (80%) and tests (20%), to train the model and evaluate its performance. The evaluation of the network was performed by analyzing the accuracy, memory, and F1 score of the model. The evaluation architecture used, combined a convolutional network created for the purpose of tissue classification and a pre-trained network.

Fig. 5. From left to right: result of image processing for marker detection and correction.

In order to make a classification, Deep Learning algorithms were used to perform a classification between the different types of tissue: necrotic, sloughly, and granulate and we used transfer learning for the feature ex-traction process since it is adapted for small training databases. It has the advantage of reducing the amount of data required while shortening train-ing time and improving performance when compared with models built from scratch.

The transfer learning technique was performed, and different models that had been previously trained with large datasets were adjusted. The models used were the VGG16 [48], characterized by having a highly optimal response in image classification tasks as it contains many small filters that can greatly reduce the number of parameters, which, in turn, makes it slower than the others; the InceptionV3 [49], which is faster than the VGG16 as it performs convolutions on the earlier layers; the ResNet50 [49], which introduces the concept of residual blocks by making jumps between the intermediate layers; and the InceptionResNetV2, which combines two of the previous models. To adapt these pre-trained models, the input size of the images from the dataset was adjusted and four layers were added at the end: a flatten layer to obtain a feature vector with the output of the model, a dense layer with ReLu activation, a Dropout layer with a ratio of 0.3, and another dense layer with a softmax activation function to obtain a classification probability vector as output.

One of the most critical processes in the development of the supervised learning system is the precise labeling of samples [50]. Correct classification in the dataset is key, which is why a help system was implemented in the tagging process [51]. At this point, the clinical experts worked on labeling all the images from the output (see Fig. 6).

3.2. Evaluation method

The study was carried out at the Hospital de la Santa Creu in Vic, in Spain, following the approved study protocol. This study was approved by a local institutional review board (Clinical Research Ethics Committee - CEIC FORES Ref No: 2019093/PR224). The Hospital de la Santa Creu took on the process of collecting written consent for all patients included in our study.

3.2.1. Participants

The patients who participated in the study did so voluntarily and consisted of both outpatients and inpatients who met the following characteristics of acceptance and exclusion.

Inclusion criteria.

- Age 70 or older, of any gender and ethnicity.
- Able to tolerate changes of position and turns for up to 10 min comfortably.
- Skin lesion is external. Site of the external wound fits completely within the field of vision and does not involve an edge of the body.
- No device or treatment will hide the location of the external wound.
- Informed consent signed. Exclusion criteria:
- Cannot be positioned so that images can be taken at approximately 90° perpendicular to the wound.
- Undergoing therapies or treatments that cannot be safely suspended long enough to conduct an imaging session according to the center's policy.
- Has a skin lesion with excessive exudate that cannot be controlled during the imaging session. Excessive drainage can hide the characteristics of the external wound.
- From the visual assessment, the existing external wound cannot be clearly distinguished from other conditions at the site of the external wound (e.g., the rupture or deterioration of the surrounding body sur-faces due to other conditions such as cancer or other types of wounds make it impossible to determine the edge of the external wound).

3.2.2. ROI detection and area measurement

The process that was used for the implementation and validation of the area calculation algorithm using a calibrator was based on the collection of 30 samples by the professional. The samples were taken by incorporating in the same plane of the wound a blue adhesive marker with a size of 2 cm × 2 cm. In order to calculate the accuracy of the algorithm, different traditional measurements of the same wound were made, using traditional planimetry (drawing the wound on transparent acetate), Kundin (measuring the width and height of the wound and multiplying by the Kundin constant), and digital planimetry using a photo editing tool. The differences between the measurements were calculated and the accuracy results of the algorithm were obtained. Before evaluating its performance with real images, a study was carried out with prefabricated samples in a laboratory environment. The marker was pasted on a paper and the outlines of different geometric shapes were simulated. Captures were made from different angles to assess the accuracy and the level of error we could obtain. In order to validate the measurement obtained, a comparison was made between the calculated area and the area obtained with Visitrak and the area obtained with a graphic editor, which we will call digital planimetry. In order to validate the position of the marker, the comparison between its own sides and inclinations was also made.

3.2.3. Tissue classification

The process that was used for the implementation and validation of the tissue classification algorithm was based on the collection of 727 samples by the professional. These samples were labeled by a wound expert professional and used to generate a training dataset for the convolutional neural network. In order to calculate the accuracy of the algorithm, 20% of labeled samples were separated from the dataset and later used to validate the accuracy. Finally, the different accuracy indicators in the convolutional network were calculated.

3.2.4. Statistical analysis

During the selection process, the samples were classified according to etiology, as shown in Table 1.

Quantitative variables that followed the normal distribution were ex-

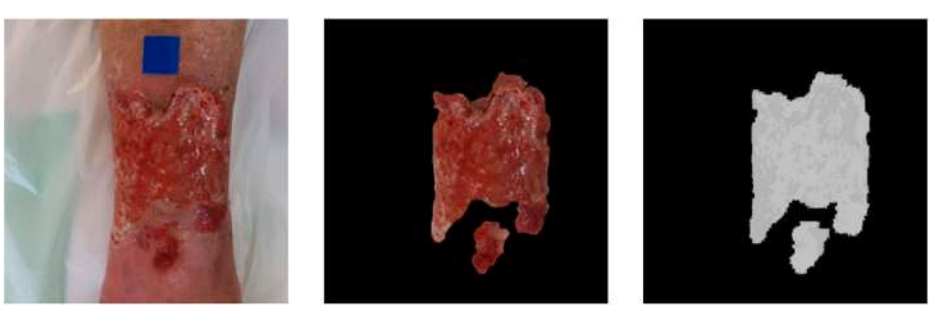


Fig. 6. Example of original image, ROI mask, classification of necrotic, sloughly, and granulated tissues.

Table 1
Percentage of wounds registered by etiology.

Etiology	% of wounds
Venus Ulcer	24
Pressure Ulcer	22,1
Diabetic Ulcer	12,2
Traumatic Ulcer	9,8
Arterial Ulcer	8,8
Mixed Ulcer	6,1
Hematoma	4,8
Suture dehiscence	4,2
Others	4
Surgical Ulcer	3,4

Table 2
Performances of measurement, error comparison and ICC.

Method	MeanRE	MedianRE	RangeRE	ICC (95% CI)
Our Digital approach	2907	1.7043	0.001–14.187	0,98
Planimetry (Visitrak)	15.619	9.2567	0–74.799	0,95
Kundin method	22.125	22.611	2.884–65.351	0,92

pressed as absolute and relative frequencies, medians, arithmetic means, and standard deviations with a confidence interval of 95%. For quali-tative vari-ables, absolute percentages were calculated. The ANOVA model, Kruskal- Wallis test and inter-rater reliability were used to analyze the relationship between quantitative and qualitative variables. The ICC subject in this study represents the multiple measurements of the wound images. P-values lower than 0.05 were considered statisti-cally significant.

4. Results

Next, the results obtained in the different phases of the study will be presented. The results obtained were compared with existing and vali-dated methods in order to validate their reliability.

4.1. ROI detection and area measurement

An empirical comparison between superpixels and kmeans algo-rithms was made evaluating their speed, ability to adhere to image boundaries and im-pact on segmentation performance.

First, an estimation study is performed using the assignment of N seg-ments and Sigma manually and fixedly. After the review of the results that will be obtained, the use of a polynomial regression will be pro-posed for the most efficient calculation for each situation: Has been used 50, 100 and 200 N segments and 1, 3 and 5 values of Sigma, getting the best results using 100 SP and Sigma 3. The images not segmented properly are selected to repro-cess them with SP with different values: 150, 200 and 300. Considering the diversity of wound typologies, and her resolution, a polynomial regression is proposed for the calculation of the N segments and Sigma values.

In order to evaluate the reliability of the contour detection algo-rithm, the clinical professional provided a reference measure. A com-parison was made between the outline obtained by superpixels and regiongrowing, and the outline drawn in the image by the professional himself, using a professional photo editor (Photoshop/Gimp). Once the two contours of the sample were obtained, they were compared using the Hausdorff distance [52].

The result of the area measurement was compared to traditional and man-ual methods; we used Visitrak (planimetry) [18] and the Kundin [20] method (measuring length and width with a ruler). To obtain a Gold Standard, the planimetry sample was digitized with a scanner to create a completely flat photograph (i.e. digital planimetry). The calculation was done manually with photo editing software, by selecting the marker as the calibrator and making the equivalence in pixels. Fig. 7 shows different measurement comparisons to Gold Standard (see also

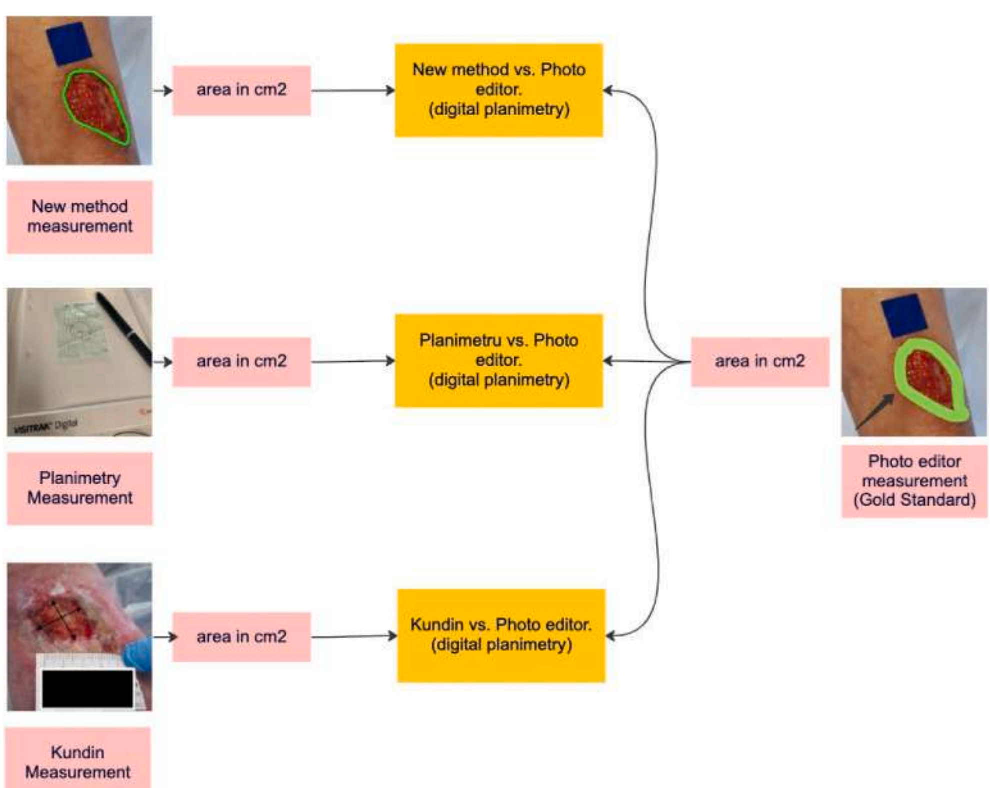


Fig. 7. Comparison proposal between new method, planimetry (Visitrak), Kundin vs Photo editor (Gold Standard). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

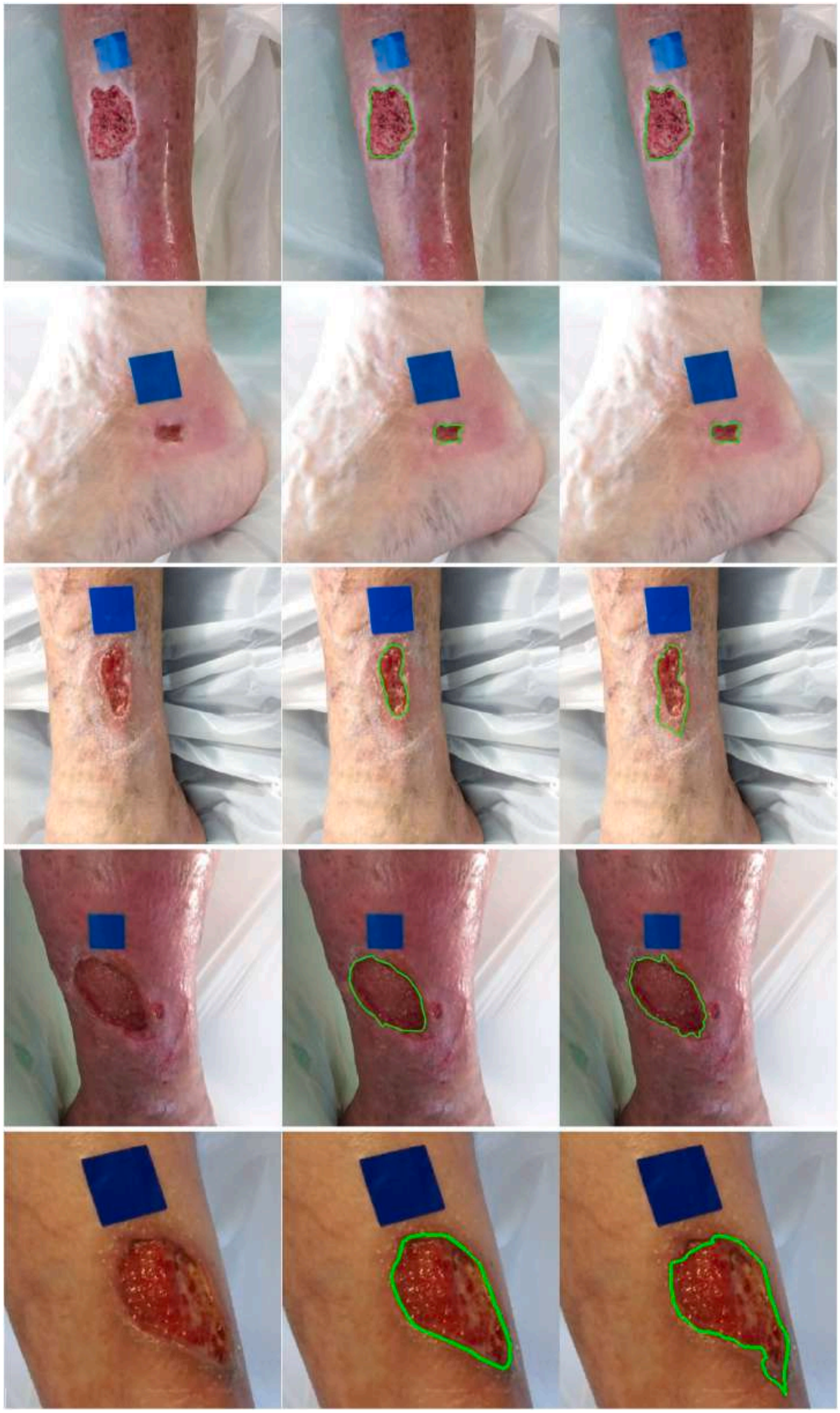
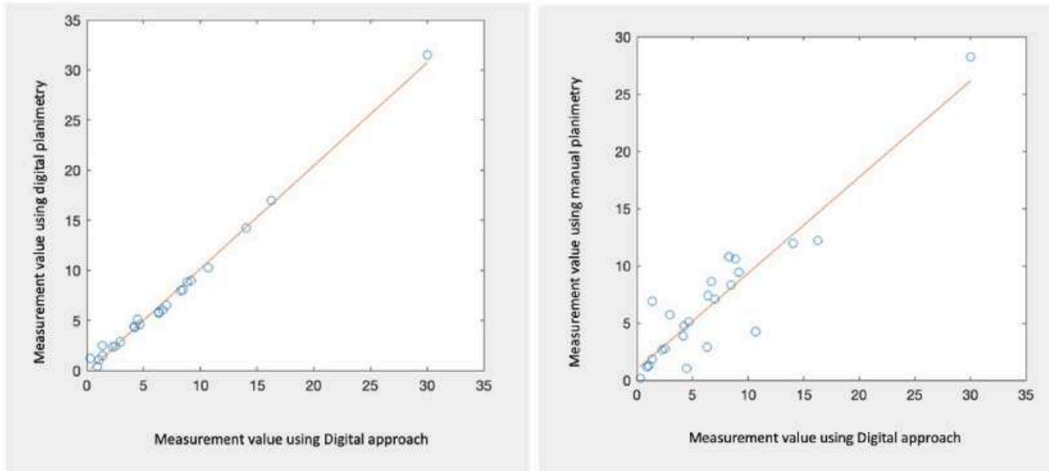


Fig. 8. Example of original wound, contour using superpixels, Gold Standard contour. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Fig. 8).

After that, a clinical professional used a desktop application to define the contour with high resolution conditions. In order to validate the algorithm, the healthcare professional obtained the measurements of the same wounds using planimetry [53] and calculating the area with the Visitrak [54] device (see Fig. 9). The Kundin [55] ruler procedure was also used to measure height and width.

The median of the relative error (RE) of measurements was calculated as the absolute error divided by the value provided by the calculation with the Professional Digital Tool. Additionally, the Kruskal-Wallis test was used to determine whether there is a statistically significant difference between the medians of the RE results of the different



(a) Relationship between digital method proposed and a digital planimetry (n=28). (b) Relationship between digital method proposed and manual planimetry with Visitrak (n=28).

Fig. 9. Contour and area result correlation between Gold Standard and Digital method. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

groups of measurements (see Fig. 10). The null hypothesis that the differences between the medians are not statistically significant, and the alternative hypothesis that the differences between some of the medians are statistically significant, are established.

According to the result of the p-value < 0.05, we can reject the null hypothesis that the differences between RE medians are not statistically significant. We have enough evidence to conclude that the type of system used leads to statistically significant differences in the resulting area measurements.

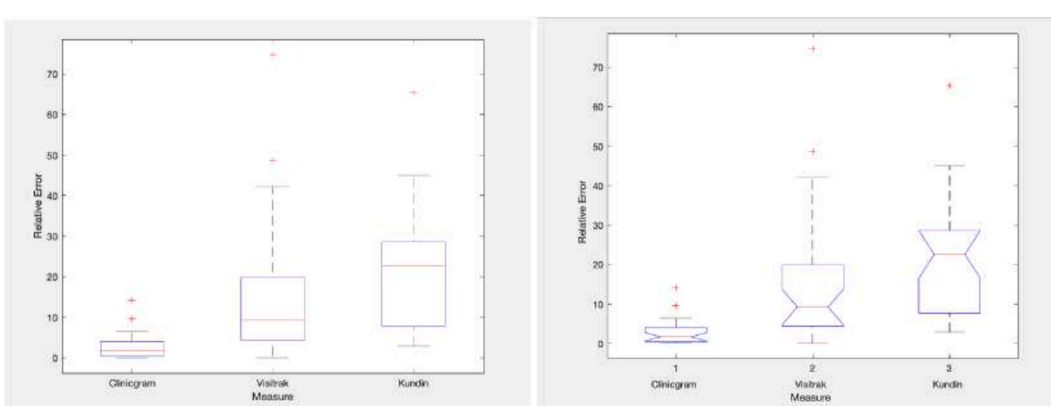
We tested whether the medians between the different groups (differentiated by the wound area comparison in the samples) are statistically significant, whereby p-values greater than 0.05 would indicate that there is no significant difference between the medians of the groups. Since the data do not follow a normal distribution, and the n of each group varies in each case, the Kruskal-Wallis test and ANOVA were performed. Matlab was used for this purpose. The results indicate that the measurement between the manual planimetry and Kundin method vs our Digital approach method have significant differences (p-value $<$ 0.04 in both cases). High inter-rater reliability were observed across all measurements (0.99–1.00). Therefore, considering that the most accurate reference is the digital planimetry, our proposal is the closest in terms of relative error (see Table 2).

4.2. Tissue classification

Depending on the model used in the pre-trained box and the hyperparameters used in our network, the results in terms of accuracy can be found in Table 3.

The data have been balanced so that there is the same amount of each class of tissue, and have been divided into 80% for a training set (n = 727) and 20% for testing. As discussed above, different CNN-based pre-trained mod-els were used, the accuracy of classification of which were compared between different tissues based on the accuracy and loss metrics of training (Tables 3 and 4) and the ROC curves (Figs. 11 and 12) of the prediction results with the test data. The model that gives optimal results in both training and testing is the ResNet50, with 85% accuracy in training and predicting necrotic tissue by 99%. However, the results with the other models were optimal with an accuracy of more than 70% in all except the InceptionRes- Net5V2, which has an accuracy of 49%. It can be seen in the ROC curves that the tissue class that has been predicted with the highest accuracy in all cases, is necrotic tissue.

From the perspective of classification performance, for the transfer learn-ing of the wound small dataset, the improved ResNet50 architecture using the LReLU activation function has better overall performance.



(a) Relative error comparison with different methods (b) Kruskall Wallis test

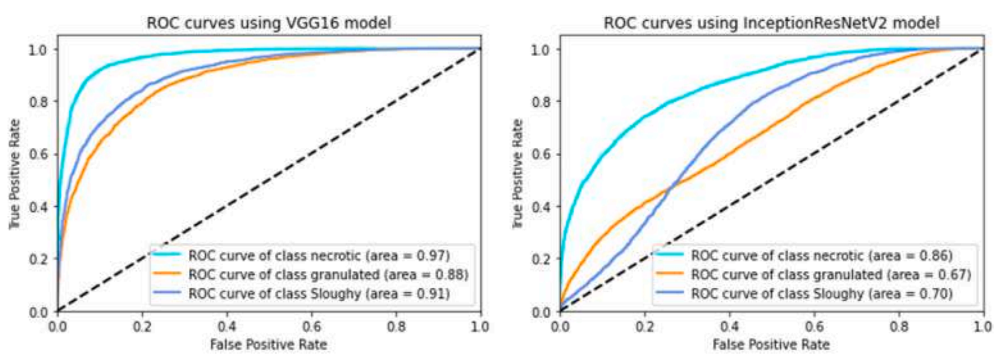
Fig. 10. Analysis comparison between different measurement methods.

Table 3
Performances measures of tissue classification by our proposed machine learning approach VGG16 and InceptionResNetV2.

	VGG16				InceptionResNetV2			
	precision	recall	f1-score	support	precision	recall	f1-score	support
Necrotic	0.85	0.88	0.87	3026	0.55	0.85	0.67	3026
Slough	0.74	0.68	0.70	3026	0.43	0.59	0.50	3026
Granulated	0.73	0.77	0.75	3026	0.42	0.04	0.07	3026
accuracy			0.78	9078			0.49	9078
macro avg	0.77	0.77	0.77	9078	0.47	0.49	0.41	9078
accuracy	0.77	0.78	0.78	9078	0.47	0.49	0.41	9078

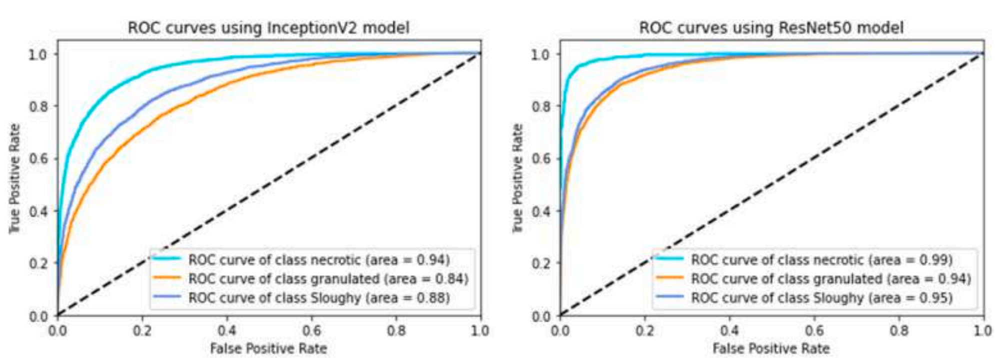
Table 4
Performances measures of tissue classification by our proposed machine learning approach Inception and Resnet50.

	InceptionV3				Resnet50			
	precision	recall	f1-score	support	precision	recall	f1-score	support
Necrotic	0.84	0.77	0.80	3026	0.96	0.90	0.93	3026
Slough	0.67	0.64	0.65	3026	0.79	0.83	0.81	3026
Granulated	0.67	0.75	0.71	3026	0.82	0.83	0.82	3026
accuracy			0.72	9078			0.85	9078
macro avg	0.72	0.72	0.72	9078	0.86	0.85	0.85	9078
accuracy	0.72	0.72	0.72	9078	0.86	0.85	0.85	9078



(a) ROC for VGG16 (b) ROC for InceptionResNetV2

Fig. 11. ROC curves for VGG16 and InceptionResNetV2.



(a) ROC for InceptionV3 (b) ROC for ResNet50

Fig. 12. ROC curves for InceptionV3 and Resnet50.

5. Discussion

Different techniques have been evaluated with the aim of making the assessment of wounds by the healthcare professional easier and faster in comparison to others [28,56–58]. While the decision is and will always be the same professional, the incorporation of a decision-support system [59], where elements based on artificial vision and machine learning help the professional in the classification of the wound and the patient, can help avoid complicated procedures.

Techniques with a noncontact patient wound like [22,57,60–65] were analyzed, providing an advantage in terms of accuracy over other traditional methods [54,55]. Our approach combine region of interest detection, area calculation, and tissue classification.

The main limitation has to do with the surface of the wound. If the wound bends at the tip and is hidden from the plane of the photograph, or is larger than the camera lens, the area measurement and classification methods are only partially valid. The assessment must be supplemented with additional photographs from different angles. Improper placement of the marker would also lead to problems with the final measurement of the wound. Although distortion or poor proportionality detection algorithms have been implemented, the clinician should take the photograph in a 90-degree plane and keep the marker in the same plane as the photograph. If it moves and is placed in a plane later, it would also cause significant computational problems. Another factor to consider is the brightness. If samples are taken under different light conditions, tissue classification algorithms may make errors.

Despite these obvious risks, we believe that digital transformation tools such as these, which provide advanced functionalities for computer vision and machine learning, will inevitably have an important place in clinical practice both for the value that the tool brings to the professional, and for the improvement of care for the patient.

6. Conclusions

In this work, different methods based on computer vision have been eval-uated to calculate the area, determine the contours, and classify the most relevant tissues of wounds using inexpensive hardware. This study found that a smartphone gives sufficiently consistent results to be useful in clinical practice.

Determining the area of the wound and the classification of its tissues gives the healthcare professional a detailed view of not only the wound at a precise time, but also how it can evolve over time. With these two vari-ables, one can define the concept of healing time. This variable is important for determining what factors predispose the healing process and whether a treatment is effective or not.

Different machine learning models have also been trained and have given us results in tissue classification. Digitized capture of the amount of tissue that can be in a wound is a major breakthrough in wound management. The detection of necrotic tissue is, without a doubt, one of the most important functionalities to take into account in the healing process, as its presence determines whether or not to apply treatment.

This study demonstrated that CNNs used in this study – VGG16, InceptionV3, and Resnet50 – provided high efficiency in the computer vision aspect and especially in necrotic label detection. With InceptionResnetV2 we obtained poor results.

The Transfer Learning technique uses a convolutional neural network that has already been trained with other data but with the same objective, image classification. This technique is widely used in Deep Learning, which only requires changing the last layer of the pre-trained network to adapt it to the treatment problem. This would solve the problem of the amount of data required to train a classical Machine Learning model.

The ResNet50 pre-trained neural network has an architecture that incorporates a bottleneck that uses 1x1 convolutions, thus reducing the number of parameters and matrix multiplications. This allows for much faster deep network training by jumping connections so that some neurons are connected to neurons in layers that are not necessarily contiguous, also alleviating the problem of gradient fading. The combination of a pre-trained network and our data set has provided good results. The filters of the small-dimensional network allow the convolution to capture the details of the wound tissues.

ResNet50 uses small kernels that classify image details better than other networks. Considering that we want to solve a problem where tissues, colors and textures form all the samples, this network allows us to have good results with a small dataset.

We believe this work is important as it shows that the digital transformation of wound care is becoming more and more prevalent. This type of procedure will no doubt end up being part of the set of tools that healthcare professionals use to address patients.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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