The 'Wound-QoL': A Short Questionnaire Measuring Quality of Life in Patients with Chronic Wounds Based on Three Established Disease-specific Instruments

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ABSTRACT

Aim of this study was to develop a short questionnaire measuring health-related quality of life (HRQoL) in chronic wounds. Three validated instruments assessing HRQoL in chronic wounds, the Freiburg Life Quality Assessment for wounds, the Cardiff Wound Impact Schedule, and the Würzburg Wound Score, were completed by 154 German leg ulcer patients in a longitudinal study. For implementation in the new, shorter questionnaire Wound-QoL, those of all 92 items were selected that covered the core content of the three questionnaires and showed good psychometric properties. Internal consistency, convergent validity, and responsiveness were analysed using the study data on the selected items (a new approach called virtual validation). Subscales were determined with factor analysis. Item, instruction, and response scale wording were harmonized. 17 items were included in the Wound-QoL which could be attributed to three subscales on everyday life, body, and psyche. Both global score and subscale scores were internally consistent with Cronbach's alpha between 0.71 and 0.91. The global score showed significant convergent validity (r = 0.48 to 0.69) and responsiveness (r = 0.18 to 0.52); the same was true for the subscale scores. The Wound-QoL for measurement of HRQoL in chronic wounds proved to be internally consistent, valid, and responsive in German leg ulcer patients. The findings of this virtual validation study need to be confirmed in a longitudinal validation study on the final Wound-QoL which is currently being conducted.

INTRODUCTION

Chronic wounds can heavily impair the patients' quality of life by causing severe pain, social isolation, restricted mobility, and sleeping problems, to name only some of many possible effects on the patients' daily life (1,2)). Wounds are considered chronic if they do not heal, i.e. reach complete epithelialization within, for example, 8 weeks (3). Chronic wounds can, for example, result from diabetes (diabetic foot ulcers), chronic venous insufficiency, or from being confined to bed (decubitus ulcer).

Valid measurement of health-related quality of life (HRQoL) in these patients is indispensable for evaluating patient impairment and patient-relevant treatment effects. Accordingly, evaluation of HRQoL has become a standard in wound research and wound care (4). Three wound-specific HRQoL questionnaires are available in German language and are currently being used in treatment evaluation: the Freiburg Quality of Life Assessment for wounds (FLQA-w; 5), the Cardiff Wound Impact Schedule (CWIS; 6) and the Würzburg Wound Score (WWS; 7). FLQA-w and WWS have been developed and validated in German, and the CWIS has been translated to German using a standard linguistic validation process (8). All three instruments have been shown to have high internal consistency and validity in a head-to-head comparison (9)). However, these instruments are quite long, covering four to seven pages with up to 47 items. The WWS has the lowest number of items (n = 19), but provides no possibility of evaluating different domains of HRQoL by calculating subscale scores. Furthermore, the instruments comprise a lot of text in instructions, item questions, and response scales which further increases the patient burden for completing the questionnaire. Long questionnaires may impair patient acceptance and increase the number of missing values, as observed for example in the Swedish version of the CWIS (10). This is of particular relevance in chronic wounds, because the majority of affected patients are elderly (11) who can benefit from short and easy-to-read questionnaires (12). Therefore, there is need

for a short multidimensional instrument for usage in clinical research and practice where time is restricted and often multiple assessments are made.

This article presents the development and preliminary validation of the 'Wound-QoL', a short, multidimensional questionnaire measuring HRQoL in chronic wounds. The content of the Wound-QoL is based on the items of the three above-mentioned wound-specific instruments FLQA-w, CWIS, and WWS. We chose this approach because we assumed that all relevant areas of HRQoL impairment due to chronic wounds will be covered by at least one of the three instruments which were developed by three different research groups independently from each other.

METHODS

This study comprised the following steps which are described in more detail below: (a) The three HRQoL instruments FLQA-w, CWIS, and WWS were completed by patients under routine care. (b) After defining the exact item pool, (c) all items in the pool were grouped by content, and (d) psychometric item properties were determined. (e) Based upon these qualitative and quantitative analyses, items for implementation in the Wound-QoL were selected and wording was harmonized. (f) Subscales were determined via factor analysis. (g) The Wound-QoL was examined for internal consistency and validity in a so-called virtual validation, which is a newly-developed approach that has – to our knowledge – not been used previously.

Internal consistency refers to the degree of the interrelatedness among the items. It can be seen as an estimate of reliability, i.e. the degree to which the measurement is free from measurement error (13).

Validity refers to the degree to which an instrument measures the construct it purports to measure (13).

The wound-specific HRQoL instruments FLQA-w, CWIS, and WWS

The FLQA-w (5) measures wound-specific HRQoL with 30 Likert-scaled items divided into the following subscales: Physical Complaints (7 items); Occupational and Everyday Life (6 items); Social Life (3 items); Psyche (8 items); Stress caused by Therapy (6 items). Global HRQoL ratings are additionally assessed with three 11-point visual-numeric rating scales.

The CWIS (6) consists of three scales: Well-being (7 items); Social Life (7 items); Physical Symptoms and Daily Living (12 items), with the latter two scales being assessed twice for a) the extent of experience and b) how stressful the experience was during the preceding 7 days. This results in 45 Likert-scaled items overall. No global score is computed

for the CWIS. In addition, overall HRQoL is assessed with two 11-point numeric rating scales (0 to 10).

The WWS (7) consists of 17 Likert-scaled items, but no subdimensions of HRQoL are assessed. In addition, it is assessed if the patients need a walking aid and how many minutes daily wound treatment takes.

Some item wordings within the three questionnaires refer explicitly to impairments due to the wound (for example: 'To what extent are you restricted in mobility due to the wound' in the WWS). Other items do not explicitly refer to the wound (e.g. 'disturbed sleep' in the CWIS), or the relation is made only in the instruction (for example: 'The following questions concern how you manage in everyday life with your wounds' in the FLQA-w).

Step 1: Longitudinal assessment of FLQA-w, CWIS, and WWS

The questionnaires FLQA-w, CWIS, and WWS were implemented in a prospective, non-interventional multi-centre study on adult patients with chronic wounds under routine care. The patients were recruited at the University Medical Center in Hamburg, Germany (Comprehensive Wound Center) and at the Bundeswehrkrankenhaus (Armed Forces Hospital) in Ulm, Department of Vascular Medicine, Germany. An approval from the local ethics committee of the Hamburg Medical Chamber was obtained prior to the study, and written informed consent was obtained from all patients.

Each patient filled in all three questionnaires in randomly varied order at baseline (T1) and at a follow-up visit after 4 to 12 weeks (T2). As concordant criteria, four measures of generic HRQoL were assessed at both T1 and T2: Current health state was measured with the EQ-5D-3L questionnaire covering 5 dimensions (mobility; self-care; usual activities; pain/discomfort; anxiety/depression) and with the Euroqol visual analogue scale (EQ VAS) ranging from 0 = worst imaginable to 100 = best imaginable health (14,15)). The two 11-

point numerical rating scales (NRS) which are part of the CWIS measured quality of life and satisfaction with quality of life in the preceding 7 days.

In addition, socio-demographic data were collected in the patient questionnaire at T1. Clinical data were collected in physician questionnaires at both T1 and T2.

Step 2: Determination of item pool

The three instruments FLQA-w, CWIS, and WWS comprise a total number of 92 five-point Likert-scaled items. In the CWIS, 19 items are assessed twice regarding how often the patient had experienced the respective impairment and how stressful the experience was. That is, item wording is equal, but instruction and response scale differs. We computed Pearson correlations between each of these 19 pairs of corresponding items to determine the extent of redundancy in the information collected, using T1 data of the longitudinal study. No cut-off value for considering an intercorrelation as highly redundant had been defined a priori. Based upon this data we decided on whether to keep both experience and stress items in the item pool or to use only one of these two item groups.

Step 3: Item grouping by content

All items of the item pool were grouped qualitatively. Items in each group covered equal or similar content, and items could be assigned to more than one group if they related to more than one area of life. This step was performed by a methodologist specialized in quality of life measurement; the results were double-checked by two clinicians with daily experience with chronic wound patients.

Step 4: Determination of psychometric item properties

As supporting data for the process of item selection, the following quantitative properties of the items were determined, using T1 data of the longitudinal study:

- Percentage of missing values, i.e. percentage of patients who did not give an answer to the respective item

- Pearson intercorrelation of each pair of items as an indicator of redundant item information

- Percentage of patients who chose the top boxes, that is, one of the two response levels indicating the highest impairment (e.g. 'often' or 'always' for the FLQA-w item 'feelings of anger and rage'), assuming that a high percentage indicates that the respective item content is of high relevance to the patients and should therefore be included in the Wound-QoL.

Step 5: Item selection and harmonization

The results of the qualitative and quantitative item analysis (step 3 and 4) were discussed in depth by an expert group including CB (research psychologist and methodologist specialized in patient reported outcomes development), KB (study nurse with several years' experience in both management of chronic wounds and patient-reported outcomes assessment in patients with chronic wounds), and MA (leader of a special consultation hour for chronic wound patients; professor of quality of life research and health economics).

All relevant areas of HRQoL in chronic wounds as covered by the item pool should be included in the Wound-QoL. Therefore, from each group of items at least one item should be selected for implementation in the new questionnaire 'Wound-QoL' on the basis of the criteria of patient relevance, non-redundancy, generality, and unambiguity, as described below:

- Patient relevance of the impairment assessed by the item was judged by both clinical experience (qualitative) and percentage of patient responses in top boxes (quantitative).

- No two items of redundant content should be chosen for the Wound-QoL, as judged by qualitative item grouping and quantitative level of intercorrelation.

- Among items with similar content, those were given preference that were more general (for example an item on mobility in general) over those relating to a more specific experience (for example an item on mobility outside the home). This was done in order to cover a wider range of impairments in one item and to thereby reduce the overall number of items in the Wound-QoL.

- Items should be unambiguous, that is, no two different impairments should be addressed in the same item, and items should use only common words.

The reasons for each choice of items by the expert group were documented.

Upon selecting items for the Wound-QoL, instruction wording and a consistent response scale for all items was chosen. In some cases, item wording was improved and harmonized to make items more understandable and less ambiguous.

In addition, it was made explicit within each item that only impairments resulting from the wound were assessed to make sure that only disease-specific quality of life is measured but not impairments due to comorbidities or life circumstances (e.g. worrying in general versus worrying about the wound).

The final Wound-QoL questionnaire was designed in two different layouts which were given to n = 18 members of the working group who were asked for aspects of the layout they regarded as suitable and easy-to-fill-in for patients with chronic wounds. The results of this small survey were discussed in the working group, finding a consensus on the final layout.

Step 6: Determination of subscales

An explorative principal axes factor analysis with both orthogonal and oblique rotation was performed on the final items of the Wound-QoL using the study data of T1. Items were assigned to the factor they loaded highest on to derive Wound-QoL subscales on different dimensions of HRQoL in chronic wounds.

Step 7: Virtual Validation of the Wound-QoL

Finally, a so-called virtual validation of the Wound-QoL was conducted. Wirth 'virtual' we mean that we used the data of the longitudinal study (see step 1) and analysed the items that were selected for the Wound-QoL as if they had been given in a single questionnaire (instead of being scattered over the three original questionnaires). Thus, in the virtual validation, item order and the partly changed wording and questionnaire instructions in the final Wound-QoL could not be taken into account.

A Wound-QoL global score was computed as the arithmetic mean over all items, allowing for one missing response. The subscale scores were computed as the arithmetic means over the respective items; in case of missing data in any of the respective items, the subscale score was considered missing for the patient.

The following psychometrical properties of the Wound-QoL were analysed within the virtual validation:

- To examine internal consistency (a form of reliability, (13)), Cronbach's alpha was computed for the Wound-QoL global and subscale scores at T1.
- Item selectivity was computed for each item as corrected item-score-correlation, both with regard to the Wound-QoL global score and to the subscale scores at T1

- To determine convergent validity, the Pearson correlation of the Wound-QoL global and subscale scores with the following convergent criteria, as described in step 1, was calculated: (a) NRS on overall quality of life; (b) NRS on satisfaction with quality of life; (c) current health state as measured with EQ-5D-3L; (d) EQ VAS on current health state.

- Responsiveness was determined by computing Pearson correlations of Wound-QoL global and subscale scores with change in the above-mentioned convergent criteria. This was done by computing partial correlations of T2 data using T1 data as covariates. Responsiveness refers to the ability of an instrument to detect change over time in the construct to be measured; it can be estimated by the association of change in the instrument score with change in other measures on convergent criteria (13).

For comparison, we also determined internal consistency, validity, and responsiveness for the FLQA-w and WWS global scores. For the CWIS, these psychometric properties were investigated for the three scales because there is no global CWIS score.

All analyses were conducted with SPSS 20.0 for Windows. Significance level was set at $p = 0.05$.

Ethical considerations

This non-interventional questionnaire study was conducted in accordance with the Declaration of Helsinki and had been approved by the local ethical review committee in Hamburg.

RESULTS

Step 1: Longitudinal assessment of FLQA-w, CWIS, and WWS

Among the n = 165 patients included in the study, n = 154 (93.3 %) at least partially completed the Likert-scaled HRQoL items of the three questionnaires FLQA-w, CWIS, and WWS and were thus eligible for inclusion in the analysis reported here. Demographic and clinical characteristics of these 154 patients are reported in Table 1. 54.5 % were male; mean age was 65.3 years. Most current wounds were documented by the physician as ulcus cruris (63.0 %). The wounds had persisted for an average 26.6 months.

Results on psychometric properties of the three original HRQoL questionnaires, which were, among others, high internal consistency and validity, are not subject of this article (8).

>>>>>insert Table 1 here<<<<<

Step 2: Determination of item pool

Pearson correlation between each of the 19 pairs of corresponding 'experience' and 'stress' items in the CWIS ranged from r = 0.66 to r = 0.90 at T1 (average correlation: r = 0.84). For all but three of these item pairs, intercorrelations were higher than r = 0.8. Thus, the items on *experience of* and *stress due to* different impairments did not gather exactly the same information, but were statistically highly redundant; in average, the information overlap was 71 %. As a consequence, we decided to keep only the items on *stress due to* the impairments in the item pool. This reduced the initial pool of 92 items to the final item pool of 73 items.

Step 3: Item grouping by content

The 73 items could be assigned to 12 different categories with two to twelve items each. Five items were also assigned to a second category, because they covered more than one area of HRQoL. For example, the FLQA-w item 'My leisure activities are impaired due to the wound

treatment' was assigned to the two categories 'Impairment of leisure activities' and 'Impairment due to treatment'. The categorization of all 73 items cannot be given in this article on account of space restrictions, but category names with the respective number of items can be found in Table 2.

>>>>>insert Table 2 here<<<<<

Step 4: Determination of psychometric item properties

Due to space restrictions, the complete table of psychometric properties for the whole item pool is not given in this article, but numbers are given for the items which were chosen for implementation in the Wound-QoL (Table 2).

In summary, there were only three items with more than 5 % missing values. The WWS item on 'decreased income opportunities due to the wound' was not answered by 11.7 % of respondents, possibly because of the high percentage of retired persons among patients with chronic wounds. The CWIS items on 'family/friends being overly protective' and 'difficulty in finding appropriate footwear' showed 5.2 % of missing items each. The percentage in the remaining items ranged from 0 % to 3.2 %. The percentage of patients choosing the top boxes which indicate high impairment showed a wide range from 5.8 % to 77.9 %, depending on the item.

Step 5: Item selection and harmonization

The expert group meeting took place in May 2012. Based on the qualitative item grouping complemented by the quantitative item data, 17 items were chosen for implementation in the Wound-QoL. These items covered all item groups apart from one that consisted of two WWS items on feeling sick or disabled in comparison to healthy people. We decided not to include this topic for two reasons: Firstly, the items did not assess whether the fact of being disabled

was a subjective burden to the single patient. Secondly, we feared that the items might upset patients by suggesting they were sort of 'unnormal', making it unethically questionable to include the items.

Among the selected items, seven originated from the CWIS, eight from the FLQA-w, and two from the WWS. None of these items showed a pairwise correlation higher than $r = 0.8$. The percentage of patients choosing the top boxes of these items which indicate high impairment in the respective area ranged from 18.2 to 77.9 % at T1 (Table 2). We decided to assess all impairments within the period of 'the last seven days' in both instruction and the introductory phrase. We chose the five-step intensity assessment of 'not at all' to 'very much' as the uniform response scale instead of relating to frequency (e.g. 'never' to 'always') or agreement (e.g. 'strongly agree' to 'strongly disagree').

Lastly, the final item wording (Table 2, right column) was adapted in order to be compatible with the introductory phrase and the response scale and to ensure easy and unambiguous understanding by the patients. Furthermore, each item was related explicitly to the wound, for example by adding the term '…because of the wound'.

Step 6: Determination of subscales

Data of $n = 142$ patients without missing values among the 17 items at T1 could be included in the factor analysis. Both factor analysis with oblique and with orthogonal rotation led to the same number of three factors with eigenvalue > 1 ('Kaiser's criterion') and to the same assignment of items to factors. Here, results of the orthogonal rotation, i.e. the solution with independent factors, are reported.

According to factor loadings, the items were assigned to three subscales: The first scale was called 'Body'; it covered five items on physical impairments such as pain, wound discharge, and problems with sleeping. The second scale on 'Psyche' covered five items on

psychological problems such as being afraid of deterioration, being unhappy, or feeling frustrated due to slow healing. The scale on 'Everyday life' covered six items on for example leisure activities and dependency on help by others. These three factors explained 23.3 % (Everyday Life), 15,2 % (Body), and 13.1 % (Psyche) of overall variation, summing up to 51.6 % cumulative explanation of variance.

The item on financial burden showed its highest loading on the physical dimension, but we chose not to include it in the respective subscale, because the item content was not related to the body, and the factor loading was rather low with 0.40. However, the item remained in the Wound-QoL and its global score.

Step 7: Virtual Validation of the Wound-QoL

The Wound-QoL global score at baseline was 2.94 on average which corresponds with the response 'moderately' on the 5-point response scale (Table 3). The stated impairment was slightly lower in the body subscale with 2.60, and slightly higher in the psyche subscale with 3.36.

>>>>>insert Table 3 here<<<<<

The distribution of global score and subscales at baseline is given in Figure 1. It shows that the global score is about normally distributed around the value 3 ('moderately') which represents the middle of the response scale.

>>>>>insert Figure 1 here<<<<<

At T2, the average global score was only slightly (however significantly) lower with an average reduction of 0.18 points (Table 3). The same was true for the subscales with an average reduction of 0.17 to 0.20. Impairment in generic HRQoL and current health state as measured by the convergent criteria instruments also decreased on average, but this change was not significant.

The internal consistency of both Wound-QoL global score and subscale 1 was high with Cronbach's alpha = 0.91 (Table 4). Internal consistencies of subscales 2 and 3 were also acceptable with 0.83 and 0.71, especially considering the small number of only 5 items in each of both scales.

Convergent validity testing showed moderate correlations of the Wound-QoL global score with all four criteria (Table 4). The highest association was found regarding the EQ-5D-3L questionnaire on current health state with r = 0.69. The Wound-QoL subscales showed a similar pattern of convergent validity, with the associations being lower for subscale 3 (Psyche) with r = 0.33 to 0.48. All correlations were highly significant (p<0.001). The convergent validity of the other HRQoL questionnaires FLQA-w, CWIS, and WWS regarding the four criteria was lower or about as high as that of the Wound-QoL. At maximum, there was a difference of 0.04 units in favour of the WWS: Convergent validity regarding overall QoL was r = 0.48 in the Wound-QoL and r = 0.52 in the WWS.

As compared to convergent validity, responsiveness values were lower (Table 4): The Wound-QoL global score correlated to a small extent with the visual and numerical rating scales (r = 0.18 to 0.33) and moderately with the health state questionnaire EQ-5D-3L (r = 0.52; all p<0.05). For the Wound-QoL subscales, a similar pattern of responsiveness values was found, with the associations again being lower for subscale 3 (Psyche). Except for the criterion EQ VAS, all subscale responsiveness results were statistically significant (p<0.05). Responsiveness of the other QoL questionnaires regarding the four criteria was lower or about as high as that of the Wound-QoL. However, with respect to the criterion of satisfaction with QoL, a higher correlation of r = 0.42 was found for the WWS than for the Wound-QoL with r = 0.32.

>>>>>insert Table 4 here<<<<<

Item selectivity of the 17 items regarding the Wound-QoL global score ranged from 0.31 to 0.71. The items with the highest selectivity, i.e. those being most typical of the global score, were those on limited activities with others (item selectivity = 0.75) and limited leisure activities (0.73). Item selectivity for subscale 1 on Everyday Life ranged from 0.66 to 0.83 (the latter again in the item on activities with others). The values for subscale 2 on Body ranged from 0.56 to 0.70 (highest for the item on pain), and the values for subscale 3 on Psyche ranged from 0.34 to 0.59 (highest for the item on being worried due to the wound). The Wound-QoL in its final layout (English version) is shown in Figure 2.

>>>>>insert Figure 2 here<<<<<

DISCUSSION

There had been need for a multidimensional instrument measuring HRQoL in patients with chronic wounds which is both short and easy-to-understand. Their features should help minimize patient burden and ensure high data quality. We developed the one-page questionnaire 'Wound-QoL' on the basis of three different wound-specific instruments by covering the instruments' core contents with a smaller number of items. Using data of a longitudinal study including the three instruments, we performed a so-called virtual validation of the newly-developed 'Wound-QoL' questionnaire. The results indicate good internal consistency, validity, and responsiveness.

The main limitation of this study is that the questionnaire could not be assessed in its final format yet. The Wound-QoL items differ from the original items with regard to item order, instruction wording, and response scale. Item wording was optimized while largely keeping item content. Thus, the virtual validation results can only serve as an estimation of the true psychometric properties of the Wound-QoL. We are however optimistic that the

Wound-QoL will also prove valuable in the longitudinal validation study which is currently being conducted, for the following reasons: Due to its brevity (one page), its consistent response-scale, and its focus on comprehensible and consistently wound-related item wording we assume that the Wound-QoL may provide an even more reliable and valid HRQoL evaluation than the original instruments have been proved to do.

For a patient-reported outcomes instrument to be valid, it must measure exactly what it is meant to measure. The problem with proving the validity of quality of life instruments is that in virtually all of these instruments – except for mere short versions of existing questionnaires –, there is no proven gold standard to measure them against (16). If there was, there would be no need to develop a new questionnaire. As a substitute, correlations with existing questionnaires on the same or on a related concept such as generic instead of disease-specific HRQoL are often used as proxy criteria. This is why we put so much emphasis on qualitative, content-based development of the Wound-QoL instead of just picking those items which in combination would show the highest correlation with convergent criteria.

There was only a small increase in average quality of life as measured with the Wound-QoL and other patient-reported outcomes during the observation period of the study. This might be due to the fact that within the period of 4-12 weeks between the study assessments, chronic wound treatment could not yet have a huge impact on HRQoL in many cases. However, for validation purposes it is only important that there is inter-individual heterogeneity in both current HRQoL and change in HRQoL; in contrast, the size of the group effect when averaging changes over all patients is not relevant. Accordingly, the responsiveness correlations reported here showed that changes in the Wound-QoL correspond with changes in convergent criteria.

A further limitation of this study is the focus mainly on leg ulcers. The three questionnaires WWS, FLQA-w, and CWIS have been developed predominantly for patients

with leg ulcers. Only in the CWIS, diabetic foot ulcers were included, too. The majority of patients in our longitudinal study also had leg ulcers. Thus, generalisation of the study findings to other sorts of chronic wounds needs to be done carefully. Furthermore, two of the three established instruments had been validated in German language, whereas the third had been developed in English and was subsequently translated to German.

Data assessment was conducted by two centres, a specialist wound centre and a military hospital, where patients may not be representative for the population of patients with leg wounds in Germany. In order to increase the representative character of the study, we also included patients with community ulcers in different regions since the Hamburg Comprehensive Wound Center includes four peripheral office-based practices which mostly provide health care to the general population.

In the virtual validation it was found that the WWS had good – in some cases even slightly better – validity and responsiveness values as compared to the Wound-QoL. The WWS also consists of only 17 Likert-scaled items as the Wound-QoL does, but it covers four pages instead of only one due to repetition of the response scale. More importantly, no subscales have been developed for the WWS, and it is only available in the original German version. In contrast, the Wound-QoL has been translated to English using a thorough procedure including double translation by professional translators, double back translation, comparison of all translations against the original, developers' and translators' conference discussing each single item, and final verification by a fifth, independent translator.

In conclusion, the newly-developed Wound-QoL was found to be internally consistent, valid, and responsive in German leg ulcer patients in the virtual validation analysis. It can be used as a short and easy-to-understand instrument to assess HRQoL in patients with chronic wounds, especially leg ulcers. These findings need to be confirmed in

the longitudinal validation study on the final Wound-QoL which is currently being conducted.

ACKNOWLEDGMENTS

LIST OF ABBREVIATIONS

CWIS   Cardiff Wound Impact Schedule

EQ-5D-3L   Euroqol questionnaire on current health state

EQ VAS   Euroqol visual analogue scale on current health state

FLQA   Freiburg Life Quality Assessment

HRQoL   Health-related quality of life

NRS   numerical rating scale

n   number of patients

p   level of significance

QoL   Quality of life

r   Pearson correlation coefficient

T1   baseline assessment

T2   follow-up assessment

VAS   visual analogue scale

WWS   Würzburg Wound Scale

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Table 1: Demographic and clinical characteristics of the study participants at T1

(n = 154)

	Mean	SD	Minimum	Maximum
Age (years)	65.3	14.8	28	91
Body Mass Index	28.9	7.8	15.5	63.6
Duration of wound persistence (months)	26.6	50.6	1	432
	N	**%**		
Sex				
Male	84	54.5		
Female	70	45.5		
School education degree				
No qualification	3	1.9		
General secondary education	67	43.5		
Intermediate secondary education	51	33.1		
Advanced technical college entrance qualification	9	5.8		
General qualification for university entrance	24	15.6		
Current wound				

Ulcus cruris	97	63.0		
Pyoderma gangraenosum	14	9.1		
Ulcers due to surgery	13	8.4		
Vasculitis	11	7.1		
Diabetic foot ulcers	7	4.5		
Other	12	7.8		

T1, baseline assessment; SD, standard deviation; n, number of patients

Table 2: Overview on categorization of items, item selection, and item adaptation for the Wound-QoL

Category	Number of items*	Items selected for the Wound-QoL **	Percentage of missing values at T1 (in n=154 patients)	Percentage of patients choosing top boxes at T1 (in n=154 patients)	Final item wording in the Wound-QoL: "In the last seven days…"
Physical impairments	11	Pain from the wound site (CWIS)	3.2 %	37.7 %	…my wound hurt
		Is your night's sleep impaired due to the wound? (WWS)	0.0 %	26.6 %	…the wound has affected my sleep
Impaired mobility	7	I worry about bumping the wound site (CWIS)	0.0 %	70.1 %	…I have been afraid of knocking the wound
		To what extent is your mobility restricted due to the wound? (WWS)	0.0 %	48.1 %	…I have had trouble moving about because of the wound
		Climbing stairs is difficult for me (FLQA-w)	0.6 %	52.6 %	…climbing stairs has been difficult because of the

					wound
Discharge, smell, and appearance	6	Discharge from the wound (FLQA-w)	0.0 %	42.2 %	…there was a disturbing discharge from the wound
		Unpleasant odour or smell from the wound(s) (CWIS)	3.2 %	13.6 %	…my wound had a bad smell
Psychological impairment	12	I feel frustrated with the time it is taking for the wound(s) to heal (CWIS)	0.6 %	77.9 %	…I have felt frustrated because the wound is taking so long to heal
		I feel anxious about my wound(s) (CWIS)	0.0 %	65.6 %	…I have worried about my wound
		Dejection (FLQA-w)	0.0 %	18.2 %	…the wound has made me unhappy
Feeling disabled	2	(none)			(none)
Expectation of healing or worsening	5 (+3)	I worry that I may get another wound in the future (CWIS)	0.0 %	46.1 %	…I have been afraid of the wound getting worse or of new

					wounds appearing
Impairment of everyday life	7	Problems with everyday activities (e. g. shopping) (CWIS)	3.2 %	32.5 %	…I have had trouble with day-to-day activities because of the wound
Impairment of leisure activities	3 (+2)	My leisure activities are restricted due to the condition (FLQA-w)	1.3 %	53.9 %	…the wound has limited my leisure activities
Impairment of social life	7	I limited activities with others (FLQA-w)	0.0 %	41.6 %	…the wound has forced me to limit my activities with others
Being dependent on help	4	I felt dependent on the help of others (FLQA-w)	0.6 %	38.3 %	…I have felt dependent on help from others because of the wound
Impairment due to treatment	6 (+3)	The treatment is a strain on me (FLQA-w)	1.9 %	29.2 %	…the treatment of the wound has been a burden

					…the wound has been a financial burden to me
Financial burden	3	The wound is a financial burden for me (FLQA-w)	1.9 %	23.4 %	
Total number	**73**	**17**			**17**

* Multiple assignments were possible. In brackets, the number of items with primary assignment to another category is given.

** In brackets, the questionnaire from which the item originated is given: FLQA-w, Freiburg Life Quality Assessment for wounds; CWIS, Cardiff Wound Impact Schedule; WWS, Würzburg Wound Score.

Table 3: Change in Wound-QoL scales and convergent criteria from T1 to T2

	Mean T1	SD T1	Mean T2	SD T2	Change from T1 to T2 (mean)	Change from T1 to T2 (SD)	Change from T1 to T2 (p)	Correlation of T1 and T2 (r)	N
Wound-QoL scales (scaled 1-5):									
Global Score	2.94	0.85	2.76	0.87	0.18	0.52	<.001	0.82	126
Subscale 1: 'Everyday Life'	2.94	1.18	2.76	1.20	0.17	0.74	.011	0.81	121
Subscale 2: 'Body'	2.60	1.01	2.44	0.98	0.17	0.67	.005	0.78	126
Subscale 3: 'Psyche'	3.36	3.15	0.77	0.89	0.20	0.67	<.001	0.69	137
Convergent criteria:									
Overall Satisfaction with quality of life (NRS, scaled 0-10)	5.40	2.15	5.68	2.06	-0.28	2.05	.115	0.53	136
Satisfaction with quality of	5.64	2.42	5.78	2.36	-0.14	2.10	.438	0.62	136

life (NRS, scaled 0-10)									
Current health state as assessed with the 5-item questionnaire EQ-5D-3L (scaled 0-100)	61.80	28.81	62.86	29.38	-1.05	21.37	.568	0.73	135
Current health state as assessed with the visual analogue scale EQ VAS (scaled 0-100)	55.65	21.64	57.01	22.27	-1.36	17.68	-1.36	0.68	137

T1, baseline assessment; T2, follow-up assessment; NRS, numerical rating scale; SD, standard deviation; p, level of significance in t test for paired samples; r, Pearson correlation coefficient; n, number of patients

Table 4: Psychometric properties of the Wound-QoL global and subscale scores and of the WWS, CWI

validation'

	Wound-QoL Global Score	Wound-QoL Subscale 1: 'Everyday Life'	Wound-QoL Subscale 2: 'Body'	Wound-QoL Subscale 3: 'Psyche'	FLQA-w Global score	CWIS Subscale 'Well-being'
Number of Likert-scaled items	17	6	5	5	30	7
Internal consistency, T1						
Cronbach's alpha	0.91	0.91	0.83	0.71	0.89	0.75
n	142	146	148	153	148	151
Convergent validity regarding overall QoL (NRS), T1						

	r	-0.48	-0.43	-0.43	-0.33	-0.49	0.31
	p	<.001	<.001	<.001	<.001	<.001	<.001
	n	147	145	147	152	152	150
Convergent validity regarding satisfaction with QoL (NRS), T1							
	r	-0.55	-0.50	-0.45	-0.44	-0.53	0.46
	p	<.001	<.001	<.001	<.001	<.001	<.001
	n	147	145	147	152	152	150
Convergent validity regarding current health state (EQ-5D-3L), T1							
	r	-0.69	-0.66	-0.57	-0.48	-0.70	0.47
	p	<.001	<.001	<.001	<.001	<.001	<.001
	n	144	142	144	149	149	147
Convergent validity							

regarding current health state (EQ VAS), T1						
r	-0.60	-0.61	-0.50	-0.40	-0.62	0.42
p	<.001	<.001	<.001	<.001	<.001	<.001
n	148	146	148	153	153	151
Responsiveness regarding change in overall QoL (NRS), T1						
r	-0.33	-0.36	-0.32	-0.19	-0.32	0.16
p	<.001	<.001	<.001	.026	<.001	.063
n	124	119	124	135	135	133
Responsiveness regarding change in satisfaction with QoL (NRS), T1						
r	-0.32	-0.35	-0.28	-0.22	-0.36	0.24

p	<.001	<.001	.002	.010	<.001	.006
n	124	119	124	135	135	133
Responsiveness regarding change in current health state (EQ-5D-3L), T1						
r	-0.52	-0.54	-0.39	-0.28	0.51	0.24
p	<.001	<.001	<.001	.001	<.001	.006
n	123	119	123	134	134	132
Responsiveness regarding change in current health state (EQ VAS), T1						
r	-0.18	-0.15	-0.15	-0.12	-0.21	0.12
p	.046	.111	.096	.169	.015	.181
n	125	120	125	134	136	134

T1, baseline assessment; QoL, quality of life; NRS, numerical rating scale; VAS, visual analogue scale; r, Pea
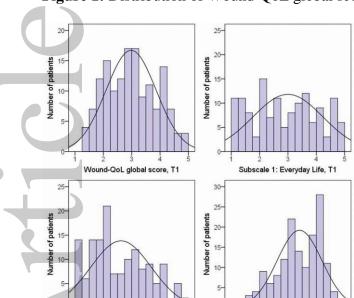
level of significance; n, number of patients

Figure 1: Distribution of Wound-QoL global score and subscales at T1

Figure 2: The final Wound-QoL questionnaire (English version: translated from the original German version used in this study)

Quality of life with chronic wounds – "Wound-QoL" questionnaire

With the following questions, we aim to find out how your chronic wound(s) affect(s) your quality of life.
In every line, please tick what has applied to you in the last 7 days.

In the last seven days…	not at all	a little	moderately	quite a lot	very much
1 …my wound hurt	O	O	O	O	O
2 …my wound had a bad smell	O	O	O	O	O
3 …there was a disturbing discharge from the wound	O	O	O	O	O
4 …the wound has affected my sleep	O	O	O	O	O
5 …the treatment of the wound has been a burden	O	O	O	O	O
6 …the wound has made me unhappy	O	O	O	O	O
7 …I have felt frustrated because the wound is taking so long to heal	O	O	O	O	O
8 …I have worried about my wound	O	O	O	O	O
9 …I have been afraid of the wound getting worse or of new wounds appearing	O	O	O	O	O
10 …I have been afraid of knocking the wound	O	O	O	O	O
11 …I have had trouble moving about because of the wound	O	O	O	O	O
12 …climbing stairs has been difficult because of the wound	O	O	O	O	O
13 …I have had trouble with day-to-day activities because of the wound	O	O	O	O	O
14 …the wound has limited my leisure activities	O	O	O	O	O
15 …the wound has forced me to limit my activities with others	O	O	O	O	O
16 …I have felt dependent on help from others because of the wound	O	O	O	O	O
17 …the wound has been a financial burden to me	O	O	O	O	O