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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.

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.

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

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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