

AI-assisted software for chronic wound detection: Development, validation, and certification strategy

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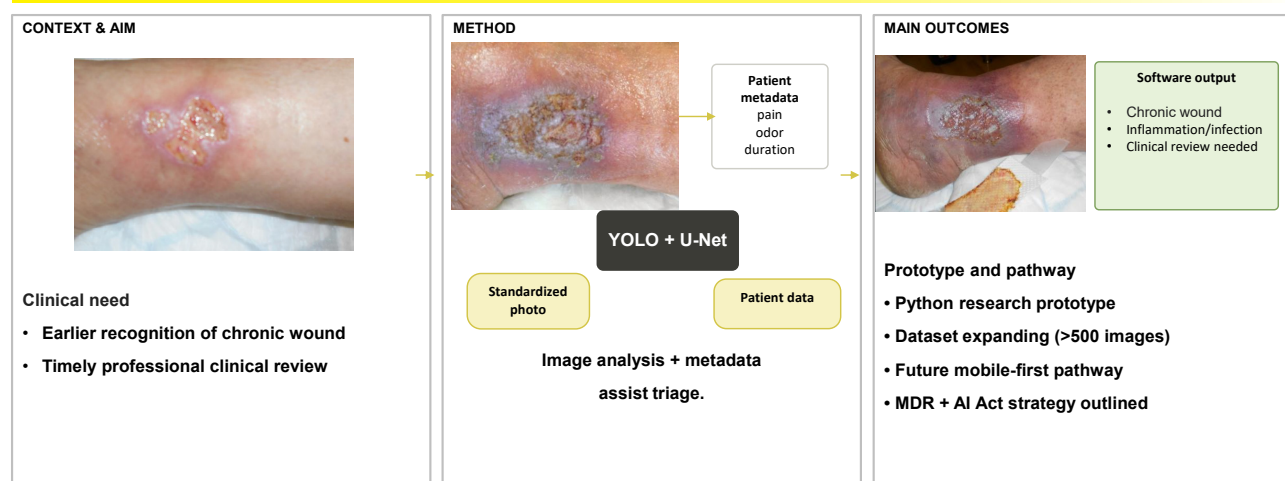
Aims. This study evaluates the feasibility of an artificial intelligence (AI)-assisted software tool for early identification and classification of chronic wounds and for supporting decisions on whether professional clinical review is needed.

Methods. A pilot assistive software solution was developed by integrating wound image analysis with patient-reported metadata. The system combines You Only Look Once (YOLO) for wound localization and U-Net for tissue segmentation. A standardized wound imaging and annotation protocol was designed in collaboration with the University Hospital Bulovka. Diagnostic performance will be evaluated using sensitivity, specificity, positive predictive value and negative predictive value.

Results. A Python-based prototype and a multimodal software architecture were developed. More than 500 standardized wound images have been collected to date, and the dataset is being expanded iteratively according to model performance, class balance, annotation quality and validation requirements. A regulatory certification strategy was outlined under the Medical Device Regulation and the AI Act.

Conclusion. The study establishes a technical and regulatory foundation for future AI-based wound care tools intended to support earlier triage and professional assessment of chronic wounds.

AI-ASSISTED SOFTWARE FOR CHRONIC WOUND DETECTION



AI-assisted wound analysis may support earlier identification of chronic wounds requiring professional clinical attention.

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INTRODUCTION

Chronic wounds, including venous ulcers, arterial ulcers, diabetic foot ulcers and pressure injuries, remain a significant clinical challenge because delayed recognition and protracted specialist assessment may prolong healing and increase the risk of complications. Management depends on timely identification, structured documentation, and referral to appropriate wound care specialists.

The need for structured assessment is consistent with international wound care frameworks. The European Wound Management Association (EWMA) wound bed preparation framework stresses effective and accurate patient and wound assessment and early identification of non-healing wounds, while the International Working Group on the Diabetic Foot (IWGDF) practical guidelines emphasize prevention, classification, and multidisciplinary management of diabetes-related foot disease^{1,2}. The present work builds on these principles by exploring whether AI-assisted image analysis and patient-reported metadata can support earlier identification of wounds requiring clinical review.

AI-based image analysis is increasingly investigated in wound care, particularly for wound localization, tissue segmentation, measurement, classification, and monitoring³⁻⁵. When combined with standardized photography and structured metadata, AI may provide a supportive triage signal for patients, caregivers, and clinicians.

Consultations with Czech wound care specialists indicated that many patients present late at specialist clinics, after wound progression has already become clinically problematic. A future mobile-first application could allow patients or caregivers to capture standardized wound images and enter basic clinical information, with the software providing an assistive recommendation on whether professional review should be sought. Such output would support, not replace, clinical judgement.

The primary aim of this study is to evaluate the feasibility of using artificial intelligence (AI) to identify chronic wounds and determine whether they require professional clinical assessment. The work also includes the collection of a sufficiently robust and properly annotated dataset for training and validating the AI-based detection model, the development of a pilot version of an assistive software tool tailored for chronic wound recognition, and the assessment of its diagnostic accuracy.

Furthermore, the study outlines a regulatory certification strategy for AI-based medical device software (MDSW) under the European Medical Device Regulation (MDR).

MATERIALS AND METHODS

Data collection

The data are being collected from university hospitals in the Czech Republic, especially the University Hospital Bulovka, selected because of its clinical experience in the professional management of chronic wounds.

The dataset is being expanded iteratively for AI software development. At the time of revision, more than 500 standardized wound images had been collected. The final number of images required for development and validation has not been predetermined; it will depend on model performance, class balance, annotation quality, and the results of validation testing. Additional images will be collected if testing indicates that a larger or more balanced dataset is needed.

The dataset includes images of wounds captured at different stages of healing to support the ability of the model to recognize wound changes over time. Individual patients may contribute images of multiple wounds, and the same wound may be photographed at several intervals during the healing process. All images are annotated with wound characteristics such as color, size, tissue type, pain level, wound odor, wound duration, elevated body temperature, and comorbidities.

A standardized wound photography protocol is followed for data collection, based on the Guidelines for wound photography prepared by Šeflová et al.⁶. A calibrated ruler, placed approximately 2 cm near the wound, serves as a reference for size and orientation. Color markers are used for standardization of color representation across images. Emphasis is also placed on patient comfort and ethical standards. Patients are informed of the procedure, and verbal consent is required. Intimate regions are covered. All collected patient data are anonymized to comply with GDPR and other data protection regulations.

The collected data will be divided into training and testing subsets. The planned baseline split is 80:20, while the final validation approach may be refined according to dataset composition, class balance, and the results of initial model testing.

The study was not designed as a clinical trial. Clinical photographs were obtained after verbal patient consent. Intimate body areas were covered during image acquisition, and the collected data were anonymized and handled in accordance with applicable personal data protection requirements, including the General Data Protection Regulation (GDPR).

Software development

The development process for assistive AI-based software follows the standardized Software Development Lifecycle (SDLC), a six-phase framework ensuring systematic and efficient software creation.

The software was programmed using Python, which was chosen for its extensive library support, including TensorFlow and PyTorch, and its suitability for implementing deep learning tasks. Python compatibility with healthcare-oriented research tools and open-source architectures, such as YOLO and U-Net, makes it particularly suitable for this project.

The current prototype is a Python-based research prototype intended for controlled development, training, and validation. The longer-term objective is to translate the system into a mobile-first application pathway in which a patient, caregiver, or clinician could capture standardized

wound photographs and enter basic clinical metadata. At this stage, the final deployment model, user group, licensing model, and distribution pathway have not yet been determined. These decisions will depend on usability testing, clinical validation, risk management, data protection requirements, and the future conformity assessment strategy.

The AI-based assistive software was designed to support early detection and monitoring of chronic wounds by leveraging machine learning and deep learning techniques. The system employs a multimodal architecture, integrating both image data and structured patient-provided information to improve diagnostic precision. Specifically, the model consists of two computational branches: a convolutional neural network (CNN) branch processes visual input from wound images, while a second branch manages non-image data collected from the user. Categorical patient inputs are numerically encoded, for example via one-hot encoding, and the two branches are subsequently fused into a joint representation that outputs a binary classification indicating whether professional clinical attention is recommended.

For image-based analysis, the system utilizes two complementary neural network architectures. YOLO (You Only Look Once) is applied for real-time object detection and localization of the region of interest (ROI) within uploaded wound photographs. Once the ROI is localized, it is forwarded to U-Net for detailed image segmentation and tissue-type classification. U-Net is a well-established CNN architecture for biomedical image segmentation, known for its encoder-decoder structure with precise pixel-level labeling.

In parallel, the software collects structured data from patients or clinical users through an input interface. Users are prompted to enter clinical and contextual information, including pain level (none, low, moderate, severe), wound odor (yes/no), wound duration (in days or months), body temperature status (fever yes/no), and relevant comorbidities such as diabetes, obesity, or cardiovascular disease. This information is intended to support multimodal decision-making, particularly in visually ambiguous cases.

Software Testing

Firstly, unit testing is conducted, where individual components of the software, such as the YOLO-based

detection module and the U-Net segmentation algorithm, are evaluated. These tests validate whether each module functions as intended. Then, integrated testing reviews the operation of the whole software workflow.

The performance of the AI software will be verified using the following metrics: sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). These metrics will be evaluated using a testing or validation dataset that includes images the model has not encountered during training. The threshold for sensitivity will initially be set at 80%, while final performance targets may be refined during validation according to the intended clinical use and risk management conclusions. Table 1. summarizes the diagnostic performance metrics planned for software validation.

Certification strategy

To place a medical device on the market, it is necessary to meet the requirements of the Medical Device Regulation (EU) 2017/745 (MDR), undergo a conformity assessment by one of the notified bodies, and issue a Declaration of Conformity. Additionally, the recently enacted Artificial Intelligence Act (AI Act) will impose further requirements on medical devices incorporating artificial intelligence once it becomes fully effective in 2027.

While the goal of this study is not to create regulatory documentation, since that does not fall within the scope of scientific research, as it is considered administrative documentation, one of the secondary objectives of this study was also to facilitate the potential future conformity assessment process for the manufacturers.

To achieve this, a certification strategy was proposed for the developed pilot AI-driven software according to the Medical Device Regulation. This strategy includes a rationale for qualification, classification, determination of applicable classification rule and a suggestion of the right conformity assessment pathway, as well as a technical file structure suitable for the characteristics of the AI-based medical device software (MDSW), ensuring its alignment with MDR requirements. Furthermore, appropriate key ISO standards are identified to support compliance with MDR requirements.

Table 1. Diagnostic performance metrics planned for software validation.

Metric	Definition	Formula	Practical Question
Sensitivity	The ability to correctly identify true positive cases.	$\text{Sensitivity} = \text{TP} / (\text{TP} + \text{FN})$	If the patient has the condition, what is the probability the test is positive?
Specificity	The ability to correctly identify true negative cases.	$\text{Specificity} = \text{TN} / (\text{TN} + \text{FP})$	If the patient does not have the condition, what is the probability the test is negative?
Positive Predictive Value (PPV)	The proportion of true positive results among all positive identified results.	$\text{PPV} = \text{TP} / (\text{TP} + \text{FP})$	If the test is positive, what is the probability the patient has the condition?
Negative Predictive Value (NPV)	The proportion of true negative results among all negative identified results.	$\text{NPV} = \text{TN} / (\text{TN} + \text{FN})$	If the test is negative, what is the probability the patient does not have the condition?

RESULTS

A few publicly available multimodal wound image databases have been created, for example by Kręcichwost et al.⁷ Their database includes 188 image sets collected from 79 patients. However, because available public datasets remain limited in size, standardization, and image quality, the present study uses images collected through the collaborating clinical sites for development and testing of the software.

The research data are being collected from major hospitals in Prague, especially University Hospital Bulovka, Department of Surgery led by Prof. MUDr. Robert Gürlich, CSc. More than 500 standardized clinical wound

images have been collected to date, and the dataset will be expanded further according to model performance, annotation quality, class balance, and validation needs. The wounds are photographed using standard mobile phones at a distance of approximately 30 cm under natural lighting conditions. Clinicians record descriptions of each image, including size, color, tissue type (epithelialized, granulated, or necrotic), pain level (none/low/moderate/severe), wound odor (yes/no), wound duration (in days/months), elevated body temperature (yes/no), and comorbidities. Based on these markers, they assess whether the wound should be qualified as chronic, whether signs suggesting inflammation or infection are present, and whether professional clinical review is recommended.



Fig. 1. Clinical documentation of Patient A: post-traumatic wound and healing progress at admission and after 7 days.



Fig. 2. Clinical documentation of Patient B: two-year history of lower extremity ulceration and improvement after two weeks.

Representative examples from clinical documentation are shown in Fig. 1 and Fig. 2.

The software is developed in Python, chosen for its machine learning ecosystem and robust libraries such as TensorFlow and PyTorch. The system architecture supports a multimodal approach, integrating both image data and structured patient inputs. This is achieved through two software branches: one for processing wound images and another for handling encoded clinical and contextual information provided by the user. These branches are merged in a final layer to produce a binary classification indicating whether clinical review is recommended.

For visual analysis, the software employs two established deep learning models: the YOLO algorithm to detect and localize the wound region within submitted photographs, and a U-Net convolutional neural network for precise segmentation of tissue types.

After consultations with wound care specialists, the following key functionalities were identified for photographic wound analysis:

- Measure wound dimensions.
- Identify wound color.
- Differentiate tissue types, including epithelialization, granulation, and necrotic tissue.

In addition to photographic analysis, the software allows users to input other information, such as:

- When the wound originated (in days or months).
- The presence of odor (yes/no).
- The level of pain (none/low/moderate/severe)
- If the patient has an elevated body temperature (yes/no)
- Comorbidities, such as diabetes, obesity, or cardiovascular conditions, etc.

Using these data, the developed AI-based assistive software:

- Detects whether the wound is chronic.
- Assesses whether signs suggesting inflammation or infection are present.
- Recommends whether the patient should seek professional clinical review.

Preliminary testing using simulated validation data has shown encouraging results, supporting the feasibility of the proposed AI-driven assistive solution. Further testing on an expanded and properly balanced clinical dataset will be required before any clinical deployment.

Based on Annex VIII, Rule 11 of the MDR, the AI software is classified as Class IIa, as it informs clinical decisions but does not pose an immediate or serious risk to patients. The conformity assessment procedure therefore follows Annex IX, Chapters I and III. A technical documentation structure has been outlined according to Annex II, including device description, general safety and performance requirements (GSPR), risk management, and clinical evaluation.

The documentation is complemented by a draft list of applicable harmonized standards, including ISO 14971 for risk management, IEC 62304 for software lifecycle pro-

cesses, and ISO 13485 for quality management systems. In anticipation of additional regulatory requirements under the AI Act, the strategy also considers obligations related to data governance, transparency, human oversight, and algorithmic accountability. These elements are intended to support alignment with current MDR requirements and future European AI regulatory expectations.

DISCUSSION

Prevention and diagnosis in wound care using artificial intelligence

The revised discussion focuses on the use of AI for prevention, triage, and diagnostic support in wound care. This focus reflects the central contribution of the manuscript: the development of an assistive software concept that may help distinguish chronic or clinically concerning wounds from wounds that do not require urgent specialist assessment.

The proposed software is aligned with two practical principles emphasized in international wound care frameworks: structured wound assessment and timely professional intervention. The EWMA wound bed preparation model highlights the importance of effective and accurate patient and wound assessment and early identification of non-healing wounds¹. The IWGDF practical guidelines similarly emphasize prevention, classification, and multidisciplinary management of diabetes-related foot disease². In this context, AI-assisted wound analysis should be understood as a supportive triage and documentation tool, not as a replacement for professional wound care.

Artificial intelligence has undergone substantial development from rule-based systems to machine learning and deep learning algorithms. In wound care, deep learning methods are particularly relevant because wound assessment frequently depends on image-based features, including wound boundaries, tissue composition, color, exudate, and visible progression over time^{3,5}.

Recent studies have explored AI-based wound assessment as an alternative or complement to traditional visual assessment. Cross and Harding⁸ introduced an AI approach to risk profiling in the prevention and treatment of chronic wounds, using demographic information, medical history, lifestyle factors, wound characteristics, and other relevant variables. Ganesan et al.⁴ reviewed 58 articles and concluded that AI-based tools using deep learning can assist in automatic wound segmentation, classification, and healing prediction.

A systematic review by Anisuzzaman et al.³ reviewed more than 250 articles on image-based wound assessment systems, including hardware and mobile applications. The authors highlighted progress in segmentation and prognosis, while also emphasizing persistent limitations, including dataset diversity, image quality, labeling quality, performance across different skin tones, and privacy concerns. These limitations are directly relevant to the present study and support the need for standardized photography, clinical annotation, and cautious validation before clinical use.

Several individual studies support the technical feasibility of image-based AI in wound assessment. Shenoy et al.⁹ used a dataset of 1,335 wound images and developed Deepwound for automated postoperative wound assessment and surgical site surveillance. Rajathi et al.¹⁰ proposed a CNN-based method for tissue classification of varicose ulcer wound images. Carrión et al.¹¹ developed a deep learning pipeline for automatic wound detection and size estimation using nonuniform wound images. Chairat et al.¹² explored automatic color and measurement calibration with AI-assisted wound tissue assessment on smartphone images.

Other work has addressed prediction and monitoring. Robnik-Sikonja et al.¹³ developed a machine learning-based prediction model for wound healing using data from 214 patients with 300 chronic wound cases. Cho et al.¹⁴ developed a model to predict healing rates of chronic wounds within 12 weeks. Rochon et al.¹⁵ developed and evaluated wound imaging software and a digital platform to assist review of surgical wounds using patient smartphones.

Together, these studies demonstrate that AI can support wound localization, tissue segmentation, measurement, classification, monitoring, and risk prediction. However, they also show that the clinical value of such systems depends on data quality, standardized acquisition, representative datasets, transparent validation, and integration into clinically meaningful workflows. The present study contributes to this field by combining standardized wound photography, patient-reported metadata, YOLO-based localization, U-Net segmentation, planned diagnostic performance evaluation, and a regulatory certification strategy within one translational framework.

The intended role of the software is therefore deliberately limited and assistive. Its output should indicate whether professional clinical review appears warranted, based on image analysis and structured metadata. Future development should test this workflow in realistic user settings and determine whether the tool is most appropriate for patient-facing use, caregiver-supported home monitoring, or supervised use by healthcare professionals.

Challenges

This study, like most similar research, faces limitations regarding the availability, diversity, and balance of data. More than 500 standardized images have been collected so far, but the final dataset size required for meaningful model training and validation has not been predetermined. It will be determined by model performance, class balance, annotation quality, and validation results. If testing indicates insufficient performance or inadequate representation of specific wound types, additional images will be collected and the dataset will be expanded accordingly.

Another limitation is demographic homogeneity. Because the data predominantly originate from Czech patients, including many patients with light skin tones, the model may not be sufficiently representative for broader use without further data collection. Future datasets should include greater demographic diversity and additional clinical settings before wider deployment.

A further challenge is variability in wound annotation due to the partly subjective nature of clinical image interpretation. To mitigate this risk, clinicians involved in annotation are required to follow consensus-based guidance and standardized photographic procedures. Establishing a larger, professionally annotated chronic wound image database at the European level would be beneficial and would align with the broader objectives of the European Health Data Space (EHDS).

Future directions

This study establishes a foundation for leveraging AI in wound care diagnostics. Moving forward, a key priority is continued collection and annotation of high-quality data. More than 500 standardized images have already been collected at University Hospital Bulovka. The dataset will be expanded as needed according to model performance, class balance, annotation quality, and validation results rather than according to a fixed predetermined image count.

A preliminary version of the AI-driven assistive software has already been developed using Python with YOLO libraries for wound localization and the U-Net architecture for tissue segmentation. Further training, testing, and validation will rely on established clinical metrics, including sensitivity, specificity, positive predictive value, and negative predictive value.

The longer-term development objective is a mobile-first application pathway for standardized wound image capture and metadata entry. The final deployment model, target user group, access model, and licensing approach have not yet been determined and will require usability testing, clinical validation, data protection assessment, risk management, and regulatory evaluation.

CONCLUSION

This study addressed the challenge of delayed recognition and assessment of chronic wounds by developing a pilot AI-assisted software concept for earlier triage and professional review. By combining YOLO-based wound localization, U-Net tissue segmentation, standardized wound photography, and structured patient-reported metadata, the proposed system provides a foundation for an assistive tool capable of identifying wounds that may require professional clinical attention.

The research achieved several key milestones, including the development of a multimodal software architecture, the collection of more than 500 standardized clinical wound images to date, and the definition of a validation approach based on sensitivity, specificity, positive predictive value, and negative predictive value. Further testing on a larger and properly balanced clinical dataset will be required before clinical deployment.

Importantly, the study extends beyond algorithmic development by outlining a structured certification strategy aligned with the EU Medical Device Regulation and the EU AI Act.

In conclusion, this work provides both a technical and regulatory foundation for future AI integration in chronic wound diagnostics and triage. Future research should focus on expanding and balancing the dataset, refining the model, addressing algorithmic transparency and bias, validating the system in clinically relevant conditions, and defining the most appropriate future deployment pathway.

ABBREVIATIONS

AI, Artificial intelligence; CNN, Convolutional neural network; EHDS, European Health Data Space; EU, European Union; EWMA, European Wound Management Association; FN, False negative; FP, False positive; GDPR, General Data Protection Regulation; GSPR, General safety and performance requirements; IWGDF, International Working Group on the Diabetic Foot; MDR, Medical Device Regulation; MDSW, Medical device software; NPV, Negative predictive value; PPV, Positive predictive value; ROI, Region of interest; SDLC, Software Development Lifecycle; TN, True negative; TP, true positive; YOLO, You Only Look Once.

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Conflict of interest statement: None declared.

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