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SCI-QOL and WOUND-Q Have the Best Patient-reported Outcome Measure Design: A Systematic Literature Review of PROMs Used in Chronic Wounds

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Background: Chronic wounds are a significant burden on healthcare systems due to high costs of care (2%–4% total healthcare cost) and a considerable burden on patient's quality of life. Patient-reported outcome measures (PROMs) are questionnaires developed to enable patient self-assessments of their outcomes. A gap in knowledge exists because previous reviews on wound-specific PROMs did not evaluate the quality of the development. The main question is which PROM has the best quality development properties and should be used in clinical care and research.

Methods: PubMed, Embase, and CINAHL were searched from their inception through December 2021. Studies that included patients aged 18 years or older, with chronic wounds, and who reported using a condition-specific PROM for wounds were extracted. We excluded generic PROMs, comments, guidelines, and editorial letters. The COSMIN-guidelines were used to evaluate the quality of the PROMs.

Results: Of the 16,356 articles, a total of 251 articles describing 33 condition-specific PROMs for wounds were used. In total, 17 of 33 (52%) PROMs were developed for specific wound types, and nine of 33 (27%) PROMs were developed for any type of wound. Two of 33 (6%) PROMs were not rated because no development article was available. Only the SCI-QOL (Spinal Cord Injury-QOL) and the WOUND-Q rated "very good" in PROM design.

Conclusions: Thirty-three condition-specific PROMs were found. Only the SCI-QOL and the WOUND-Q rated very good in PROM design. The WOUND-Q is the only condition-specific PROM, which can be used in all types of chronic wounds in any anatomic location. *(Plast Reconstr Surg Glob Open 2023; 11:e4723; doi: 10.1097/GOX.0000000000004723; Published online 10 January 2023.)*

INTRODUCTION

Chronic wounds in patients are defined as wounds with healing time exceeding 3 months.[1,2] Chronic wounds have many different causes and numerous treatment modalities. Due to a rising incidence of obesity, diabetes, and aging populations, chronic wounds are becoming a more common healthcare problem.[3] In developed countries, chronic wounds have been estimated in up to two percent of the population, with a total prevalence occurring in approximately 1.67 per 1000 people.[4] In the United States, chronic wounds affect around 6.5 million patients.[3] This means that millions of patients require treatment for chronic wounds, each year.

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Caring for chronic wound patients imposes a significant burden on healthcare systems due to high costs of care, with roughly 2%–4% of the total healthcare costs in Europe used toward wound management.[4] Chronic wounds cost AU $3.78 billion in Australia, €4.5 billion in the United Kingdom, and US $25 billion in the United States.[3,5] Up to 40% of hospital beds are occupied by patients with wounds, and up to half of all recourses in the community are allocated toward the management of wounds.[4] An analysis of US Medicare claims for 2014 showed that 15% of beneficiaries (8.2 million) had an episode of care for a chronic wound or infection, with costs estimated between 28.1 and 96.8 billion.[6]

Qualitative studies have shown that (1) a diagnosis of chronic wounds imposes a variable impact on patients' quality of life (QOL), and may affect their physical, social, or psychological well-being[7,8]; and (2) patients often report pain, exudate, and odor as common physical symptoms, and the increased time spent at the hospitals for treatment imposes a loss of income due to their inability to work as well as social isolation.[3,5,9] Furthermore, 73% of patients have disturbed sleep and 50% have their mood affected.[3]

The quality of wound healing and wound care has been traditionally assessed from objective data related to healing time, wound depth, and complications. However, these data may not reflect the outcomes most important to patients, including physical symptoms and functional limitations reported previously, which provide important additional information. The Cochrane reviews show that these outcomes are often overlooked in studies on wound treatment.[10–13]

Patient-reported outcome measures (PROMs) enable patient assessments of their own health outcomes and quality of care, and may be used to inform individual patient care, quality assessments of care practices, and to better understand patient outcomes of treatment interventions.[14] However, in order for the PROMs to be useful they must be rigorously developed, including the target population and in the context in which the PROM will be used. However, in order for the PROMs to be useful, they must be rigorously developed, qualitative, well-documented research supplying evidence that the items, domains and concepts in the PROMs are interpretable, comprehensive, and applicable.[15]

Four previous reviews of PROMs used in chronic wounds have been published.[16–19] These reviews report that generic tools (eg, SF-36, EQ-5D) are often used. Such tools are limited in terms of content validity because they fail to ask about important wound-specific issues (eg, odor, exudate). Reviews by Palfreyman et al, González-Consuegra et al, Poku et al focus on PROMs for people with venous ulcers.[16–18]

Palfreyman et al found five generic and seven condition-specific PROMs. They found problems with both types of the generic and condition-specific instruments in terms of detecting changes in QOL related to ulcer healing. The applicability of the current disease-specific instruments to the venous ulcer population seems particularly poor.[18]

Takeaways

Question: What disease-specific PROMs for patients with wounds exist? What is the quality of the PROMs development?

Findings: Of the 16,356 articles, a total of 251 articles describing 33 condition-specific PROMs for wounds were found. Most PROMs were developed for one specific wound type, and nine PROMs were developed in patients with any type of wound. Only two PROMs, the SCI-QOL (Spinal Cord Injury-QOL) and the WOUND-Q, rated very good in PROM design.

Meaning: The WOUND-Q is the only condition-specific PROM that can be used in all types of chronic wounds in any anatomic location, with a good quality of PROM development.

González-Consuegra et al found three generic and five condition-specific PROMs.[17] Poku et al four generic and six condition-specific PROMs. No generic PROM showed adequate content and criterion validity, and the six condition-specific PROMs showed poor criterion and construct validity.[18] Gorecki et al focus on chronic wounds and particular reference to pressure ulcer research.[19] They found three generic and 14 chronic wound condition-specific PROMs but no pressure ulcer-specific measures. None of the existing measures cover all quality-of-life domains important in pressure ulcers.[19]

The aim of this study was to identify existing condition-specific PROMs used for patients with chronic wounds in general and find out if we can advise clinicians which PROM to use. Therefore, we performed a systematic literature review and systematically evaluate the quality of their development properties.

Our hypothesis is that newer developed PROMs have better quality development properties. We support this with the idea that several guidelines have recently been published to help with the development of a comprehensive PROM design with a modern psychometric approach. These guidelines are, for example, the US Food and Drug Administration,[20] the Scientific Advisory Committee of the Medical Outcomes Trust,[21] and the International Society for Pharmacoeconomics and Outcomes Research.[22,23]

METHOD

Literature Search

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were used to guide the reporting of this systematic literature review.[24] Multiple databases [Pubmed, Embase (biomedical and pharmacological bibliographic database), and CINAHL (nursing database)] were electronically searched from their inception through December 17, 2021, to identify PROMs used in patients diagnosed with chronic wounds. In each database, a similar search strategy was utilized. Search terms were grouped into three general

categories: patient-reported outcome (PRO), QOL, and chronic wounds. Detailed search strategies are outlined in Supplemental Digital Contents 1, 2, and 3. (**See figure 1, Supplemental Digital Content 1,** which shows the PubMed search on December 17, 2021. **http://links.lww.com/PRSGO/C318.**) (**See figure 2, Supplemental Digital Content 2**, which shows the Embase search on December 17, 2021. **http://links.lww.com/PRSGO/C319.**) (**See figure 3, Supplemental Digital Content 3**, which shows the CINAHL search on December 17, 2021. **http://links.lww.com/PRSGO/C320.**)

Study Selection and Data Extraction

Two reviewers (TVA, FTB) independently screened titles and abstracts using Covidence, a Cochrane platform to support systematic reviews.[25] Full-text screening was performed to determine study eligibility. A third reviewer (EVH) resolved discrepancies. The references of included studies and previous reviews were screened to identify additional studies for inclusion.

Studies were included if their full text was available in English or Dutch and if they reported using a condition-specific PROM for patients above 18 years and with chronic wounds. Studies using generic PROMs alone and not a study but a comment, guideline, or editorial letter were excluded. The development articles of the PROMs used in the identified studies were searched for analysis. The quality of each PROM's development was appraised using the COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) guidelines.[26–28] Two primary reviewers (TVA, FTB) worked independently to rate the quality of each PROM, and regular consensus meetings were held to review each individual's ratings and come to a consensus. A third reviewer (EVH) resolved any discrepancies if consensus was not established.

Evaluation of the Quality of the PROM Development

The COSMIN standard for evaluating the quality of studies on the development of a PROM contains two parts with subscores: 1. Standards for evaluating the quality of the PROM design to ensure relevance of the PROM. 2. Standards for evaluating the quality of a cognitive interview study or other pilot test performed to evaluate comprehensibility and comprehensiveness of a PROM. The worst score of both parts counts as the final overall PROM development score.[27] For the COSMIN standard questions, see Supplemental Digital Content 4. (**See figure 4, Supplemental Digital Content 4,** which shows the COSMIN PROM development questions. **http://links.lww.com/PRSGO/C321**.)

RESULTS

Literature Search Identified 16,356 Studies

A total of 16,356 studies were identified through our database search, among which 533 studies were included for full text review and 251 were included in the analysis. Details of the search results are presented in the PRIMSA flow diagram in Figure 1.

33 Condition-specific PROMs Identified and Analyzed

From these 251 studies, we identified 33 condition-specific PROMs for patients with chronic wounds: 1. CCVUQ: Charing Cross Venous leg Ulcer Questionnaire,[29] 2. CWIS: Cardiff Wound Impact Schedule,[30] 3. DFS: Diabetic Foot Ulcer Scale,[31] 4. DFS-SF: Diabetic Foot Ulcer Scale – Short Form,[31,32] 5. FPQLI-WV: Ferrans and Powers Quality of Life Index – Wound Version,[33] 6. FLQA: Freiburg Life Quality Assessment,[34] 7. FLQA-M: Modified Freiburg Life Quality Assessment in venous diseases,[35] 8. FLQA-W: Freiburg Life Quality Assessment wound module,[36] 9. HIDRAscore,[37] 10. HIDRAdisk,[38] 11. HS-PTGA: Hidradenitis suppurativa-Patient Global Assessment,[39] 12. HS-QoL: Hidradenitis suppurative HS-QoL,[40] 13. HSQoL-24,[41] 14. HiSQOL: Hidradenitis Suppurativa Quality of Life,[42] 15. HSIA,[43] 16. HSSA,[43] 17. Hyland Leg Ulcer Questionnaire,[44] 18. LUCT: Leg Ulcer Consultation Tool,[45,46] 19. PU-QOL: Pressure ulcer PU-QOL,[47–49] 20. NeuroQol,[50] 21. QOLEB: Questionnaire used to quantify Quality of Life in individuals with Epidermolysis Bullosa,[51,52] 22. SCI-QOL: Spinal Cord Injury-QOL,[53,54] 23. Skindex,[55] 24. Skindex-29,[56] 25. Skindex-16,[57] 26. Skindex-Mini,[58] 27. SPVU-5D: Sheffield Preference-based Venous Leg Ulcer 5,[59,60] 28. TSAS-W: Toronto Symptom Assessment System for Wounds,[61] 29. VLU-QoL: Venous Leg Ulcer Quality of Life questionnaire,[62,63] 30. WOUND-Q,[64] 31. Wound-QoL,[65] 32. WOWI: Well-being in wounds inventory,[66] 33. WWS: Wurzburg Wound Scales.[67] A list of the characteristics for each PROM is displayed in Supplemental Digital Content 5. (**See figure 5, Supplemental Digital Content 5**, which shows the list of PROMs. **http://links.lww.com/PRSGO/C322**.)

Seventeen of 33 (52%) PROMs were developed for one specific wound type (eg, ulcer, hidradenitis suppurativa), four of 33 (12%) were developed for skin disease in general, and nine of 33 (27%) were validated for use in any type of wound. The Skindex-Mini and the Wurzburg wound scales (WWS) were not rated because there was no development article available at the time of the search.[58,67] There is no development article available for the Skindex-Mini, only a research letter. The Skindex-Mini is a shorter version of the Skindex-29 and Skindex-16, which have been scored. There is no development article available for the Wurzburg wound scale. Results of the PROM evaluation using COSMIN are presented in Figure 2.

In Subscore PROM Design, Only Two of 33 (6%) Scored Very Good. In Subscore Cognitive Interview/Pilot Test, Only Eight of 33(24%) Scored the Highest Rating of Doubtful

In subscore PROM design score, a total of 12 of 33 (36%) PROMs rated inadequate, 16 of 33(48%) rated as doubtful, one of 33(3%) rated adequate, and two of 33 (6%) scored very good. Two PROMs, the SCI-QOL (Spinal Cord Injury-QOL) and the WOUND-Q, rated very good in PROM design.[53,54,64] In subscore cognitive interview/

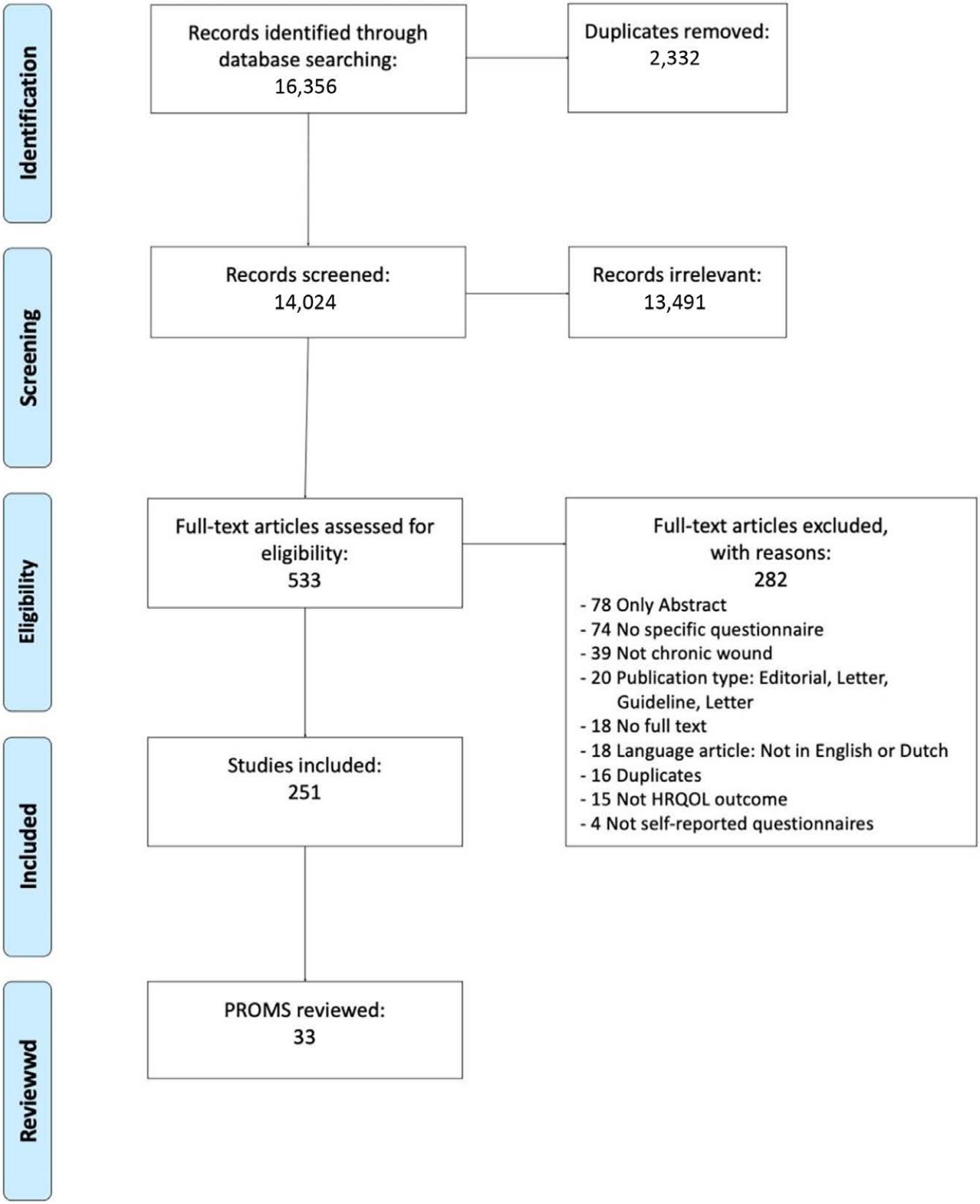

Fig. 1. PRISMA flowcharts of studies included and excluded.

PROM	PROM design							Cognitive interview (CI) study[2]				TOTAL PROM DEVELOPMENT
	General design requirements					Concept elicitation[1]	Total PROM design	General design requirements	Comprehen-sibility	Comprehen-siveness	Total CI study	
	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in sample representing the target population			CI study performed in sample representing the target population				
1 - CCVUQ	D	D	V	V	D	I	I	D	I	I	I	I
2 - CWIS	V	D	V	V	V	D	D	A	D	D	D	D
3 - DFS	V	D	V	V	V	D	D	D	D	D	D	D
4 - DFS-SF	V	V	V	V	V	D	D	D	D	D	D	D
5 - FPQLI-WV	V	V	V	V	D	D	D	A	I	D	I	I
6 - FLQA	V	V	V	V	V	D	D	V	D	D	D	D
7 - FLQA-M	V	D	V	V	I	I	I				I	I
8 - FLQA-W	V	V	V	V	I	I	I				I	I
9 - HIDRAscore	V	V	I	V	A	I	I				I	I
10 - HIDRAdisk	V	V	I	V	A	I	I				I	I
11 - HS-PTGA	V	V	V	V	V	D	A				I	I
12 - HS-QOL	V	V	V	V	V	I	I	A	I	D	I	I
13 - HSQoL-24	V	D	V	V	V	D	D				I	I
14 - HisQOL	V	V	V	V	V	I	I	V	V	D	D	I
15 - HSIA	V	D	V	V	V	V	D	V	I		I	I
16 - HSSA	V	D	V	V	V	V	D	V	I		I	I
17 - Hyland	V	V	V	D	D	I	I	D	I	I	I	I
18 - LUCT	V	V	V	V	V	D	D	V	I	D	I	I
19 - PU-QOL	V	V	V	V	V	D	D	V	V	D	D	D
20 - NeuroQol	V	V	V	V	I	D	I	I	I	D	I	I
21 - QOLEB	V	V	V	V	V	I	I	V	I	I	I	I
22 - SCI-QOL	V	V	V	V	V	V	V	D	I	D	I	I
23 - Skindex	V	V	V	V	V	D	D	V	I	I	I	I
24 - Skindex 29	V	V	V	V	D	D	D	V	I	I	I	I
25 - Skindex 16	V	V	V	V	D	D	D	V	I	I	I	I
26 - Skindex-Mini												3
27 - SPVU-5D	V	V	V	V	V	D	D	D	D	D	D	D
28 - TSAS-W	V	V	V	V	V	D	D	V	I	I	I	I
29 - VLU-QOL	V	V	D	V	A	D	D			I	I	I
30 - WOUND-Q	V	V	V	V	V	V	V	V	D	D	D	D
31 - WoundQol	V	V	V	V	V	I	I			I	I	I
32 - WOWI	V	V	V	V	A	I	I			I	I	I
33 - WWS												3

Fig. 2. Content analysis of PROMS. V, very good; A, adequate; D, doubtful; I, inadequate; NA, not applicable. 1, When the PROM was not developed in a sample representing the target population, the concept elicitation was not further rated; 2, Empty cells indicate that a CI study (or part of it) was not performed; 3, No validation article was found during time of search.

pilot test scores, 23 of 33 (70%) studies scored inadequate, eight of 33 (24%) scored doubtful, and two of 33 (6%) were not scored.

None of the PROMs Scored Adequate or Very Good in Overall PROM Design

In overall PROM design scores, 24 of 33 (72%) PROMs received an inadequate score in the overall quality of the development rating, and seven of 33 (21%) rated doubtful. None of 33 (0%) PROMs scored adequate or very good. Two of 33 (6%) PROMs were not scored because no validation article was found during time of search (Fig 2).

DISCUSSION

This review showed that there are 33 condition-specific PROMs for patients with chronic wounds. In PROM design, only two PROMs, the SCI-QOL and the WOUND-Q, rated very good. The WOUND-Q is the only PROM that scored very good that can be used in any etiology of a wound. Overall, the scores were low in this category because of three reasons: (1) the PROM development study was not performed in a sample representing the target population, (2) the sample representation was doubtful, and (3) the reason why the scores were low in this category was the low score on the concept elicitation (eg, no skilled group interviewers used, interviews were not recorded or transcribed verbatim, data were analyzed by one researcher).

The scores in the cognitive interview/pilot test category are low because no cognitive interviews were performed, patients were not asked about the comprehensibility or comprehensiveness of the PROM, or the PROM was not tested in its final form. Another reason for scoring doubtful was because not all data were provided to give an adequate or very good scoring.

The examined PROMs have significant limitations. In overall PROM design, none of the PROMs scored an adequate or very good because of inadequate or doubtful score in cognitive interview/pilot testing section. The worst score of both the PROM design and cognitive interview section counts as the final overall PROM development score.

As reported, four previous reviews of PROMs used in chronic wounds have been published.[16–19] These reviews focus on the identification of PROMs; the impact of chronic wounds on QOL; and evaluating domain, item, and content validity. A comparison between these previous reviews cannot be made because these reviews do not focus on the evaluation of the quality of the development properties.

According to the COSMIN methodology, PROM development leaves something to be desired. Only two PROMs (the SCI-QOL and the WOUND-Q) rated very good, and one PROM (the HS-PTGA) rated adequate in PROM design. Most of the low scores are caused by an absence of a particular question or feedback from patients as part of one item; this must be taken into account by developing future PROMs, whereby scores can efficiently be increased. Participation and feedback from patients, rather than only from physicians/experts, in the development of a PROM is a crucial step in the guidelines outlined by the US Food And Drug Administration,[20] the Scientific Advisory Committee of the Medical Outcomes Trust,[21] the International Society for Pharmacoeconomics and Outcomes Research,[22,23] and the COSMIN.[68] Therefore, taking this into account, is an important step in future research.

PROMs also scored a low rating because of an absence or incompleteness of particular scoring points. For example, PROMs scored inadequate on the basis of testing in a sample, not representing the target group, or the absence of testing the questionnaire in its final form. This is open for discussion but does not necessarily demonstrate a decreased quality of the PROM. The overall score of the COSMIN methodology is based on the lowest rating achieved per category. This means that one missing item determines the final score in a category as inadequate, while other items in this category might be carried out complete and adequate.

Another limitation to this study is that three of the authors (TVA, EVH, MH) of this study co-developed the WOUND-Q. We want to address that one of the primary reviewers (FTB) was not involved in any development of any PROM scored. Secondly, the two primary reviewers worked independently and the third reviewer, who resolved any discrepancies, was blinded to the scores. This is, however, a conflict of interest.

We have used the COSMIN checklist, published in 2018, to evaluate the quality of development of the PROMs.[27] Some of the PROMs may be of higher quality than indicated by the COSMIN checklist simply because the studies were performed longer ago, and some of the measurement properties were not reported. Future studies could be performed to evaluate the quality of content validity studies of the PROMs.

CONCLUSIONS

This review showed that there are 33 condition-specific PROMs for patients with chronic wounds. Only nine of 33 (27%) condition-specific PROMs are valid to use in any type of wound, whereas 17 of 33 (52%) PROMs are developed for one specific type of wound: for example, ulcer, hidradenitis suppurativa. Only two of 33 (6%) PROMs, the SCI-QOL and the WOUND-Q, rated very good in PROM design. We suggest using the WOUND-Q in clinical use because the WOUND-Q is the only PROM that scored very good that can be used in any etiology of a wound. None of the PROMs scored adequate or very good in overall PROM design because of inadequate or doubtful cognitive interview/ pilot testing.

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