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Accuracy of digital measurement for quantitative and qualitative indicators of wound healing and repair: a systematic review protocol

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ABSTRACT

Introduction Chronic wound care remains a critical public health challenge in terms of prevalence, quality of life and healthcare costs on a global scale. Currently used methods to assess the size and content of wounds include direct contact techniques based on double-layer film, ruler measurements, digital photography and visual examination. Nowadays, despite these evaluations, close monitoring and tracking of these chronic wounds remain a great challenge. The use of telemonitoring through digital measurement tools may offer a potential means of improving healing management processes. Many studies have evaluated the size and content of the wound through digital devices such as mobile phones and computers. However, the clinical accuracy of these tools remains to be clarified. The objective of this systematic review is to assess and consolidate the current state-of-the-art digital devices for both quantitative (length, width, surface area, perimeter, volume and depth) and qualitative (granulation, fibrin, necrosis and slough) indicators of wound care.

Methods and analysis We will include studies using digital measurement methods from databases such as EBSCO, Cochrane Library, MEDLINE, Web of Science and EMBASE, limited to French and English publications until November 15, 2023. Following the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines, selection involves two independent reviewers conducting title and abstract screenings, study selections, data extractions and risk-of-bias assessments using QUADAS-2. Discrepancies will be resolved through discussion or a third reviewer.

Ethics and dissemination Primary data will not be collected in this study; thus, ethical approval will not be required. The study's findings will be published in a peer-reviewed journal.

PROSPERO registration number CRD42023396642.

INTRODUCTION

Chronic wound (CW) management has emerged as a growing major healthcare problem leading to clinical and economic burden. In the last 20 years, there has been an increase in the prevalence of CW.[1] In 2018, 1.5–2 million people were affected by CW injury in Europe.[2] CWs have a serious impact on health and quality of life, resulting in chronic pain, function and mobility loss, mental depression, anxiety, social discomfort and isolation, prolonged hospitalisation and even death, associated with tremendous healthcare expenditure.[3–5]

A wound is defined as a loss of epithelial continuity, with or without the loss of underlying connective tissue (muscle, bone or nerve), which may be caused by trauma, burns (thermal or chemical), surgery, vascular damage (arterial, venous, lymphatic or mixed) or metabolic disease such as diabetes.[6] Wounds are generally categorised into acute and chronic. Unlike acute wounds that typically heal within 3 weeks, CW usually needs 2 to 8 weeks of healing process.[4 7 8] The most common CW include diabetic foot ulcers (DFUs), venous leg ulcers (VLUs) and pressure ulcers/injuries.[9] Nearly 650 000 French people reported CW in 2012, among them 65% were affected by VLUs, 23% by pressure sores and 11% by DFUs.[10]

It is crucial to monitor the wound healing progression by the physician to optimise care management according to the evolution of the wound. There are several wound measurement methods: direct contact techniques based on double-layer film, ruler

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ One major strength is the extensive synthesis of data, which includes the largest number of articles.
⇒ Biases found in the primary research findings will be evaluated and reported, but they might not be evident at the end and could skew the results of the systematic review.
⇒ The primary limitation is that results may be influenced by a small number of studies, heterogeneity of patients, treatment settings and measured outcomes.

measurements, digital photography and visual examination.[11 12] However, although such techniques remain the gold standard for the clinical assessment of CW, they are plagued by significant heterogeneity and great dependence on the operator.[13] Overestimating the wound area can have adverse consequences on wound healing.[14] CW care management requires repeated medical appointments, which are time-consuming for both the patient and the doctor.[13] It is estimated that the management of chronic wound healing costs nearly €1 billion euros annually in France.[10] Hence, it is necessary to efficiently assess wound healing using an efficient assessment device for both quantitative and qualitative indicators.[7 15]

The prevalence of most types of wounds was found to be highest in patients aged 75 years or over.[16 17] The elderly suffering from CW have reduced mobility and often fail to attend medical appointments to monitor wound healing.[18] On the other hand, CW themselves reduce the mobility and quality of life of CW patients.[19] Moreover, the shortage of well-trained wound specialists makes it impossible for most patients with CW to access specialised wound care in primary and rural healthcare settings. Thus, the development of remote monitoring systems can significantly promote wound care access to elderly patients, patients with disabilities and those living in rural areas.[20] Therefore, these systems play a role to play in the near future, not only in reducing the financial burden of wound care for healthcare systems but also in promoting outpatient care, by limiting the time and cost of travel for patients and their relatives during outpatient medical appointments. In addition, the use of artificial intelligence and portable devices like smartphones in wound care is increasing, so it is time to strengthen remote intelligent diagnosis and prognosis systems for wound care. Hence, we believe it is appropriate to compile all the data pertaining to the quantitative and qualitative indicators of wound healing monitoring to assess the interest and accuracy of available digital measurement tools.

Review question
What is the accuracy of digital tools for monitoring a wound that requires directed healing?

Objectives
This systematic review aims:
1. To evaluate the concordance of digital measurement tools for quantitative indicators of wound healing monitoring (length, width, surface area, perimeter, volume, and depth).
2. To evaluate the accuracy of digital tools for measuring qualitative and quantitative indicators of wound healing monitoring (granulation, fibrin, necrosis and slough).

METHODS
Principles
The Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) will be used to report this protocol.[21] The PRISMA-P checklist is attached as online supplemental file 1. This study has been registered with the International Prospective Register of Systematic Reviews (PROSPERO, registration number: CRD42023396642).

Eligibility criteria
Types of participants
Patients with a CW that requires directed healing (not limited to wounds such as burns, ulcers, pressure ulcers, diabetic foot wounds and traumatic wounds) and patients who benefit from a digital wound assessment tools will be included.

Types of interventions
Research on the assessment of wounds using computer and mobile software applications will be included.

Types of outcomes
Studies included will report inter-rater reliability, correlation coefficient, accuracy, precision and error (mean or absolute error) for quantitative analysis. For qualitative analysis, the accuracy, agreement, inter-rater reliability and mean error or relative error will be reported. Any adverse events reported during the study will also be reported.

Search strategy for identifying relevant studies
The search strategy will be conducted as described below.

Bibliographic database searches
Relevant records will be identified by searching Embase, MEDLINE, Web of Science, Cochrane Library and EBSCO from inception until November 15, 2023, restricted to French and English languages.

Text words and medical subject heading terms related to digital wound assessment tool and healing will be used including: 'Wound', 'Foot, Diabetic', 'Foot Ulcers', 'Skin Ulcers', 'Pressure Ulcers', 'Injuries and Wounds', 'Healing, Wound', 'Wound Epithelialization', 'Computer-Assisted Image Interpretation', 'Application, Portable Software' or 'Applications, Computer Software'.

Online supplemental file 2 shows the full search strategy for EMBASE that will be adapted to fit with other databases.

Searching for other sources
We will examine the references of all relevant publications for additional relevant information sources missed during our search, and full texts will be retrieved. References of relevant reviews will also be examined.

Selection of studies for inclusion in the review
All potentially relevant studies will be imported into Rayyan software, and duplicates will be removed. For studies published in more than one report, the one reporting the largest sample size will be considered. Two reviewers will independently screen the titles and abstracts for inclusion using Rayyan software based on

the previously stated criteria. Any disagreement will be resolved by discussion between the two reviewers. Studies with inaccessible full text either online or from the corresponding author will be excluded. After this, two reviewers will independently review the full text of each potentially eligible study, compare their results and resolve any discrepancy by discussion. Inter-rater agreements between investigators for study inclusion will be assessed using Cohen's κ.[22]

Data extraction and management

A data extraction form will be used by two reviewers independently to collect information on the first author, year of publication, country where the study was conducted, sample size, patients' characteristics (type of wounds, sex, age, if any), type of equipment and image analysis system, measurement conditions, types of the gold standard used and outcomes (concordance, accuracy, precision and error). We will exclude studies in which relevant data are impossible to extract even after contacting the corresponding author. Any disagreement will be resolved by discussion between two reviewers.

Assessment of risk of bias and applicability concerns

Methodological assessment of risk of bias and applicability of included studies will be evaluated based on the quality assessment of diagnostic accuracy studies (QUADAS)–2, a revised tool for the QUADAS (www.quadas.org).[23] This tool allows us to distinguish between bias and applicability, identifying four key domains supported by signalling questions to aid in the judgement of risk of bias, rating risk of bias and concerns about applicability. Two independent reviewers will assess each study's risk of bias and applicability concerns, and disagreements will be resolved through discussion.

Presentation and reporting of results

The study selection process will be summarised using a flow diagram. The results of the included studies will be presented in the form of the table and narrative summary. This will provide an overview of the characteristics such as geographic area, year, population size, baseline population characteristics, type of intervention system, measurement condition, reference standard and measurement indicators. The results of the risk of bias and acceptability assessment using QUADAS-2 will be presented in a table and included in the narrative summary.

Patient and public involvement

Patients and the public were not involved in the design or planning of the study.

Potential amendments

We do not plan to modify the protocol to avoid reporting bias. However, if necessary, any amendment in the review process will be reported for transparency.

ETHICS AND DISSEMINATION

As no primary data will be collected in this study, no ethical approval is required. This review aims to evaluate the accuracy of digital tools by evaluating both quantitative and qualitative indicators for monitoring wound healing and to offer a detailed description of devices. The final report will be published in a peer-reviewed journal.

Timeline

Bibliographic database searches (November 2023), selection of included studies (March 2024), data extraction and management (April 2024), data synthesis and analysis (June 2024) and manuscript submission (July 2024).

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Supplemental material

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PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	**No**	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	2
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	9
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	4 - 5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	5
METHODS					

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	**No**	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	6-7
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	7, supplemental file 2
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	7-8
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	7-8
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	8
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	8-9
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	8
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	8, The result of the included

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	**No**	
					studies will be presented in the form of the table and narrative summary
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☐	☒	

Systematic Review -Research Equation

#1	'Foot, Diabetic' OR 'Diabetic Feet' OR 'Feet, Diabetic' OR 'Foot Ulcer, Diabetic' OR 'Foot Ulcers' OR 'Ulcer, Foot' OR 'Ulcers, Foot' OR 'Plantar Ulcer' OR 'Plantar Ulcers' OR 'Ulcer, Plantar' OR 'Ulcers, Plantar' OR 'Ulcer, Varicose' OR 'Ulcers, Varicose' OR 'Varicose Ulcers' OR 'Venous Stasis Ulcers' OR 'Stasis Ulcer' OR 'Venous, Stasis Ulcers' OR 'Venous, Ulcer' OR 'Venous Stasis' OR 'Ulcers, Venous Stasis' OR 'Venous Stasis Ulcer' OR 'Venous Hypertension Ulcers' OR 'Hypertension Ulcer, Venous' OR 'Hypertension Ulcers, Venous' OR 'Ulcer, Venous Hypertension' OR 'Ulcers, Venous Hypertension' OR 'Venous Hypertension Ulcer' OR 'Venous Ulcer' OR 'Ulcer, Venous' OR 'Ulcers, Venous' OR 'Venous Ulcers' OR 'Stasis Ulcer' OR 'Stasis Ulcers' OR 'Ulcer, Stasis' OR 'Ulcers, Stasis' OR 'Skin Ulcers' OR 'Ulcer, Skin' OR 'Ulcers, Skin' OR 'Leg Ulcers' OR 'Ulcer, Leg' OR 'Ulcers, Leg' OR 'Pressure Ulcers' OR 'Ulcer, Pressure' OR 'Ulcers, Pressure' OR 'Bedsore' OR 'Bedsores' OR 'Pressure Sore' OR 'Pressure Sores' OR 'Sore, Pressure' OR 'Sores, Pressure' OR 'Bed Sores' OR 'Bed Sore' OR 'Sore, Bed' OR 'Sores, Bed' OR 'Decubitus Ulcer' OR 'Decubitus Ulcers' OR 'Ulcer, Decubitus' OR 'Ulcers, Decubitus' OR 'Injuries and Wounds' OR 'Wounds and Injury' OR 'Injury and Wounds' OR 'Wounds, Injury' OR 'Trauma' OR 'Traumas' OR 'Injuries, Wounds' OR 'Research-Related Injuries' OR 'Injuries, Research-Related' OR 'Injury, Research-Related' OR 'Research Related Injuries' OR 'Research-Related Injury' OR 'Injuries' OR 'Injury' OR 'Wounds' OR 'Wound'
#2	'Healing, Wound' OR 'Healings, Wound' OR 'Wound Healings' OR 'Re-Epithelialization' OR 'Re Epithelialization' OR 'Wound Epithelialization' OR 'Epithelialization, Wound' OR 'Adhesive, Fibrin Tissue' OR 'Tissue Adhesive, Fibrin' OR 'Fibrin Adhesive' OR 'Adhesive, Fibrin' OR 'Fibrin Glue' OR 'Glue, Fibrin' OR 'Fibrinogen Adhesive' OR 'Adhesive, Fibrinogen' OR 'Fibrin Sealant System' OR 'Sealant System, Fibrin' OR 'Autologous Fibrin Tissue Adhesive' OR 'Fibrin Sealant' OR 'Sealant, Fibrin' OR 'Crosseal' OR 'Fibrin Klebe System Immuno' OR 'Transglutine' OR 'Fibrin Sealant, Human' OR 'Human Fibrin Sealant' OR 'Sealant, Human Fibrin' OR 'Tisseel' OR 'Tissel' OR 'Tissucol' OR 'Beriplast' OR 'Fibrin Seal' OR 'Seal, Fibrin'
#3	'Imaging, Multimodal' OR 'Hybrid Imaging' OR 'Imaging, Hybrid' OR 'Multimodal Imaging' OR 'Computer-Assisted Image Interpretation' OR 'Computer-Assisted Image Interpretations' OR 'Image Interpretations, Computer-Assisted' OR 'Interpretation, Computer-Assisted Image' OR 'Interpretations, Computer-Assisted Image' OR 'Image Interpretation, Computer Assisted' OR 'Computer-Assisted Signal Processing' OR 'Signal Processing, Computer Assisted' OR 'Signal Processing, Digital' OR 'Digital Signal Processing' OR 'Signal Interpretation, Computer-Assisted' OR 'Computer-Assisted Signal Interpretation' OR 'Computer-Assisted Signal Interpretations' OR 'Interpretation, Computer-Assisted Signal' OR 'Interpretations, Computer-Assisted Signal' OR 'Signal Interpretation, Computer Assisted' OR 'Signal Interpretations, Computer-Assisted' OR 'Application, Mobile' OR 'Applications, Mobile' OR 'Mobile Application' OR 'Mobile Apps' OR 'App, Mobile' OR 'Apps, Mobile' OR 'Mobile App' OR 'Portable Software Apps' OR 'App, Portable Software' OR 'Portable Software App' OR 'Software App, Portable' OR 'Portable Software Applications' OR 'Application, Portable Software' OR 'Portable Software Application' OR 'Software Application, Portable' OR 'Smartphone Apps' OR 'App, Smartphone' OR 'Apps, Smartphone' OR 'Smartphone App' OR 'Portable Electronic Apps' OR 'App, Portable Electronic' OR 'Electronic App, Portable' OR 'Portable Electronic App' OR 'Portable Electronic Applications' OR 'Application, Portable Electronic' OR 'Electronic Application, Portable' OR 'Portable Electronic Application' OR 'Computer Software' OR 'Software, Computer' OR 'Open Source

	Software' OR 'Open Source Softwares' OR 'Software, Open Source' OR 'Softwares, Open Source' OR 'Source Software, Open' OR 'Source Softwares, Open' OR 'Computer Programs' OR 'Computer Program' OR 'Program, Computer' OR 'Programs, Computer' OR 'Software Tools' OR 'Software Tool' OR 'Tool, Software' OR 'Tools, Software' OR 'Software Engineering' OR 'Engineering, Software' OR 'Computer Applications Software' OR 'Applications Software, Computer' OR 'Applications Softwares, Computer' OR 'Computer Applications Softwares' OR 'Software, Computer Applications' OR 'Softwares, Computer Applications' OR 'Computer Software Applications' OR 'Application, Computer Software' OR 'Applications, Computer Software' OR 'Computer Software Application' OR 'Software Application, Computer' OR 'Software Applications, Computer' OR 'Computer Programs and Programming' OR 'Software Algorithm' OR 'Software Algorithms' OR 'Algorithm, Software' OR 'Intelligence, Artificial' OR 'Computational Intelligence' OR 'Intelligence, Computational' OR 'Machine Intelligence' OR 'Intelligence, Machine' OR 'Computer Reasoning' OR 'Reasoning, Computer' OR 'AI (Artificial Intelligence)' OR 'Computer Vision Systems' OR 'Computer Vision System' OR 'System, Computer Vision' OR 'Systems, Computer Vision' OR 'Vision System, Computer' OR 'Vision Systems, Computer' OR 'Knowledge Acquisition (Computer)' OR 'Acquisition, Knowledge (Computer)' OR 'Knowledge Representation (Computer)' OR 'Knowledge Representations (Computer)' OR 'Representation, Knowledge (Computer)'
#4	#1 AND #2 (population) AND #3 (intervention)