Abstract

Background: Chronic wounds are an increasing problem in the aging population, patients experience a lower health-related quality of life and the care for these patients is associated with high costs. Thorough wound assessments facilitate objective monitoring of wound status and progress. A wound assessment tool can guide clinicians in these wound assessments and in recording wound progress or deterioration.

Objective: Systematically identify assessment tools for chronic wounds, investigate their measurement properties, and summarize the data per assessment tool.

Design: Systematic review

Methods: The databases Medline (PubMed interface), Embase, CINAHL, and CENTRAL were systematically searched until May 2020 (updated in February 2021). Studies reporting the development and/or the evaluation of measurement properties of assessment tools for chronic wounds were included. The “Consensus-based Standards for the selection of health Measurement Instruments” risk of Bias checklist was applied to evaluate the methodological quality of the included studies. Each reported measurement property was rated against criteria for good measurement properties. The evidence was summarized and the quality of the evidence was graded using a modified Grades of Recommendation, Assessment, Development, and Evaluation approach. Study selection, data extraction and quality appraisal were conducted independently by two reviewers and double-checked by a third reviewer.

Results: Twenty-seven studies describing the measurement properties of fourteen assessment tools for chronic wounds were included. None of the studies reported a content validity evaluation by a relevance study or a comprehensiveness study in professionals. Six articles reported the development or revision of an existing assessment tool. The reported measurement properties included: structural validity (5 studies), reliability (18 studies), hypotheses testing for construct validity (18 studies) and responsiveness (7 studies). Internal consistency, cross-cultural validity / measurement invariance and measurement error were not reported. If criterion validity was assessed, the results were allocated to hypotheses testing for construct validity as no ‘gold standard’ is available.

Conclusions: Fourteen assessment tools for chronic wounds were identified. Construct validity (by hypotheses testing) and responsiveness of the Pressure Ulcer Scale for Healing version 3.0 were supported by sufficient ratings based on moderate to high level quality of

evidence. Reliability of the (Revised) Photographic Wound Assessment Tool had a sufficient rating based on moderate quality of evidence. The ratings of the measurement properties of the other wound assessment tools were either insufficient or indeterminate, or a sufficient result was supported by low to very low quality of evidence.

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Tweetable abstract:

"A systematic review giving a clear overview of the measurement properties of available assessment tools for chronic wounds."

Contribution of the paper

What is already known about the topic?

- Healthcare professionals are challenged with managing a variety of wounds and a wound assessment tool can guide the clinician in wound assessment and in recording wound progress or deterioration.
- There is a lack of consensus regarding the key elements needed to conduct a comprehensive wound assessment.

What this paper adds

- Twenty-seven papers containing fourteen instruments for the assessment of chronic wounds were included and examined for their measurement properties.
- The construct validity and responsiveness of the Pressure Ulcer Scale for Healing (PUSH) version 3.0 and the reliability of the (revised) Photographic Wound Assessment Tool (PWAT and revPWAT) have adequate ratings based on moderate to high quality evidence.
- Most measurement properties of available assessment tools for chronic wounds have indeterminate or inadequate ratings and are based on low to very low quality evidence.

Keywords

Chronic wound, Decision support systems, Foot ulcer, Leg ulcer, Measurement properties, Pressure ulcer, Systematic review, Reliability, Validity

Background

Chronic wounds are defined as wounds that fail to proceed through the normal phases of wound healing in an orderly and timely manner. (1) The most common chronic wounds are vascular ulcers (venous, arterial or mixed leg ulcers), diabetic ulcers, and pressure ulcers (PU). (1) Chronic wounds are an increasing problem in the aging population. In 2017, 570 million people were diagnosed with a wound in 195 countries. (2) The prevalence of chronic wounds is estimated at between 1% and 2% in high-income countries and is expected to rise due to the increase in obesity, diabetes mellitus and auto-immune diseases. (3, 4) For example, 463 million people or 1 in 11 adults worldwide had in 2020 diabetes. The International Diabetes Federation calculated that there would be 578 million adults with diabetes by 2030 and 700 million by 2045. (5) The risk for an adult with diabetes to develop a diabetic foot ulcer (DFU) during his lifetime is 25% and it is estimated that every 30 seconds a limb is lost due to diabetes. (6) On average chronic leg and foot ulcers take 12 to 13 months to heal and recur in up to 70% of the patients. (1)

The care of patients with chronic wounds is associated with high costs. It is reported that in high-income countries, between 2-4% of the total healthcare budget are spent on chronic wound care. (1, 7) The average cost of treating a chronic wound in Europe is between 6000 and 10000 euro per year. (7)

Chronic wounds can be associated with chronic pain, odor, changes in self-image, limited activity and sleep problems. Depression is a very common comorbidity in patients with chronic wounds and at least 30% of these patients suffer from depressive symptoms or anxiety. These symptoms lead to a lower health-related quality of life. (8) A cross-sectional study by Yan et al. found that health-related quality of life was poor in hospitalized patients with chronic wounds. (9)

Many patients do not have access to clinicians with both wound care expertise and specialist knowledge. Data supporting this are available from the Czech Republic, Belgium, Italy, Portugal, Sweden and the United Kingdom. (2) Healthcare professionals are challenged with managing a variety of wounds with complex aetiologies and multiple potential treatment options. Yet, they do not necessarily feel confident in designing a wound care management plan. (10, 11) The knowledge level has also been found to be suboptimal yet treatment options are evolving rapidly. (11) This leads to variations in wound management in clinical practice. The Burden of Wounds Study in the United Kingdom identified that 25% of patients with chronic wounds did not have a differential diagnosis, indicative of the challenges non-specialist clinicians experience with holistic wound assessments. Although the primary reason for consultation was not necessarily wound-related, only half of patients with a wound saw a hospital physician, which may explain the lack of differential diagnoses for chronic wounds. Most patients were primarily seen by clinicians in the community with limited knowledge of wound care. (12, 13)

To assess a patient in a holistic way, a comprehensive and systematic wound assessment is a necessity. Thorough wound assessment facilitates objective monitoring of the status and progress of the wound. (14)

In 2017 Coleman et al. published a generic wound care assessment minimum data set, including wound assessment parameters. (15) However no guidance or suggestions on how to measure these wound parameters were described. A wound assessment tool can guide the clinician in wound assessment and in recording wound progression or deterioration. (2) Using a wound assessment tool will result in a score or numeric value that illustrates a clinical change. (14)
Wound assessment tools consider factors that are related to the wound and the surrounding skin but there are many variations in the included parameters. This suggests a lack of consensus regarding the key elements of a comprehensive wound assessment. (2) By identifying and examining the measurement properties (validity, reliability and responsiveness) of the available assessment tools for chronic wounds, we try to define the ability of the tool to evaluate wound evolution and support (non-expert) clinicians in using the right tool for the right purpose. (14)

Aims

Wound assessment is a critical aspect in wound management. The aim of this systematic review was:

1. To systematically identify assessment tools for chronic wounds
2. To examine their measurement properties and to summarize the data per assessment tool

Methods

Design

This systematic review was conducted in accordance with the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) guideline for systematic reviews of patient-reported outcome measures (16) and consisted of a sequential ten-step process as shown in Figure 1. Although this procedure was originally developed for systematic reviews of patient-reported outcome measures (PROMs), it can also be used for other types of health-related measurement tools, such as physician-reported outcome measures or assessment tools. (16) The protocol for this review was developed in accordance with the process developed at Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist (17) and has been registered in the PROSPERO International Prospective Register of Systematic Reviews (ID: CRD42020183920). (18)

147

148 **Search Methods**

149 A scoping review was performed to get an overview of the already existing literature. Key
150 articles were used to further delineate and define the research question and the eligibility
151 criteria. The following electronic databases were systematically searched until May 13th
152 2020: MEDLINE (PubMed interface), EMBASE, CINAHL (EBSCO interface), and CENTRAL.
153 On February 5th 2021, an update was conducted to check for additional potential articles. No
154 time limits or language restrictions were applied during the screening phase. The search was
155 conducted by the first author and supported by a librarian technician specialised in medical
156 databases.
157 The search strategy, structured by PICO, consisted of search terms including indexing terms
158 and free text words for the concepts 'chronic wounds', 'assessment tools' and 'measurement
159 properties'. Search terms of the same concept were combined using the Boolean operator
160 OR. The concepts were combined using the Boolean operator AND. For the 'measurement
161 properties' concept, the sensitive search filter as developed by Terwee et al. (2009) was
162 applied (19). A filter of search terms related to pressure ulcer prevention and risk assessment
163 was applied to narrow the results. Supplemental material table 1 shows the full search
164 strategy for MEDLINE (PubMed interface), which was later adapted for the other databases.
165

166 **Study Selection**

167 Results of database searches were imported into the reference manager software EndNote
168 X9.3.3 (Clarivate Analytics, Philadelphia, PA). Duplicates were removed via the duplicate
169 search function and a manual check of the duplicate list. Articles were screened
170 independently by two reviewers using the screening software Rayyan. (20) Reasons for
171 exclusion were specified. Disagreement or doubt was resolved by consensus and if
172 consensus could not be reached, a full-text screening was conducted and a third reviewer
173 was consulted. The full texts of the remaining articles were individually assessed for eligibility
174 by two reviewers. Any doubts were resolved by a third reviewer. Articles were excluded if the
175 full text was not available in English, Dutch, German, French or Spanish. Additional relevant
176 studies were identified by cited and citing references of included studies via Google Scholar
177 and MEDLINE (PubMed Interface). Studies were included if they reported the development
178 and/or the evaluation of one or more measurement properties (e.g., content validity, reliability,
179 responsiveness) of an assessment tool for chronic wounds. The assessment of vascular
180 ulcers, diabetic ulcers, and pressure ulcers were included since they are the most common
181 types of chronic wounds. There was no exclusion for age, geographical location, healthcare
182 setting, ethnicity, or skin colour. Studies that only investigated the predictive validity, reviews,
183 discussion papers, letters, comments, and editorials were excluded.
184

Data extraction

Data from included studies were extracted independently by two reviewers using standardised data extraction tables and double-checked by a third reviewer. The extracted data contained: the authors, year of publication, tool development, sample characteristics of raters (sample size, gender, mean age (SD), role / function), tool administration (mode of administration, sample characteristics of patients, country, language) and the reported measurement properties. Data extraction tables are available as supplementary material. For two studies, the information was unclear or incomplete and the corresponding authors were contacted to provide additional details. The information provided by them had no impact on the inclusion / exclusion of studies. The assessment tools were summarized in Table 2 to include the wound types that were investigated and the wound parameters.

Quality appraisal

The quality assessment was performed independently by two reviewers and double-checked by a third reviewer. The methodological quality was assessed using the COSMIN Risk of Bias checklist. (21) The quality of each single study on a measurement property was rated as very good (V), adequate (A), doubtful (D), or inadequate (I). The level of measurement of the assessment tools included was at a ratio level. If statistical tests were not aligned to this level of measurement (e.g., Cohen's kappa), the assessment was downgraded. The methodological quality assessment of studies examining content validity consisted of the evaluation of a relevance study and a comprehensiveness study in professionals. In agreement with the latest revision of the COSMIN methodology, all studies were considered and not only those of very good or adequate quality. (22) The result of each study on a measurement property was rated against the updated criteria for good measurement properties according to COSMIN. (16) Each reported measurement property was rated sufficient (+), insufficient (-), or indeterminate (?). If the measurement property “reliability” was assessed by correlation, this was rated as indeterminate (?). If a correlation was used to state a hypothesis, the criteria for good measurement property was $r \geq 0{,}75$.

Data synthesis

Step 1: The measurement properties were qualitatively summarized per assessment tool for chronic wounds. Only the results that had effect on the measurement properties of the tool as a whole, not on subscales or subitems of the tool, were further analysed. The overall result was rated against the criteria for good measurement properties to determine whether the measurement property of the classification system was sufficient (+), insufficient (-), inconsistent (±), or indeterminate (?).To rate the qualitatively summarized results as sufficient or insufficient, 75% of the results should have met the criteria. (16)

Step 2: The summarized quality of the evidence per measurement property, per assessment tool was rated as high, moderate, low, or very low using the modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach proposed by COSMIN. (22) The modified GRADE approach was used to downgrade the quality of evidence when there were concerns about the trustworthiness of the results taking risk of bias, inconsistency, imprecision, and indirectness into account. (16, 22) Table 1 gives an overview of the used definitions of quality levels, defined by COSMIN. (16) Grading was done by two reviewers independently. Disagreements were resolved in consensus.

Results

Search and selection of studies

A total of 6529 records were identified through systematic database searching (2602 in MEDLINE, 2158 in EMBASE, 1040 in CINAHL, and 729 in CENTRAL). After removal of duplicates, title/abstract screening, full-text reviews, and additional searches, twenty-seven studies were included in the review. One publication in the Chinese language was excluded. The PRISMA flow diagram outlining the search and selection process is shown in Figure 2.

Identified assessment tools for chronic wounds

Twenty-seven studies describing fourteen chronic wound assessment tools were identified: Pressure Sore Status Tool (PSST) (23), Bates-Jensen Wound Assessment Tool (BWAT) (24), Diabetic Foot Ulcer Assessment Scale (DFUAS) (25), DMIST-scale (26), Pressure Ulcer Scale for Healing (PUSH) version 2.0 (27), PUSH version 3.0 (28), DESIGN tool (29), DESIGN-R tool (30), Photographic Wound Assessment Tool (PWAT) (31), Revised Photographic Wound Assessment Tool (revPWAT) (32), Sessing Scale (33), CODED score (34), Leg Ulcer Measurement Tool (LUMT) (35) and Spinal Cord Impairment Pressure Ulcer Monitoring Tool (SCI-PUMT) (36). The five most commonly reported wound parameters were size (11x), depth (9x), wound margins (7x), type of necrotic tissue (7x) and amount/proportion of granulation tissue (7x), Further details of the wound parameters per assessment tool are shown in Table 2. The score of the Sessing scale depends on selecting a wound stage that most closely match the observed pressure ulcer. As no individual wound parameters are assessed, the Sessing Scale is not included in Table 2

Pressure Sore Status Tool (PSST) – Bates-Jensen Wound Assessment Tool (BWAT)

Developed in 1990, PSST incorporates thirteen subscale items and each of them are rated on a Likert scale ranging from 1 to 5 to assess the wound status. (23) In 2001, PSST was revised to the Bates-Jensen Wound Assessment Tool (BWAT) and additional tests on

measurement properties were conducted. The subscale items remained the same and the change in name reflected the increased use of the tool for wounds other than pressure ulcers. (24) In a Delphi panel study, content validity was reached by a CVI ≥ 0,78 but no supporting data were reported. (23)

Diabetic Foot Ulcer Assessment Scale (DFUAS) – DMIST-scale

The DFUAS was developed as an assessment tool specifically to assess the status of diabetic foot ulcers over time and to evaluate the effectiveness of wound management. The tool was based on existing scales for diabetic foot ulcers in Japan and Indonesia. Using the nominal group technique, wound care experts extracted the parameters that may develop during wound healing. (25) A new seven-domain diabetic foot assessment scale, called DMIST, was developed after secondary analysis of data by Arisandi et al. (2016). (25) No content validity studies were performed.

Pressure Ulcer Scale for Healing (PUSH)

PUSH (version 2.0) was developed by the National Pressure Ulcer Advisory Panel (NPUAP) Task Force in 1997. They identified the need for a precise and practical method of monitoring wound healing by evaluation of known instruments at that time (Shea Scale, Sussman Wound Healing Tool, Sessing Scale, Pressure Sore Status Tool, and the Wound Healing Scale). (27, 37) Following a pilot test in a long-term care facility, changes were made for wound size calculation and the manifestation of necrotic tissue. Additional amendments included: refining of the titles and removing of the weighting factors of each parameter to calculate the total score. As a result, PUSH 2.0 evolved to a new version PUSH 3.0. (28) There was no evaluation in a relevance study or comprehensiveness study in professionals to support content validation. Only the development of PUSH by literature review and expert opinion was briefly mentioned. (27) In 2003, a 25-item survey was made available through the NPUAP website for 4 months. Descriptive analyses and aggregation of the comments to open-ended questions were made, and gave an impression of the strengths and weaknesses of the PUSH tool. (38)

DESIGN tool – DESIGN-Rating (DESIGN-R) tool

DESIGN was developed by the Japanese Society of Pressure ulcers by detecting the need for treatment guidelines to assess pressure ulcer severity and to monitor the healing process. The tool was developed using the nominal group technique, revised after feedback during the Annual Conference of the Japanese Society of Pressure Ulcers and the final version was published in March 2002. The tool was developed to be used in a “remote” clinical setting with the aid of telemedicine. (29) Matsui et al. (2011) (30) detected the inability of DESIGN to compare the wound-healing process among different pressure ulcers in different patients due to a lack of statistical item weighting. The DESIGN-R tool was developed by weighting the

wound parameters of the tool on grading the severity status of the wounds. Zhong et al. (2013) (39) indicated that 14,5% of the raters who conducted the reliability testing, found that the tool was difficult to use.

Photographic Wound Assessment Tool (PWAT) – Revised Photographic Wound Assessment Tool (revPWAT)

PWAT was designed as a modified version of the PSST and included the six parameters of PSST that could be determined from wound photographs. (31) Thompson et al. (2013) (32) published a revision of PWAT, named revPWAT. The criteria assigned to each of the pre-existing parameters were refined and two additional parameters were integrated. The maximum of the total score of PWAT and revPWAT was respectively 24 and 32 and the title and description of both tools became vastly divergent, which made it impossible to summarize the results of both studies.

Various wound assessment tools reported in a single publication

Ferrel et al. (1995) (33) published the Sessing Scale, including seven wound stages. The scale was scored by calculating the change in numerical values over successive wound assessments over time.

Emperanza et al. (2000) (34) designed a pressure ulcer severity score based on assessment by experienced clinicians, named CODED.

The Leg Ulcer Measurement Tool (LUMT) is an evaluation tool designed to assess leg ulcer status and change over time. (34) Content validity was investigated by checking the feasibility of the tool, followed by a consensus study.

Two expert panels developed a 30-item tool, including new items and items from PUSH and BWAT, called the Spinal Cord Impairement Pressure Ulcer Monitoring Tool (SCI-PUMT). (36) No content validity measurement data were reported.

Study characteristics

The studies were published in English between 1992 and 2020 and conducted in the USA (n=11), Canada (n=4), Japan (n=3), Indonesia (n=3), Brazil (n=2), Hong Kong (n=1), Spain (n=1), China (n=1) and Turkey (n=1). None of the studies reported content validity evaluation using the principles of COSMIN. (22) Six articles reported the development or revision of an existing assessment tool. The reported measurement properties included: structural validity (5 studies), reliability (18 studies), hypotheses testing for construct validity (18 studies) and responsiveness (7 studies). Internal consistency, cross-cultural validity / measurement invariance and measurement error were not assessed. If criterion validity was assessed, the results were allocated to hypotheses testing for construct validity. Criterion validity was not assessed as no ‘gold standard’ is available. In six studies, the assessment of the wound was based only on photographs. If this had an impact on the quality of the study, the ratings of the

involved measurement properties were adapted. The detailed characteristics of the included studies and the reported measurement properties can be reviewed in Supplemental Material Table 2.

Summarized quality of evidence per assessment tool

Measurement properties were examined for different assessment tools in separate studies and pooling of data was not possible due to heterogeneity in designs, samples, tools, settings, etc. The results per measurement property per assessment tool were qualitatively summarized and the measurement properties of each tool were assessed, and accompanied by the information on the quality of evidence. A summary of the results is presented in Table 3.

Pressure Sore Status Tool (PSST) – Bates-Jensen Wound Assessment Tool (BWAT)

Structural validity of PSST was calculated by a preliminary factor analysis which led to an insufficient (-) result of very low quality. Reliability testing was described in three publications, but no Intraclass Correlation Coefficients (ICC) were calculated, only correlations, which led to indeterminate (?) results. (23, 24, 40) Only in the validation study of BWAT in 2019 (24), the ICC of the total score interrater reliability was 0,58, which was an insufficient (-) result. Some hypotheses for construct validity were tested, based on the differences in total score between groups with different pressure ulcer stages. With R-values >0,55 and significant differences between the subgroups (24, 41), these results are insufficient and indeterminate to draw conclusions.

Diabetic Foot Ulcer Assessment Scale (DFUAS) – DMIST-scale

Interrater reliability of DFUAS was evaluated by two studies but the quality of evidence was very low. (25, 42) In the study of Oe et al. (2020) (26), the calculated ICC for the total DMIST score was 0,91 but the methodological quality was very low. Correlations between the total score of DFUAS or DMIST with other wound assessment tools (BWAT, PUSH, DESIGN) were > 0,75, which means sufficient (+), but the quality of evidence was very low.

Pressure Ulcer Scale for Healing (PUSH)

Structural validity was evaluated for both versions using a principal component analysis. This analysis provided evidence to support that the variables “surface area”, “exudate amount” and “surface appearance”, also named “tissue type” in version 3.0, provided the best model of healing and explained between 39% and 74% of the variation over time. (27, 28, 37) Though the quality of the evidence was moderate, the results did not meet the criteria for good measurement properties for structural validity by COSMIN and were scored indeterminate (?).

Reliability of PUSH 3.0 was evaluated in four studies (43-46) but no strong conclusion was made because correlations or Kappa instead of ICC were calculated. The summarized indeterminate (?) result was of low quality.

To evaluate construct validity, pairwise comparisons of observations between time periods (weeks) were made by Thomas et al. (1997) (27) and Stotts et al. (2001). (28) Significant differences were measured but not consistently, especially when smaller wounds were observed. Other studies divided the patients in groups with healed and unhealed ulcers to detect significant differences, resulting in sufficient data. (46-48) In the study of Gardner et al. (2005) (46), the correlation between PUSH 3.0 and PSST was ≥ 0,72. The summarized result of construct validity of PUSH 3.0 was sufficient with moderate quality of evidence.

The responsiveness of PUSH 3.0 was investigated in two studies by a repeated measures analysis. (46, 47) Additionally, Hon et al. (2010) and Choi et al. (2016) (44, 48) calculated responsiveness by the effect size (ES) and standardized response mean (SRM) while Gardner et al. (2011) (49) used the principle of a piecewise linear regression. The overall rating of responsiveness of PUSH 3.0 was sufficient, based on high quality evidence.

DESIGN tool – DESIGN-Rating (DESIGN-R) tool

One study evaluated the reliability and construct validity of DESIGN (29) and one study did similar tests for DESIGN-R. (39) The result rating was mostly sufficient (+) but the quality of evidence was very low.

Photographic Wound Assessment Tool (PWAT) – Revised Photographic Wound Assessment Tool (revPWAT)

Reliability was tested in both studies by intra- and interrater reliability and additionally by a test-retest for revPWAT. All ratings were sufficient, with a moderate level of quality. In the study of Houghton et al. (2000) (31) however, the interrater reliability by inexperienced students resulted in an ICC between 0,34 (for venous leg ulcers) and 0,58 (for pressure ulcers).

Construct validity was evaluated by comparing the PWAT score by the PSST score for full bedside assessment, resulting in a 0,7 correlation. The construct validity of revPWAT was rated sufficient (+) but with a low to very low evidence level if considering the agreement between bedside assessment and photographs (1) and between photographs taken by a clinician, or photographs taken by a professional medical photographer (2).

Responsiveness of PWAT was calculated by the change in score for healing ulcers and non-healing ulcers, resulting in a non-significant difference between the groups. The level of evidence was very low.

Various wound assessment tools reported in a single publication

The sufficient (+) reliability and indeterminate (?) construct validity results of the Sessing Scale are based on a very low quality of evidence. (33)

Reliability of CODED was evaluated by Bland Altman analysis to assess agreement, which led to indeterminate (?) results, and the CODED-score was correlated positively with a subjective mean of severity of the wound to assess construct validity. (34) These results are based on very low quality research.

The Leg Ulcer Measurement Tool was evaluated in a sample of 19 patients with a chronic leg ulcer. (35) This small sample size additionally downgraded the level of quality by two, which led to very low quality results for reliability (+), construct validity by hypotheses testing (-) and responsiveness (+).

Using an exploratory factor analysis, a set of seven items was selected for inclusion in the Spinal Cord Impairment Pressure Ulcer Monitoring Tool (SCI-PUMT). (36) This result is rated as indeterminate (?) because not all information, as stated by the criteria for good measurement properties, were provided. The inter- and intra-rater reliability were sufficient, based on low quality evidence. Construct validity was rated by the R^2 statistic, which indicated that the variance of pressure ulcer volume, PUSH score and BWAT-score could be explained by the SCI-PUMT score. Yet no hypotheses were stated and the doubtful quality of the study resulted in an indeterminate (?) result of low quality for the construct validity of SCI-PUMT.

Discussion

The aim of this review was to systematically identify assessment tools for chronic wounds and to examine their measurement properties. The results indicated that twenty-seven studies describe the measurement properties of fourteen assessment tools for chronic wounds. None of the the tools were supported by content validity, identified by a relevance study and a comprehensiveness study in professionals, in any article. Content validity was only briefly mentioned in the study of Bates-Jensen in 1992 as a mean overall content of validity index of 0,9. (23)). Sufficient (+) ratings, combined with moderate to high quality of evidence, were only available for construct validity and responsiveness of PUSH 3.0 and for reliability of the (Revised) Photographic Wound Assessment Tool (PWAT and revPWAT).

In 2017, Coleman et al. published a generic wound care assessment minimum data set, including wound assessment parameters.(15) No guidance or suggestions on how to measure these wound parameters were described. By checking the design and the measurement properties (validity, reliability and responsiveness) of available chronic wound assessment tools by a systematic review, we tried to define the ability of the tool to evaluate

wound evolution and support (non-expert) clinicians in using the right tool for the right purpose.(14)

The evaluation of the measurement properties of fourteen assessment tools for chronic wounds indicated that the research per assessment tool was limited and that the conclusions resulted from low quality research. Patient samples were small and non-random techniques were applied for sampling. Inclusion was limited to a specific type of chronic wound (e.g. pressure ulcers, venous leg ulcers, diabetic foot ulcers), only the studies of Hon et al. (2010) (48), Choi et al. (2016) (44) and Thompson et al. (2013) (32) included patients with all types of chronic wounds during sampling. In many studies, information about the raters was not provided. By the lack of an appropriate 'gold standard' to assess and measure wound healing, concurrent measures such as wound area and ulcer classifications were used to assess construct validity. But these separate measures seemed to be inappropriate for the monitoring of wound evolution.

The quality of evidence for reliability and construct validity of BWAT - and for structural validity, construct validity and responsiveness of PUSH 3.0 - was moderate to high. Despite this high level of evidence, the rating of the results was indeterminate (?), as in many of the other assessment tools. These indeterminate (?) ratings for reliability can be explained by the lack of reporting of ICC or weighted kappa. The indeterminate (?) results for construct validity for the different tools can be explained by the lack of an actual hypothesis formulation or by stating significant differences between groups without clarifying if these differences can also be interpreted as valid differences or differences that are relevant for clinical practice.

By analysing the summarized results of all assessment tools, it can be concluded that only the measurement properties of PUSH 3.0 have sufficient ratings, based on low to high level evidence, for construct validity and as well for responsiveness.
The studies of Houghton et al. (2000) (31) and Thompson et al. (2013) (32) resulted in a sufficient (+) rating for the reliability of PWAT and revPWAT, based on a moderate quality of evidence by one study. The structural validity (?), reliability (+) and construct validity (?) of SCI-PUMT, based on one study, resulted in low to moderate quality of evidence ratings. The ratings of the measurement properties of the other assessment tools are all based on very low quality evidence.

If clinicians interpret and implement the results of this study, they have to consider the following aspects:
- The detected wound assessment tools serve the main purpose to evaluate wound improvement or deterioration. The tools are not intended to predict wound healing and should not be used for this purpose.
- Only the Pressure Ulcer Scale for Healing (PUSH) version 3.0 and the (revised)

Photographic Wound Assessment Tool ((rev)PWAT) are tested for all common types of chronic wounds. Combined with the available evidence, these tools can be recommended for evaluation of the status of chronic wounds in clinical practice. Other tools should be used with caution if used for other types of chronic wounds than described in the studies.
- Clinicians have to consider the feasibility to implement a wound assessment tool in clinical practice and the possibility to collect the data for each wound parameter in a correct manner. New technologies (e.g. image recognition, smart bandages, digital wound registration systems) can support a more consistent data collection of different wound parameters over time, and in different healthcare settings.

Future studies are needed to comprehensively validate the available assessment tools for chronic wounds. Such studies should focus on using correct statistics for each investigated measurement property, including appropriately determined sample sizes of real-life observations of chronic wounds, conducted by multiple raters and across multiple settings to allow the generalisability of the results. An increased uniformity in the definition and interpretation of wound parameters could help to evolve to one or two assessment tools for chronic wounds, which then can be validated in a uniform way within different healthcare settings.

Limitations

A quantitative pooling of the results was not possible because of the methodological variation between studies and the different statistical approaches that were used.

Conclusions

Fourteen assessment tools for chronic wounds were identified. Construct validity (by hypotheses testing) and responsiveness of the Pressure Ulcer Scale for Healing (PUSH) version 3.0 were supported by sufficient ratings, based on moderate to high level quality of evidence. Reliability of the Photographic Wound Assessment Tool (PWAT) and the Revised PWAT (revPWAT) had a sufficient rating, based on moderate quality of evidence. The ratings of the measurement properties of the other wound assessment tools were either insufficient or indeterminate, or a sufficient result was supported by low to very low quality of evidence. More well-designed, rigorously conducted and adequately reported studies should validate these instruments where gaps still exist.

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Conflict of interest

None

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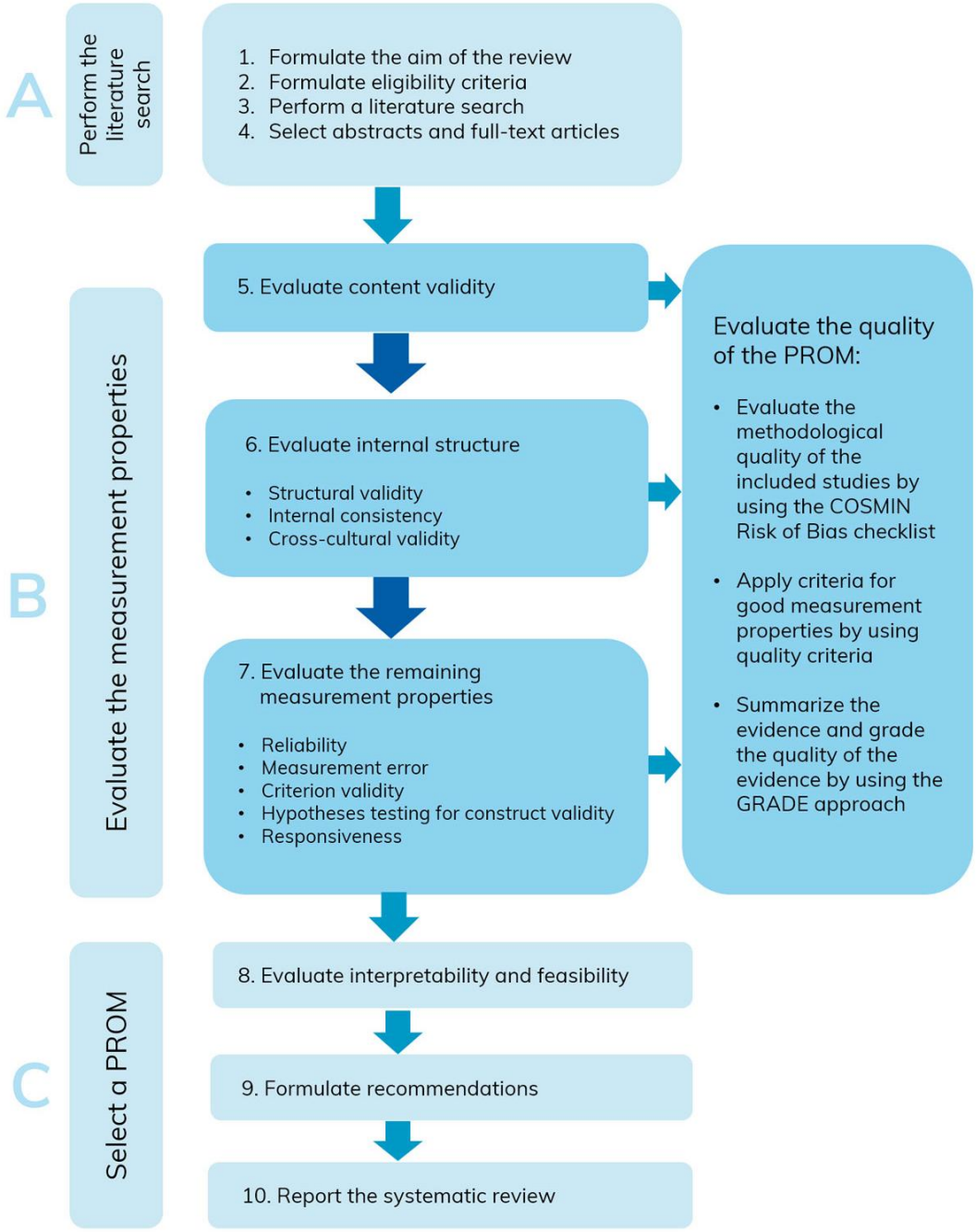
Figures

Figure 1: Sequential ten steps process for conducting a systematic review of Patient-Reported Outcome Measures by the Consensus-based Standards for the selection of health Measurement Instruments. (16)



677 Figure 2: Flowchart of study selection according to PRISMA
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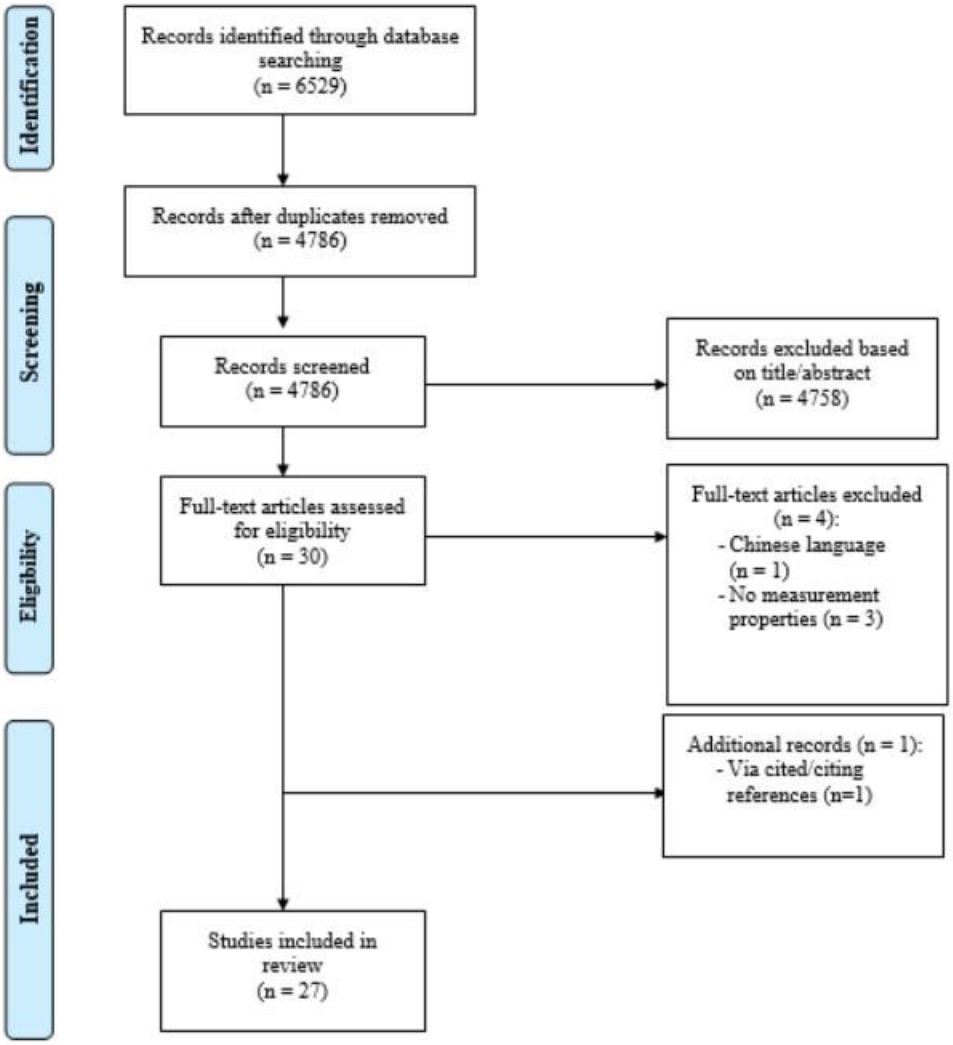

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Tables

Table 1: Definitions of quality levels, extracted from the Consensus-based Standards for the selection of health Measurement Instruments guideline (16)

Quality level	Definition
High	We are very confident that the true measurement property lies close to that of the estimate* of the measurement property
Moderate	We are moderately confident in the measurement property estimate: the true measurement property is likely to be close to the estimate of the measurement property, but there is a possibility that it is substantially different
Low	Our confidence in the measurement property estimate is limited: the true measurement property may be substantially different from the estimate of the measurement property
Very low	We have very little confidence in the measurement property estimate: the true measurement property is likely to be substantially different from the estimate of the measurement property

* Estimate of the measurement property refers to the summarized result of the measurement property of the wound assessment tool

689 Table 2: Investigated wound types, registered wound parameters and maximum score per assessment tool for chronic wounds

	PSST - BWAT	DFUAS	DMIST -scale	PUSH 2.0	PUSH 3.0	DESIGN -tool	DESIGN -R tool	PWAT	Rev PWAT	CODED	LUMT	SCI-PUMT	
Investigated wound types	PU	DFU	DFU	PU	PU, DFU, VLU	PU	PU	PU, VU	PU, VU, DFU, acute wounds	PU	Chronic leg ulcers	PU	
Wound parameters (maximum score per tool)													**X-times reported in tools**
Size	5	9	9	10	10	6	15	//	4	Diameter (cm)/5	4	10	11x
Depth	5	4	5	//	//	5	5	//	4	4	4	4	9x
Wound edges	5	5	4	//	//	//	//	4	4	//	4	2	7x
Necrotic tissue type	5	3	//	//	//	2	6	4	4	//	4	//	7x
Granulation tissue amount // proportion	5	5	//	//	//	5	6	4	4	//	4	///	7x
Necrotic tissue amount /// proportion	5	5	//	//	/	/	/	4	4	//	4	2	6x

	PSST - BWAT	DFUAS	DMIST -scale	PUSH 2.0	PUSH 3.0	DESIGN -tool	DESIGN -R tool	PWAT	Rev PWAT	CODED	LUMT	SCI-PUMT	
Investigated wound types	PU	DFU	DFU	PU	PU, DFU, VLU	PU	PU	PU, VU	PU, VU, DFU, acute wounds	PU	Chronic leg ulcers	PU	
Wound parameters (maximum score per tool)													**X-times reported in tools**
Exudate amount	5	//	//	12	3	3	6	//	//	//	4	//	6x
Inflammation / infection / bioburden	//	5	5	/	/	3	9	//	//	//	4	//	5x
Undermining	5	//	//	//	//	//	//	//	//	//	4	3	3x
Tissue type	//	//	4	12	4	//	//	//	//	//	//	//	3x
Exudate type	5	//	//	//	//	//	//	//	//	//	4	2	3x
Maceration	//	3	3	//	//	//	//	//	//	//	//	//	2x
Tunneling	//	4	//	//	//	//	//	//	//	//	//	3	2x

	PSST - BWAT	DFUAS	DMIST -scale	PUSH 2.0	PUSH 3.0	DESIGN -tool	DESIGN -R tool	PWAT	Rev PWAT	CODED	LUMT	SCI-PUMT	
Investigated wound types	PU	DFU	DFU	PU	PU, DFU, VLU	PU	PU	PU, VU	PU, VU, DFU, acute wounds	PU	Chronic leg ulcers	PU	
Wound parameters (maximum score per tool)													**X-times reported in tools**
Pocket	//	//	//	//	//	4	24	//	//	//	//	//	2x
Skin color surrounding wound	5	//	//	//	//	//	//	4	//	//	//	//	2x
Periulcer skin viability	//	//	//	//	//	//	//	//	4	//	4	//	2x
Granulation tissue type	//	//	//	//	//	//	//	//	4	//	4	//	2x
Epithelialization	5	//	//	//	//	//	//	4	//	//	//	//	2x
Size scores foot / toe	//	50	//	//	//	//	//	//	//	//	//	//	1x
Tunneling or undermining	//	//	4	//	//	//	//	//	//	//	//	//	1x

	PSST - BWAT	DFUAS	DMIST -scale	PUSH 2.0	PUSH 3.0	DESIGN -tool	DESIGN -R tool	PWAT	Rev PWAT	CODED	LUMT	SCI-PUMT	
Investigated wound types	PU	DFU	DFU	PU	PU, DFU, VLU	PU	PU	PU, VU	PU, VU, DFU, acute wounds	PU	Chronic leg ulcers	PU	
Wound parameters (maximum score per tool)													**X-times reported in tools**
Color	//	//	//	//	//	//	//	//	//	2	//	//	1x
Slough proportion	//	5	//	//	//	//	//	//	//	//	//	//	1x
Peripheral tissue edema	5	//	//	//	//	//	//	//	//	//	//	//	1x
Peripheral tissue induration	5	//	//	//	//	//	//	//	//	//	//	//	1x
Leg edema type	//	//	//	//	//	//	//	//	//	//	4	//	1x
Leg edema location	//	//	//	//	//	//	//	//	//	//	4	//	1x
Max. score per wound assessment tool	65	98	34	34	17	28	71	24	32	N/A	56	26	

690 **Abbreviations:**

DFU: diabetic foot ulcers
PU: pressure ulcers
VU: vascular ulcers
VLU: venous leg ulcers
N/A: Not applicable
PSST: Pressure Sore Status Tool
BWAT: Bates-Jensen Wound Assessment Tool
DFUAS: Diabetic Foot Ulcer Assessment Scale
PUSH: Pressure Ulcer Scale for Healing
(rev)PWAT: (revised) Photographic Wound Assessment Tool
LUMT: Leg Ulcer Measurement Tool
SCI-PUMT: Spinal Cord Impairment Pressure Ulcer Monitoring Tool
//: wound parameter not mentioned/assessed

704 Table 3: Methodological quality of the included studies and ratings of measurement properties of assessment tools for chronic wounds
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Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
Pressure Sore Status Tool (PSST)	Bates-Jensen et al. (1992)	English / USA	N/I	N/I	N/I	20 (PU)	I	?	N/I	N/I	N/I	N/I	N/I	N/I
	Bates-Jensen et al. (1995)	English / USA	N/I	N/I	N/I	16 (PU)	D	?	N/I	N/I	N/I	N/I	N/I	N/I
	Bates-Jensen et al. (1997)	English / USA	113 (PU)	I	-	N/P	N/I	N/I	496 (PU)	I	-	N/I	N/I	N/I
Bates-Jensen Wound Assessment Tool (BWAT)	Bates-Jensen et al. (2019)	English / USA	N/I	N/I	N/I	270 (PU)	A / A	? / -	270 (PU)	V	?	N/I	N/I	N/I
Overall rating / quality of evidence	*//*	*//*	*//*	***Very low***	**-**	*//*	***Moderate***	***?***	*//*	***High***	***?***	***N/I***	***N/I***	***N/I***
Diabetic Foot Ulcer Assessment Scale (DFUAS)	Arisandi et al. (2016)	? / Indonesia	N/I	N/I	N/I	10 (DFU)	I	+	70 (DFU)	I	+ / ?	N/I	N/I	N/I
	Haeruddin et al. (2020)	Bahasa / Indonesia	N/I	N/I	N/I	18 (DFU)	I	?	N/I	N/I	N/I	N/I	N/I	N/I

Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
Overall rating / quality of evidence	***//***	***//***	***N/I***	***N/I***	***N/I***	***//***	***Very low***	***?***	***//***	***Very low***	***?***	***N/I***	***N/I***	***N/I***
DMIST-scale	Oe et al. (2020)	? / Japan and Indonesia	N/I	N/I	N/I	153 (DFU)	I	+	153 (DFU)	I	+ / ?	N/I	N/I	N/I
Overall rating / quality of evidence			**N/I**	**N/I**	**N/I**	**N/I**	***Very low***	**+**		***Very low***	***?***	**N/I**	**N/I**	**N/I**
Pressure Ulcer Scale for Healing (PUSH) version 2.0	Thomas DR et al. (1997) / Bartolucci AA, Thomas DR (1997)	English / USA	47 (PU)	D	-	N/I	N/I	N/I	37 (PU)	D	?	N/I	N/I	N/I
	Stotts et al. (2001)	English / USA	103 (PU)	A	?	N/I	N/I	N/I	103 (PU)	D	?	N/I	N/I	N/I
Overall rating / quality of evidence	***//***	***//***	***//***	***Moderate***	***?***	***N/I***	***N/I***	***N/I***	***//***	***Moderate***	***?***	***N/I***	***N/I***	***N/I***
Pressure Ulcer Scale for Healing	Stotts et al. (2001)	English USA	269 (PU)	A	?	N/I	N/I	N/I	269 (PU)	D	?	N/I	N/I	N/I

Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
(PUSH) version 3.0	Gardner et al. (2005)	English / USA	N/I	N/I	N/I	N/I	N/I	N/I	32 (PU)	A / A	+ / +	32 (PU)	A	+
	Santos et al. (2007)	Portuguese / Brazil	N/I	N/I	N/I	41 (Chronic leg ulc.)	I	?	N/I	N/I	N/I	N/I	N/I	N/I
	Günes et al. (2009)	Turkish / Turkey	N/I	N/I	N/I	N/I	N/I	N/I	86 (PU)	D	+	86 (PU)	A	+
	Hon et al. (2010)	English / Canada	N/I	N/I	N/I	N/I	N/I	N/I	98 (chronic wounds)	I / A	+ / +	98 (chronic wounds)	V	+
	Gardner et al. (2011)	English / USA	N/I	N/I	N/I	18 (DFU)	D	?	N/I	N/I	N/I	18 (DFU)	I	?
	Choi et al. (2016)	? / Hong Kong	N/I	N/I	N/I	541 (acute and chronic wounds)	I	?	N/I	N/I	N/I	541 (acute and chronic wounds)	I	+
	Alves et al. (2018)	Portuguese / Brazil	N/I	N/I	N/I	35 (VLU)	D	+	N/I	N/I	N/I	N/I	N/I	N/I

Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
Overall rating / quality of evidence	*//*	*//*	*//*	***Moderate***	***?***	*//*	***Low***	***?***	*//*	***Moderate***	**+**	*//*	***High***	+
DESIGN-tool	Sanada et al. (2004)	? / Japan	N/I	N/I	N/I	14 (PU)	I	?	8 (PU)	I	+	N/I	N/I	N/I
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Very low***	***?***	*//*	***Very low***	**+**	**N/I**	**N/I**	**N/I**
DESIGN-R tool	Zhong et al. (2013)	Chinese / China	N/I	N/I	N/I	8 (PU)	I	+	8 (PU)	D	+	N/I	N/I	N/I
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Very low***	**+**	*//*	***Very low***	**+**	**N/I**	**N/I**	**N/I**
Photographic Wound Assessment Tool (PWAT)	Houghton et al. (2000)	English / Canada	N/I	N/I	N/I	137 (PU + vascular ulcers)	A / A	+/ +	46 (PU + vascular ulcers)	D	+	38 (PU + vascular ulcers)	I	-
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Moderate***	**+**	*//*	***Very low***	**+**	*//*	***Very low***	**-**
Revised Photographic Wound Assessment	Thompson et al. (2013)	English / Canada	N/I	N/I	N/I	95 (chronic wounds)	V / V/ V	+ / + / +	95 (chronic wounds)	D / D	+ / +	N/I	N/I	N/I

Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
Tool (revPWAT)														
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Moderate***	**+**	*//*	***Low***	**+**	**N/I**	**N/I**	**N/I**
Sessing Scale	Ferrel et al. (1995)	English / USA	N/I	N/I	N/I	50 (PU)	I	+	84 (PU)	I	?	N/I	N/I	N/I
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**		***Very low***	**+**		***Very low***	***?***	**N/I**	**N/I**	**N/I**
CODED	Emperanza et al. (2000)	? / Spain	N/I	N/I	N/I	10 (PU)	I	?	50 (PU)	I	+	N/I	N/I	N/I
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Very low***	***?***	*//*	***Very low***	**+**	**N/I**	**N/I**	**N/I**
Leg Ulcer Measurement Tool (LUMT)	Woodbury et al. (2004)	English / Canada	N/I	N/I	N/I	19 (chronic leg ulcers)	A	+	19 (chronic leg ulcers)	I	-	19 (chronic leg ulcers)	I	+
Overall rating / quality of evidence	*//*	*//*	**N/I**	**N/I**	**N/I**	*//*	***Very low***	**+**		***Very low***	*//*	*//*	***Very low***	**+**

Assessment tool	Author (Year)	Language / country	Structural validity			Reliability			Construct validity by hypothesis testing			Responsiveness		
			n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating	n	Meth. qual.	Result rating
Spinal Cord Impairment Pressure Ulcer Monitoring Tool (SCI-PUMT)	Thomason et al. (2014)	English / USA	167 (PU)	A	?	167 (PU)	D	+	167 (PU)	D	?	N/I	N/I	N/I
Overall rating / quality of evidence	//	//	//	**Moderate**	**?**	//	**Low**	**+**	//	**Low**	**?**	**N/I**	**N/I**	**N/I**

V: Very good, A: Adequate, D: Doubtful, I: Inadequate
+: Sufficient, -: Insufficient, ?: Indeterminate, ±: Inconsistent
N/I: Not Investigated
PU: pressure ulcers, VLU: venous leg ulcers, DFU: diabetic foot ulcers