



Measurement properties and factor analysis of the Diabetic Foot Ulcer Scale-short form (DFS-SF)

Uiara A. de Oliveira Kaizer  | Neusa M. C. Alexandre |
Roberta C. M. Rodrigues | Marília E. Cornélio | Maria H. de Melo Lima  |
Thaís M. São-João

School of Nursing, University of Campinas, Campinas, Brazil

Correspondence

Uiara A. de Oliveira Kaizer, RN, PhD,
School of Nursing, University of
Campinas, Tessália Vieira de Camargo,
126-Cidade Universitária, Campinas,
Brazil.
Email: uiara_oliveira@hotmail.com

Abstract

The purpose of this paper is to provide measurement properties evaluation and factor analysis of the Brazilian version of the diabetic foot ulcer scale-short form (DFS-SF). This methodological study evaluated the measurement properties of the DFS-SF by ceiling and floor effect reliability, responsiveness, and structural construct validity. The study included 290 people with diabetic foot under regular follow-up in a specialised outpatient clinic in inland São Paulo. Reliability was assessed by internal consistency using Cronbach's alpha and composite reliability. Ceiling and floor effects were assessed by the percentage of participants who scored the 15% worst (floor) and 15% best (ceiling) possible scale results. Validity was tested by correlating the instrument values with the domains of the Brazilian version of the Short Form Health Survey (SF-36). Responsiveness ($n = 34$) was accessed through the wound area obtained by photography and evaluated by the Image J Features program and the DFS-SF score at two moments, with a 4-week interval between them. The instrument had good evidence of reliability, shown by adequate internal consistency (Cronbach's alpha in domains >0.70) and compound reliability ($0.84 > CC > 0.92$); and of convergent validity, by significant positive correlations of moderate to strong magnitude with SF-36. Structural construct validity was examined by applying the DFS-SF confirmatory factor analysis, which indicated that the Brazilian version of the instrument is properly fitted to the original dimensional structure. The ceiling and floor effect analysis showed no ceiling or floor effects. Responsiveness was observed in the wound area, but not in the DFS-SF scores in the times. The Brazilian version of the DFS-SF presented evidence of validity and reliability, suggesting that this instrument is a valid tool for assessing the quality of life of people with diabetic foot in the Brazilian population.

KEYWORDS

diabetes mellitus, nursing, quality of life, questionnaires, validation studies

1 | INTRODUCTION

Diabetic foot ulcer (DFU) is defined as ‘the presence of deep tissue infection, ulceration, and/or destruction associated with neurological abnormalities and varying degrees of peripheral vascular disease (PVD) in people with diabetes mellitus’.¹

Foot ulceration is the most common complication of people with diabetes mellitus (DM), with high rates of morbidity and mortality.^{2,3} It is estimated that every 30 seconds, a person loses a foot or part of a lower limb because of diabetes somewhere in the world⁴ and the mortality rate in these patients is close to 40%.³

Among lower limb amputations in people with DM, 85% are preceded by ulcerations, and peripheral neuropathy and PVD are the main factors in this occurrence.⁴⁻⁶

The incidence rate of foot ulcers among people with lifelong DM ranges from 19% to 34%, and the recurrence rate of ulcer is 40% in the first year and 65% in 3 years.⁷ Prevention, therefore, is the best way to decrease the risk of people with DM developing foot ulcers, and thus reduce the economic burden on society.⁸

The consequences of foot complications in people with DM can lead to emotional problems, such as mental health changes, depressive symptoms, and suicidal behaviour, directly affecting their quality of life (QOL).^{9,10} Thus, DFU can affect peoples’ lives in different negative ways.¹¹

Currently, in the world literature, no patient-reported outcome measure (PROM) was identified as a ‘gold standard’ for assessing health-related QOL in diabetes-related foot disease.¹² Nevertheless, one PROM was assessed as a good measure to evaluate that the impact of DFU on the QOL of people with DM is the diabetic foot ulcer scale (DFS) or its short form, known as DFS-short form (DFS-SF). The DFS-SF has shown that robustness and sensitivity, as statistically significant regression correlations to the DFS and to SF-36, presents 29 questions and is a friendly tool for everyday clinical practice.¹²

DFS-SF assesses the impact of DFU on the patients’ QOL. It was designed to evaluate changes throughout treatment, ensuring that items were sensitive to changes resulting from the treatment of DFU. It is capable of discriminating between active and healed ulcer patients and is suitable for use in clinical trials of DFU patients.¹³ DFS-SF consists of 29 items divided into six domains: leisure, physical health, dependence/daily life, negative emotions, worried about ulcers/feet, and bothered by ulcer care. For each item, there is a five-point Likert scale with scores ranging from 1 (never) to 5 (all the time). The DFS-SF score is based on the sum of all items in each domain. All DFS scales are scored from 0 to 100, and higher scores indicate better QOL.

Key Messages

- the diabetic foot ulcer scale-short form is a reliable tool to assess quality of life; it showed satisfactory convergent validity with the gold standard for quality of life assessment
- the Brazilian version is properly fitted to its original version and this paper provides a robust tool to assess quality of life in diabetes foot disease

DFS-SF was created by analysing data from a double-blind, placebo-controlled, randomised trial on the efficacy and safety of becaplermin (recombinant human platelet-derived growth factor) in the treatment of DFU. From these data, items that showed poor measurement properties were excluded, and exploratory factor analyses were performed to develop a new scale. Finally, data from two additional clinical trials (study 1 – development of the DFS-SF and study 2 – validation of the DFS-SF scaling algorithm) were used to assess the replicability of the new DFS-SF subscale structure.¹³

This is a multidimensional, easy to understand, and self-applicable instrument that evaluates QOL in different aspects, such as leisure, physical health, dependence/daily life, emotions, and bothered and worried about ulcer.

Reliability and validity were evaluated in two clinical trials in people with DM and foot ulcers. Studies 1 and 2 showed good internal consistency, with alpha ranging from 0.80 to 0.74 for the bothered by ulcer care subscale at visit 1, and from 0.95 to 0.4 on the negative emotions scale at visits 24 and 23; and satisfactory convergent validity compared with SF-36 in some domains; as well as good responsiveness to clinical changes. Regarding exploratory factor analysis, both studies presented high values using the congruence coefficient of each of the factors: 0.7 for leisure; 0.90 for dependence/daily life; 0.87 for negative emotions; 0.84 for physical health; 0.88 for worried about ulcer/feet, and 0.95 for bothered by ulcer care, suggesting that it is highly stable in both samples.^{13,14}

The original DFS-SF in the English version was translated into several languages, including Chinese, Dutch, French, Spanish, Greek, Polish, Korean, and recently Brazilian Portuguese. However, only the Chinese, Greek, Polish, Korean, and Brazilian Portuguese translations have gone through a complete language validation process.^{11,15-17}

Considering the importance of implementing an instrument adapted to the Brazilian population, with evidence of reliability and validity, directed to measure the impact of DFU on people's QOL, this study aimed to evaluate the measurement properties of the Brazilian version of the DFS-SF in a group of patients with DM by composing a report based on international recommendations.¹⁸

2 | MATERIALS AND METHODS

2.1 | Study type

This is a methodological study that aims to validate the DFS-SF for the Brazilian population. The methodological research makes 'investigations of the methods of obtaining, organizing, and analysing data, dealing with the elaboration, validation, and evaluation of research instruments and techniques'.¹⁹

The DFS-SF was previously culturally adapted for Brazil,²⁰ in a study following the translation methodology standards of the Mapi Research Trust (Lyon, France).²¹

2.2 | The scale

2.2.1 | Diabetic foot ulcer scale-short form

The DFS-SF consists of 29 items divided into six domains: leisure, physical health, dependence/daily life, negative emotions, concern with the ulcer/feet, and bothered by ulcer care.¹³ Responses range from 'not at all' to 'extremely', 'none of the time' to 'all the time', and 'not at all' to 'great deal'. For each question, there is a score from 1 (never) to 5 (all the time). The item score is formed by on a five-point scale. The DFS-SF score relies on the sum of all items in each domain. All DFS scales were scored from 0 to 100, with higher scores indicating better QOL. When necessary, the item score of some domains is decoded so that the minimum possible score (1) represents the worst QOL, and the maximum possible score (5) represents the best QOL.

2.2.2 | Participants

This research included patients of an outpatient specialised clinic diagnosed with type 1 or 2 diabetes, which lived with foot disease as a result directly from DM, considering it a long-term/chronic complication, under regular clinical follow-up at the referred service, with the

following inclusion criteria: native Brazilians, over 18 years old; presenting one to two foot ulcers, from 0.5 to 30 cm² in size¹⁴; and able to read, understand, and answer the questionnaire.²²

2.3 | Procedures

2.3.1 | Settings

Data were collected through an interview at the Diabetic Foot Outpatient Clinic of a city in inland São Paulo, southeastern Brazil, from July to November 2018, in a private and quiet environment.

The DFS-SF and SF 36 instruments were applied after photographic recording of the patients' wounds to assess wound size and instrument responsiveness. The questionnaires were always applied according to a pre-established order, considering the DFS-SF as the first one because it measures the main interest outcome of this study.

2.4 | Sample size and sampling procedure

To evaluate the structural construct validity of the instrument, the sample consisted of 290 subjects, respecting the number of 5 to 10 subjects for each item of the instrument defined in the literature.²³ To assess the convergent construct validity of the DFS-SF, the sample calculation methodology was based on a Pearson correlation coefficient. This method assumed an 80% test power, a 5% significance level, a 0.30 estimate for the correlation coefficient, which, according to Cohen,²⁴ can be considered an average degree coefficient, and a 0.00 coefficient of correlation as null hypothesis. The calculation resulted in a minimum sample of 84 subjects.

To evaluate the responsiveness of the instrument, the methodology of a sample calculation for the paired Student's t-test was considered. This method assumed a 5% significance level, an 80% test power, and a 0.50 effect size, which, according to Cohen,²⁴ can be considered an average degree effect size. The calculation resulted in a sample of 34 subjects.

2.5 | Instruments

The DFS-SF and SF 36 instruments were applied after photographic recording of the patients' wounds to assess wound size and instrument responsiveness.

A sociodemographic and clinical questionnaire was developed specifically for the study, only to characterise the individuals. It consists in the following items: age, sex, education level, family support, duration of ulcer and diabetes, ulcer condition (active or healed), type of ulcer, and episode of ulcer recurrence.

2.5.1 | Medical outcomes study 36-item short-form health survey (SF-36)

The instrument consists of 36 items in eight domains, which address the following aspects: functional capacity; physical aspects; pain; general health; vitality; social, emotional, and mental health aspects. It presents a final score from 0 to 100, where 100 corresponds to the best health condition, and zero, the worst.²⁵ SF-36 was chosen as the 'gold standard' to measure the QOL of people with or without DM and among people with or without DM complications, as well as for DFS-SF validation in other studies.^{12,15,17} Permission to use the Brazilian version of SF-36v2 and scoring software (QualityMetric Health Outcomes™ Scoring Software 4.5.1) was obtained from QualityMetric Inc. (Lincoln, RI).

2.6 | Evaluation of measurement properties

In this study, reliability was assessed by the internal consistency of the DFS-SF instrument by determining the Cronbach's alpha coefficient and by assessing composite reliability. Convergent construct validity was performed by studying the correlation between the DFS-SF adapted instrument score and the SF 36 that evaluates QOL adapted to Brazil.²⁶

For carrying out the second-order confirmatory factor analysis (CFA), the Structural Equation Models were used, and the Partial Least Squares (PLS) were considered the estimation method.

The feasibility and acceptability of the Brazilian version of the DFS-SF were evaluated at the pre-test phase in a previous study.²⁰ Feasibility was assessed by the time spent applying the instrument and acceptability, by the percentage of unanswered items and the proportion of patients who did not respond to all items.²⁷

To assess the ceiling and floor effects, the percentage of patients who scored floor (equivalent to the 15% worst DFS-SF results) or ceiling (equivalent to the 15% best possible scale results) was evaluated.²⁸

To test responsiveness, the DFS-SF questionnaire was applied to 34 subjects within 4 weeks, when changes in tissue repair are expected after the proposed treatment.

2.7 | Wound area measurement – ImageJ Tool program

To measure the wound area, photography was used with a digital camera with 8 megapixels, f/2.4 aperture, LED flash, backlight sensor, and 3264 × 2448 pixel resolution, subsequently inserted into the computer for planimetry with Image J Features, downloaded from <https://imagej.nih.gov/ij/download.html>.

A percentage of wound area reduction of 10% to 15% per week or ≥ 50% after 4 weeks of treatment predicts healing.²⁹ According to studies, the four-week period has often been used as the time frame in which changes in wound area are evaluated.^{13,29}

3 | ETHICAL CONSIDERATIONS

All patients received information about the purpose of the study and it was guaranteed that the information would be confidential. The Helsinki Statement was followed. The study was approved by the local Research Ethics Committee (Opinion 2051777/2017).

4 | STATISTICS

The collected data were entered into a spreadsheet in Microsoft Excel for Windows and transferred to Statistical Analysis System for Windows version 9.4 (Statistical Analysis System Institute Inc., Cary, NC, 2008), SPSS version 24, and SmartPLS 3.2.1.

For sociodemographic and clinical information, descriptive analysis was carried out by frequency tables with absolute (n) and percentage (%) values for categorical variables and with position (mean, median, minimum, and maximum) and dispersion measurements (standard deviation) for continuous variables.

To analyse reliability, Cronbach's alpha (α), and composite reliability (CR) were used to estimate the internal consistency of the measurement that makes up the Brazilian version of the DFS-SF, determining $\alpha > .70$ as evidence of satisfactory internal consistency.²⁸

The Spearman correlation coefficient was used to analyse validity, which was evaluated by correlating the domain scores of the DFS-SF instrument and the total score of the Brazilian SF-36 instrument. To ensure the accuracy and generalisation of the findings, 95% confidence intervals were calculated for each of the correlation coefficients. Cohen²⁴ suggests the following classification of the correlation coefficient: 0.1 to 0.29 (weak), 0.30 to 0.49 (moderate), and greater than or equal to 0.50 (strong).

Factorial construct validity assessment of the DFS-SF instrument was performed by second-order CFA. To perform this procedure, structural equation models were used, considering the PLS as the estimation method. To implement these analyses, Smart PLS 3.2.1³⁰ was used.

The factor model analysis comprised two stages: the convergent and discriminant validity analysis of the proposed model. For the analysis of the convergent validity of the factor model, initially the results obtained from the average variance extracted (AVE) were evaluated for each of the factors of the model. This measure evaluates the proportion of variance of items, which is explained by the factor to which they belong. AVE values greater than 0.5 indicate that the model converges to a satisfactory result.³¹ Subsequently, the values obtained from the factorial load between the items and their respective factors were evaluated. Items with loads lower than 0.5 were considered as candidates to be excluded from the factorial model. Hair et al²³ define that the loads should be at least greater than 0.5 and ideally higher than 0.7. At this time, the CR for each domain was calculated to evaluate the internal consistency of the instrument. Values above 0.7 were considered satisfactory.^{31,32}

Discriminant validity was initially assessed using the Fornell-Larcker criterion.³² This method compares the square roots of AVEs with the correlation values between the factors. The model has discriminant validity if the square roots of AVEs are greater than the correlations between the factors. The other criterion considered to assess discriminant validity was the analysis of Cross Loadings. In this case, it was observed whether the factorial load of a given item was higher in the factor in which it was initially allocated than in the other factors of the model.

Ceiling and floor effects were assessed by estimating the best and worst 15% of each item of the scale.²⁸

Responsiveness was assessed by paired Student's t-test and paired Wilcoxon test³³ according to data distribution. Data distribution was verified using the Shapiro-Wilk test.

The significance level adopted for the statistical tests was P -value < 5%.

5 | RESULTS

A total of 295 subjects with DFU were recruited from July to November 2018, and, of these, 05 did not meet the eligibility criteria. Thus, 290 individuals took part in the study.

Participants had an average age of 62.78 (11.99) years, were predominantly male (62.06%), white (72.07%), living with a partner and children (30.69%), and inactive

(78.28%). The mean education level was 6.17 (3.99) years and family income, \$446.00. The diagnosis time of DM was over 15 years; ulcer duration was over 7 months, with predominance of Wagner 2 classification (48.27%); neuropathic ulcers (48.97%) characterised the second episode of foot ulcer (34.48%) (Table 1).

Cronbach's alpha showed satisfactory values for all domains of the instrument, as well as for the CR analysis, as shown in Table 2.

5.1 | Convergent validity of the DFS-SF

Significant positive correlations of moderate to strong magnitude were observed between the DFS-SF domains and the SF 36 domains (Table 3).

No significant correlations were observed between the DFS-SF **worried about ulcers/feet**, **negative emotions**, and **bothered by ulcer care** domains when correlated with the SF-36 **pain** domain; and between the DFS-SF **dependence/daily life** domain and the SF-36 **general health** domain.

5.2 | Confirmatory factor model

The structural equation model was conducted to confirm the model validity. Initially, the results obtained from AVE for each factor were evaluated. Convergent validity was verified, considering that most AVE > 0.50, except for the Physical health domain, with AVE 0.47, indicating that the model converges to a satisfactory result (Table 4).

Regarding discriminant validity, the Fornell-Larcker criterion was fully met (Table 5).

Concerning cross loading, all other those remaining from the items in the model presented higher correlations with their domain than with a different domain, and all of them were at least 0.5 (Table 6; Figures 1 and 2).

6 | DISCUSSION

This study aimed to present the measurement properties of the Brazilian version of the DFS-SF regarding reliability, convergent and discriminant validity, and CFA. According to studies, complications of diabetic foot affect the patients' QOL, with impact on social, leisure, and family life. When they evolve to limb amputation, they have to adapt to a new lifestyle, with a high financial cost to the individual and society.³⁴⁻³⁶

Measurement instruments used to assess the QOL of people with foot problems because of diabetes are

TABLE 1 Sociodemographic and clinical data (n = 290). Sorocaba, Brazil, 2018

| Variables | N | % | Mean (SD*) | Variation |
|----------------------------------|-----|-------|-------------------|-----------|
| Age | 290 | 100 | 62.78 (11.99) | 33–95 |
| Ethnicity/colour | | | | |
| White | 209 | 72.07 | | |
| Black/brown | 81 | 27.93 | | |
| Sex | | | | |
| Male | 180 | 62.06 | | |
| Female | 110 | 37.94 | | |
| Family arrangement | | | | |
| Living alone | 43 | 14.83 | | |
| Living with partner | 85 | 29.31 | | |
| Living with partner and children | 89 | 30.69 | | |
| Living with children | 57 | 19.65 | | |
| Others | 16 | 5.52 | | |
| Education level | | | 6.17 (3.99) | 0–17 |
| Family income | | | 1941.36 (1080.53) | 400–6000 |
| Occupation | | | | |
| Active | 63 | 21.72 | | |
| Inactive | 227 | 78.28 | | |
| Ulcer duration (months) | | | 7.34 (10.43) | 1–72 |
| DM time (years) | | | 15 (7.856) | 1–480 |
| Wagner classification | | | | |
| 0 | 0 | 0 | | |
| 1 | 140 | 48.27 | | |
| 2 | 109 | 37.59 | | |
| 3 | 39 | 13.45 | | |
| 4 | 2 | 0.69 | | |
| Wound type | | | | |
| Neuropathic | 142 | 48.97 | | |
| Neuroischemic | 84 | 28.97 | | |
| Non-neuropathic/non-ischemic | 64 | 22.06 | | |
| Number of ulcer episodes | | | | |
| First | 91 | 31.38 | | |
| Second | 100 | 34.48 | | |
| Third | 42 | 14.48 | | |
| >3 | 57 | 19.66 | | |

Abbreviation: DM, diabetes mellitus.

necessary for the clinical practice, to seek interventions aimed at this population.

The sociodemographic characteristics observed in our sample were similar to other DFS-SF cultural adaptation and validation studies,^{11,15-17} as well as to the original study.¹³ Data suggest that men are more likely to develop foot ulcer with a DM diagnosis older than 10 years.³⁷

Regarding the measurement properties of the Brazilian version of the DFS-SF, the results showed satisfactory reliability by internal consistency, with a Cronbach's alpha greater than 0.80 in all domains, confirming homogeneity between the items or that the evaluation of the extent of the instrument items reflect or measure the same construct.^{38,39}

TABLE 2 Analysis of reliability (internal consistency – Cronbach's alpha) and composite reliability of the DFS-SF domains (n=290). Sorocaba, Brazil, 2018

| Domains | Cronbach's alpha | Composite reliability |
|---------------------------|------------------|-----------------------|
| Bothered by ulcer care | 0.76 | 0.85 |
| Dependence/daily life | 0.77 | 0.84 |
| Leisure | 0.86 | 0.90 |
| Negative emotions | 0.89 | 0.92 |
| Physical health | 0.72 | 0.81 |
| Worried about ulcers/feet | 0.80 | 0.87 |

Abbreviation: DFS-SF, diabetic foot ulcer scale-short form.

TABLE 4 DFS-SF structural equation modelling (n=290) – Convergent validity. Sorocaba, Brazil, 2018

| Domains | AVE |
|---------------------------|------|
| Bothered by ulcer care | 0.58 |
| Dependence/daily life | 0.53 |
| Leisure | 0.64 |
| Negative emotions | 0.65 |
| Physical health | 0.47 |
| Worried about ulcers/feet | 0.63 |

Abbreviations: AVE, average variance extracted; DFS-SF, diabetic foot ulcer scale-short form.

TABLE 3 Correlation between DFS-SF and SF-36 (n = 90). Sorocaba, Brazil, 2018

| | DFS – Domains | | | | | |
|---------------------|----------------------------------|--|---|---|--|---|
| | Leisure r^* (P^\dagger) | Physical health r^* (P^\dagger) | Dependence/ daily life r^* (P^\dagger) | Negative emotions r^* (P^\dagger) | Worried about ulcers/feet r^* (P^\dagger) | Bothered by ulcer care r^* (P^\dagger) |
| Functional capacity | (.5881) | (.4696) | (.6875) | (.5101) | (.4213) | (.4851) |
| | (<.0001) | (<.0001) | (<.0001) | (<.0001) | (<.0001) | (<.0001) |
| Physical aspects | (.5188) | (.3427) | (.4998) | (.4077) | (.2990) | (.3244) |
| | (<.0001) | (.0009) | (<.0001) | (<.0001) | (.0042) | (.0018) |
| Pain | (.2204) | (.4420) | (.2414) | (.1990) | (.1269) | (.1725) |
| | (.0368) | (<.0001) | (.0219) | (.0600) | (.2333) | (.1039) |
| General health | (.2406) | (.3000) | (.1910) | (.3374) | (.3363) | (.3157) |
| | (.0224) | (.0041) | (.0713) | (.0011) | (.0012) | (.0024) |
| Vitality | (.3767) | (.4834) | (.4081) | (.4873) | (.3258) | (.3705) |
| | (.0003) | (<.0001) | (<.0001) | (<.0001) | (.0017) | (.0003) |
| Social aspects | (.4761) | (.4625) | (.4067) | (.4046) | (.3484) | (.3365) |
| | (<.0001) | (<.0001) | (<.0001) | (<.0001) | (.0008) | (.0012) |
| Emotional aspects | (.3597) | (.2812) | (.3503) | (.4015) | (.3909) | (.2738) |
| | (.0005) | (.0073) | (.0007) | (<.0001) | (.0001) | (.0090) |
| Mental health | (.4400) | (.4659) | (.4363) | (.6410) | (.3736) | (.4802) |
| | (<.0001) | (<.0001) | (<.0001) | (<.0001) | (.0003) | (<.0001) |

Abbreviation: DFS-SF, diabetic foot ulcer scale-short form.

* r = Spearman correlation coefficient; $^\dagger P$ -value.

In the original DFS-SF development and validation study,¹³ all items presented good internal consistency, with values ranging from 0.80 for **bothered by ulcer care** to 0.95 for **negative emotions**. In the second validation study of the DFS-SF, with 423 subjects, the alpha

values ranged from 0.74 for **bothered by ulcer care** to 0.94 for **negative emotions**.¹³

When comparing the results of this study with the other studies that validated the DFS-SF, we observed that our findings on internal consistency are in line

TABLE 5 DFS-SF structural equation modelling (n = 290) – Discriminant validity. Sorocaba, Brazil, 2018

| Fornell-Lacker criterion | | | | | | |
|---------------------------|------------------------|-----------------------|---------|-------------------|-----------------|---------------------------|
| | Bothered by ulcer care | Dependence/daily life | Leisure | Negative emotions | Physical health | Worried about ulcers/feet |
| Bothered by ulcer care | 0.76 | | | | | |
| Dependence/daily life | 0.58 | 0.72 | | | | |
| Leisure | 0.50 | 0.55 | 0.80 | | | |
| Negative emotions | 0.70 | 0.60 | 0.54 | 0.81 | | |
| Physical health | 0.41 | 0.49 | 0.46 | 0.45 | 0.68 | |
| Worried about ulcers/feet | 0.59 | 0.39 | 0.36 | 0.60 | 0.35 | 0.79 |

Abbreviation: DFS-SF, diabetic foot ulcer scale-short form.

TABLE 6 DFS-SF structural equation modelling (n = 290) – Cross Loadings. Sorocaba, Brazil, 2018

| | Bothered by ulcer care | Dependence/daily life | Leisure | Negative emotions | Physical health | Worried about ulcers/feet |
|--------|------------------------|-----------------------|---------|-------------------|-----------------|---------------------------|
| DFS_1a | 0.40 | 0.45 | 0.82 | 0.47 | 0.40 | 0.30 |
| DFS_1b | 0.34 | 0.37 | 0.80 | 0.37 | 0.33 | 0.25 |
| DFS_1c | 0.37 | 0.48 | 0.77 | 0.44 | 0.40 | 0.26 |
| DFS_1d | 0.43 | 0.42 | 0.83 | 0.45 | 0.37 | 0.34 |
| DFS_1e | 0.43 | 0.47 | 0.77 | 0.42 | 0.35 | 0.27 |
| DFS_2a | 0.22 | 0.29 | 0.30 | 0.29 | 0.62 | 0.20 |
| DFS_2b | 0.31 | 0.42 | 0.43 | 0.41 | 0.72 | 0.29 |
| DFS_2c | 0.28 | 0.31 | 0.22 | 0.31 | 0.68 | 0.19 |
| DFS_2d | 0.29 | 0.31 | 0.29 | 0.27 | 0.69 | 0.24 |
| DFS_2e | 0.28 | 0.34 | 0.30 | 0.25 | 0.70 | 0.25 |
| DFS_3a | 0.26 | 0.53 | 0.21 | 0.22 | 0.20 | 0.15 |
| DFS_3b | 0.37 | 0.74 | 0.31 | 0.36 | 0.33 | 0.25 |
| DFS_3c | 0.38 | 0.78 | 0.36 | 0.43 | 0.34 | 0.24 |
| DFS_3d | 0.54 | 0.74 | 0.54 | 0.56 | 0.42 | 0.38 |
| DFS_3e | 0.48 | 0.81 | 0.47 | 0.49 | 0.43 | 0.33 |
| DFS_4a | 0.54 | 0.42 | 0.39 | 0.78 | 0.37 | 0.48 |
| DFS_4b | 0.53 | 0.58 | 0.46 | 0.84 | 0.35 | 0.40 |
| DFS_4c | 0.60 | 0.58 | 0.51 | 0.87 | 0.41 | 0.49 |
| DFS_4d | 0.52 | 0.34 | 0.32 | 0.50 | 0.35 | 0.83 |
| DFS_4e | 0.40 | 0.28 | 0.22 | 0.46 | 0.24 | 0.82 |
| DFS_4f | 0.52 | 0.37 | 0.34 | 0.53 | 0.28 | 0.82 |
| DFS_4g | 0.61 | 0.49 | 0.50 | 0.84 | 0.41 | 0.53 |
| DFS_4h | 0.40 | 0.23 | 0.23 | 0.40 | 0.20 | 0.69 |
| DFS_4i | 0.48 | 0.28 | 0.26 | 0.71 | 0.27 | 0.46 |
| DFS_4j | 0.60 | 0.50 | 0.45 | 0.80 | 0.38 | 0.55 |
| DFS_5a | 0.75 | 0.55 | 0.49 | 0.61 | 0.41 | 0.46 |
| DFS_5b | 0.77 | 0.36 | 0.27 | 0.44 | 0.21 | 0.46 |
| DFS_5c | 0.73 | 0.38 | 0.35 | 0.48 | 0.33 | 0.44 |
| DFS_5d | 0.79 | 0.45 | 0.36 | 0.56 | 0.26 | 0.42 |

Abbreviation: DFS-SF, diabetic foot ulcer scale-short form.

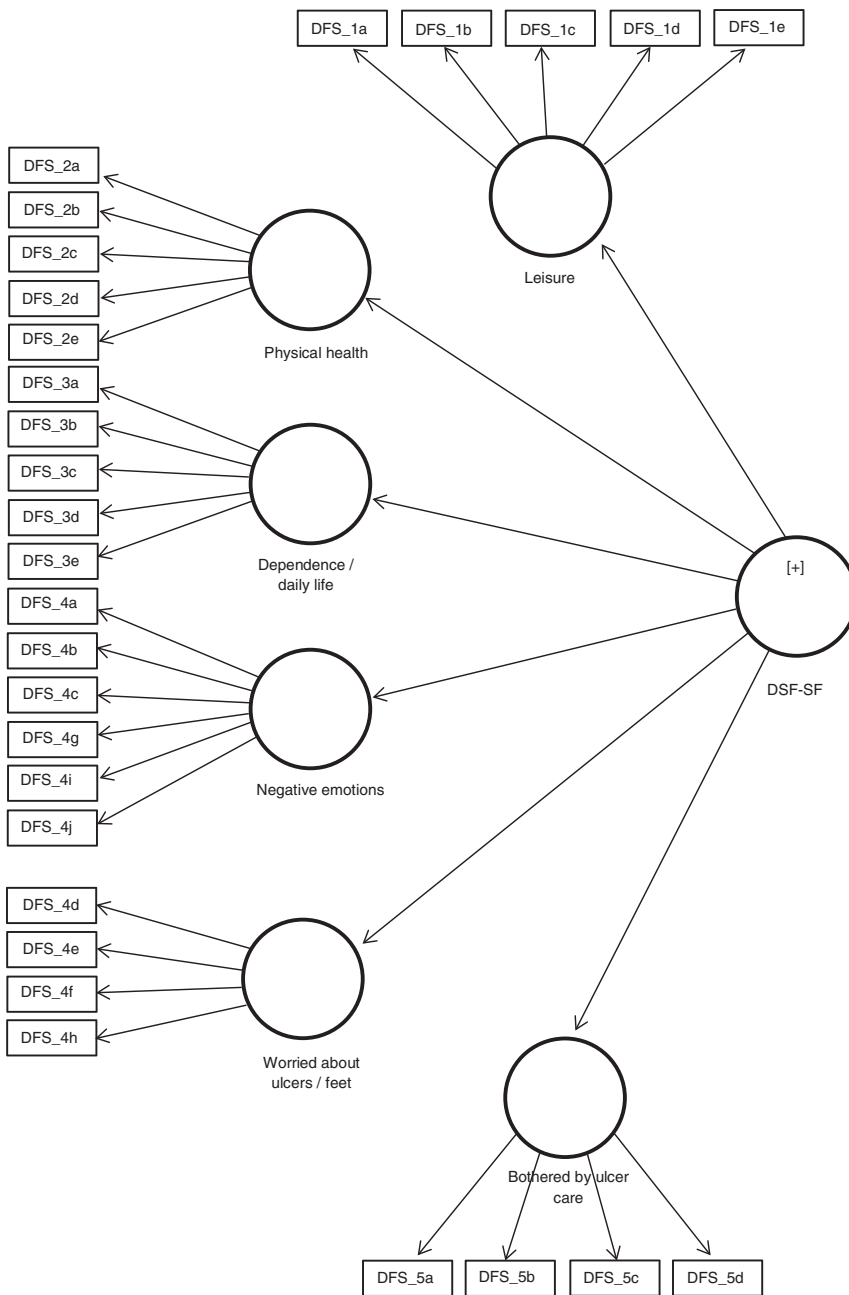


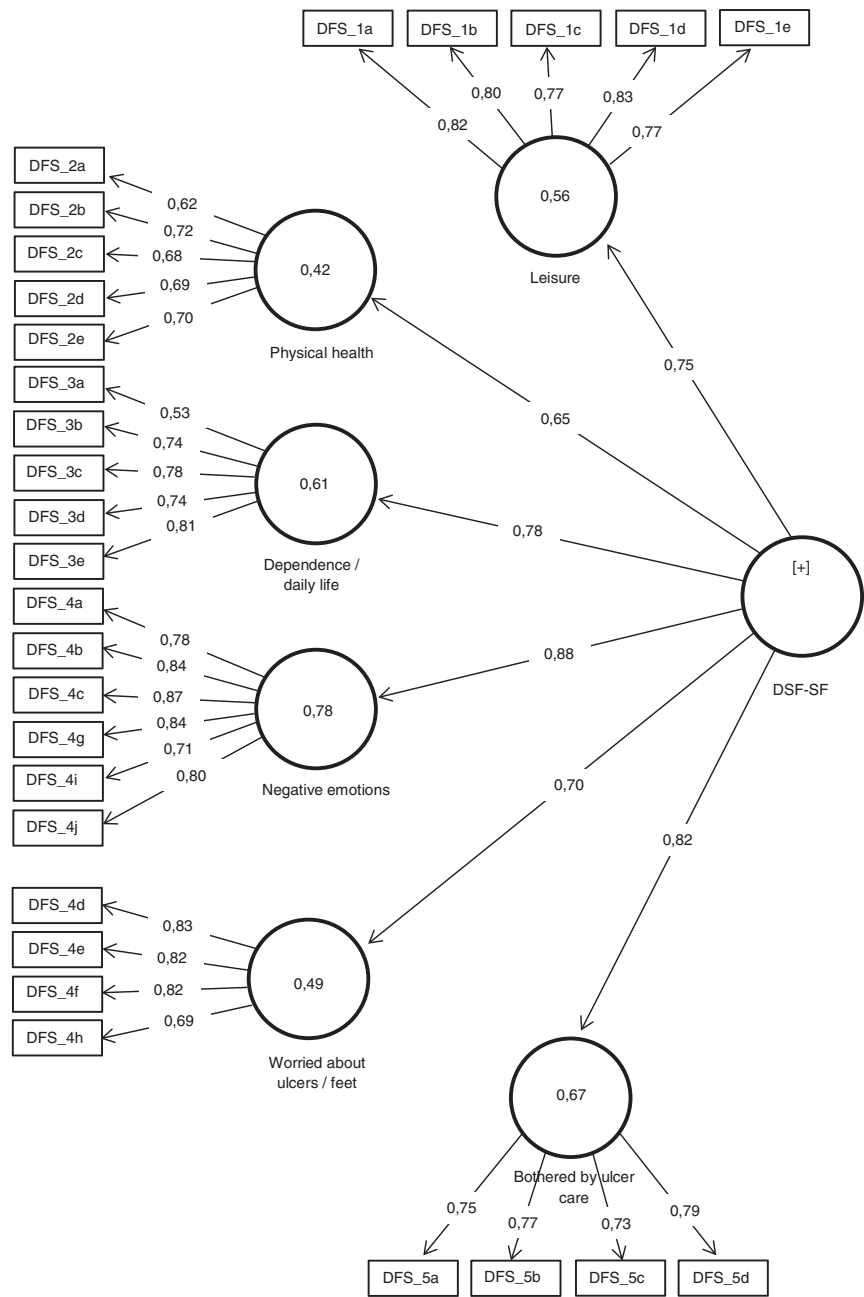
FIGURE 1 Confirmatory factor analysis: Initial DFS-SF model

with the 60-subject Chinese version – whose Cronbach's alpha showed good internal consistency, ranging from 0.80 to 0.92¹⁵ – and the 110-subject Greek version – whose Cronbach's alpha ranged from 0.79 to 0.94 on all scales.¹⁶ The DFS-SF version for the Polish population, with 212 subjects, found an internal consistency between 0.82 and 0.93.¹⁷ Recently, the Korean version presented the same reliability parameter of 0.95, while

for each of the subcategories, it ranged from 0.96 to 0.99.¹¹

In this study, CR was verified with satisfactory results, and all domain values were higher than 0.80. In the context of the assessment of structural equations, the assessment of CR is recommended, considering that it exceeds the Cronbach's alpha.²³ CR was also a measure used to verify the convergent validity of the factor model.

FIGURE 2 Confirmatory factor analysis: Final DFS-SF model



Convergent construct validity is one of the most important characteristics of a measuring instrument, because it is the degree to which a research instrument measures the construct it is intended to measure and shows how much the instrument correlates to other instruments that measure similar variables,³⁹ such as the SF-36. Thus, this study sought to correlate them with the other measurements of the same construct of the SF-36,

and positive correlations were observed, which varied mostly from moderate to strong magnitude between DFS-SF and SF-36, indicating that the domain items are similar to the constructs.

The results showed a significant convergent validity of strong correlations between the DFS-SF and SF-36 scales that are intended to measure similar constructs, such as **leisure** with **physical functioning** and **role**

physical; dependence/daily life with physical functioning, and negative emotions with mental health. However, the correlations were weak for the domains **leisure** and **bodily pain/general health, physical health and role emotional, and dependence/daily life and bodily pain.** This finding may be related to the absence of painful sensation in people with DM because of diabetic neuropathy, conceptualised as 'the presence of symptoms and/or signs of peripheral nerve dysfunction in people with DM, after excluding other causes'.⁴⁰ Peripheral neuropathy affects about half of people with DM and leads to the loss of feeling of foot protection.⁴⁰ Sensitive neuropathy impairs foot sensitivity, favouring loss of skin integrity because of the non-perception of mechanical, thermal, and overpressure traumas.^{8,41}

Considering that the interpretation of validity is relative,³⁸ we can consider that both tools have few domains that measure different characteristics, verifying the convergent construct validity with the gold standard QOL instrument. A study evaluating convergent validity using SF-36 found correlations that ranged from moderate to satisfactory magnitude with the DFS-SF domains.

During the construction and validation of the original version of the DFS-SF, the total domain scores were correlated with the SF-36 and ranged from 0.24 to 0.62 in study 1 and from 0.19 to 0.60 in study 2.¹³

In the Greek version, the Spearman correlation coefficient was similar between DFS-SF and SF-36, with moderate to strong magnitude variations, from 0.39 to 0.79 ($P < .001$). On the other hand, in the Korean version, the criterion validity presented correlation coefficients from 0.20 to 0.54 ($P < .01$) with the DFS-SF subcategories, and all correlations were statistically significant, thus demonstrating the criterion validity.¹⁶

Concerning Structural Construct Validity, it has been understood as a robust measure when using CFA, which comprises the assessment of the factorial validity of the measurement model of each construct and second order constructs. It is generally used to assess the quality of fit of a theoretical measurement model to the correlational structure between variables,⁴² thus the variables were strongly correlated with the model to which they were found, with AVE values greater than 0.5 in 5 of the DFS-SF scale items (bothered by ulcer care, dependence/daily life, leisure, negative emotions, and worried about ulcers/feet), showing that the model converges to a positive result.³¹

For the measurement model assessment, it is also common to measure the convergent and discriminant construct validity, the latter being the degree to which one construct differs from the others.²³

In this study, the model presented discriminant validity according to the Fornell-Larcker criterion, because

the square roots of AVEs were greater than the correlations between the factors; and in the analysis of Cross Loadings, the factor loading of each item was observed, according to the model. Satisfactory values regarding DFS-SF discriminant validity were also presented, because physical health and leisure affect the limitation of activities with higher or lower QOL. These observations are compatible with the questionnaire because they have discriminant validity, and a greater variation in their scores occurs only as a specific manifestation of the diabetic foot and its consequences.

Thus, the CFA showed that the Brazilian version of the DFS-SF is properly fitted to the dimensional structure of the original instrument; and the results suggest that DFS-SF measures well the constructs that affect the QOL of people with DFU. Only the original study of the creation of the DFS-SF¹³ and the Korean study¹¹ verified the CFA, unlike the other validated instrument studies, which ensures the robustness of the Brazilian version.

Regarding the ceiling and floor effects, they were not observed in this study, corroborating the studies that evaluated the ceiling and floor effect of DFS-SF.^{15,17} The ceiling effect occurs when a percentage of the population evaluated scores at the highest level of the measure, which prevents the detection of changes in situations of health improvement. In turn, the 'floor' effect occurs when a percentage of subjects scores at the lowest level of the measurement, which prevents the detection of changes in worsening situations.²⁸

Regarding responsiveness, a significant decrease in wound area was found, from 6.13 to 4.26. The instrument was not able to identify the difference observed in the area, which may be explained by the time interval of 4 weeks, a period perhaps insufficient to detect changes in OoL, although studies suggest this time to detect healing changes.^{13,29} DM causes delayed tissue repair, developing a chronic wound that does not heal at the appropriate speed because of cellular and molecular changes involved in the healing process,^{41,43-45} which may cause increased morbidity and mortality rates because of these complications.

The strength of this study is that the availability of a valid questionnaire with reliable measurement properties strengthens the management of care for patients with wound and DM to provide improvements in care.

Data collection in only one reference centre for diabetic foot care was a limitation of this study. Adding other collection sites would improve external validity, considering that Brazil is a country with wide territorial extension and different cultures. Because questionnaires were always applied in the same order and considering that no order effects were considered as a bias, this is also a limitation.

6.1 | Implications for clinical practice

Managing the care of people with diabetic foot involves periodic assessment of all factors involving wound healing, requiring changes in therapeutic treatment and on-going recommendations. Knowing the impact that DFU has on the individual's QOL will contribute to targeted interventions that collaborate for adapting a new life situation for each individual.

A valid questionnaire with reliable measurement properties strengthens these measures and can help managers prioritise research and identify knowledge gaps in the care for people with diabetic foot to provide improvements in care.

7 | CONCLUSIONS

The Brazilian version of the DFS-SF has shown evidence of validity and reliability, proving that it is a robust tool to assess the QOL of people with diabetic foot in the Brazilian population.

ACKNOWLEDGEMENTS

The authors thank the staff of the Wound and Diabetic Foot Ulcer Clinic and all the participants for their kind contribution in the data collection stage.

ORCID

Uiara A. de Oliveira Kaizer  <https://orcid.org/0000-0002-9115-8043>

Maria H. de Melo Lima  <https://orcid.org/0000-0001-6521-8324>

REFERENCES

- Bakker K, Apelqvist J, Lipsky BA, Van Netten JJ, International Working Group on the Diabetic Foot. Guidance on the management and prevention of foot problems in diabetes. Definitions & criteria. *Diabetes Metab Res*. 2016;32:2-6. <https://doi.org/10.1002/dmrr.2694> <http://iwgdf.org/guidelines/definitions-criteria-2015/>.
- Lazzarini PA, Pacella RE, Armstrong DG, van Netten JJ. Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabet Med*. 2018;23:1297-1299.
- Jupiter DC, Thorud JC, Buckley CJ, Shibuya N. The impact of foot ulceration and amputation on mortality in diabetic patients. I: from ulceration to death, a systematic review. *Int Wound J*. 2016;13(5):892-903.
- International Diabetes Federation. *IDF Diabetes Atlas*. 8th ed. Brussels, Belgium: International Diabetes Federation; 2017.
- Sinwar PD. The diabetic foot management—recent advance. *Int J Surg*. 2015;15:27-30.
- Ministério da Saúde. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. *Manual do pé diabético: estratégias para o cuidado da pessoa com doença crônica*. Brasília, Brazil: Ministério da Saúde; 2016.
- Armstrong DG, Boulton AJ, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med*. 2017;376:2367-2375.
- International Diabetes Federation. *Clinical Practice Recommendation on the Diabetic Foot: A guide for health care professionals*. International Diabetes Federation; 2017. Brussels, Belgium: Elsevier Ireland Ltd
- Upton D, Upton P, Alexander R. What about wellbeing? *J Wound Care*. 2014;23(1):14-17.
- Hoban C, Sareen J, Henriksen CA, Kuzyk L, Embil JM, Trepman E. Mental health issues associated with foot complications of diabetes mellitus. *Foot Ankle Surg*. 2015;21(1):49-55.
- Lee YN. Translation and validation of the Korean version of the diabetic foot ulcer scale-short form. *Int Wound J*. 2019;16 (Suppl 1):3-12. <https://doi.org/10.1111/iwj.13025>.
- Hogg FRA, Peach G, Price P, Thompson MM, Hincliffe RJ. Measures of health-related quality of life in diabetes-related foot disease: a systematic review. *Diabetologica*. 2012;55(3):552-565. <https://doi.org/10.1007/s00125-011-2372-5>.
- Bann CM, Fehnel SE, Gagnon DD. Development and validation of the dia-betic foot ulcer scale-short form (DFS-SF). *Pharmacoeconomics*. 2003;21:1277-1290.
- Abetz L, Sutton M, Brady L, McNulty P, Gagnon DD. The diabetic footulcer scale (DFS): a quality of life instrument for use in clinical trials. *Prac Diabetes Int*. 2002;19:167-175.
- Hui LF, Yee-Tak Fong D, Yam M, Yuk IW. Translation and validation of the Chinese diabetic foot ulcer scale-short form. *Patient*. 2008;1:137-145.
- Kontodimopoulos N, Veniou A, Tentolouris N, Niakas D. Validity and reli-ability of the Greek version of the diabetic foot ulcer scale—short form (DFS-SF). *Hormones (Athens)*. 2016;15:394-403.
- Macioch T, Sobol E, Krakowiecki A, Mrozikiewicz-Rakowska B, Kasproicz M, Hermanowski T. Health related quality of life in patients with diabetic foot ulceration—translation and polish adaptation of diabetic foot ulcer scale short form. *Health Qual Life Outcomes*. 2017;15:15.
- Streiner DL, Kottner J. Recommendations for reporting the results of studies of instrument and scale development and testing. *J Adv Nurs*. 2014;70(9):1970-1979. <https://doi.org/10.1111/jan.12402>.
- Polit DF, Beck CT. *Fundamentos de Pesquisa em enfermagem: avaliação de evidências para as práticas da enfermagem*. 7th ed. Porto Alegre, Brazil: Artmed; 2011.
- Kaizer UAO, Domingues EAR, Barbosa ACH, Rodrigues RCM, Cornélio ME. e Thais Moreira São-João TM. Adaptação Cultural Do Diabetic Foot Ulcer Scale-Short Form (DFS-SF) Para a língua Portuguesa do Brasil. *Congresso Científico da Faculdade de Enfermagem da UNICAMP*, no.1 Vol. 6; 2019. <https://econtents.bc.unicamp.br/eventos/index.php/ccfenf/article/view/18>. Accessed November 13, 2018.
- Mapi Research Trust. *Linguistic validation guidance of a clinical outcome assessment (COA)*. Lyon, France: Mapi; 2016.
- Pfeiffer E. A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. *J Am Geriatr Soc*. 1975;23(10):443-451.
- Hair Junior JF, Black WC, Babin BJ, Anderson RE, Tathan RL. *Análise multivariada de dados*. 6th ed. Bookman: Porto Alegre, Brazil; 2009.

24. Cohen J. The significance of a product moment rs. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. New Jersey: Lawrence Erlbaum Associates; 1988:75-108.
25. Ware JE Jr, Sherbourne CD. The MOS 36 ItemShort form health survey (SF 36). I. Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.
26. Ciconelli RM, Ferraz MB, Santos W, Meinão I, Quaresma MR. Tradução para a língua portuguesa e validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). *Rev Bras Reumatol*. 1999;39(3):143-150.
27. Aaronson N, Alonso J, Burnam A, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res*. 2002;11(3):193-205.
28. Terwee CB, Bot SDM, Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.
29. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American podiatric medical association and the Society for Vascular Medicine. *J Vasc Surg*. 2016;63:3S-21S.
30. Ringle CM, Wende S, Becker JM. *SmartPLS 3*. Boenningstedt, Germany: SmartPLS GmbH; 2015 <http://www.smartpls.com>.
31. Hair Junior JF, Hult GTM, Ringle CM, Sarstedt M. *A primer on partial least squares structural equation Modeling (PLS-SEM)*. SA Publishing: Los Angeles, CA; 2014.
32. Fornell C, Larcker DF. Evaluating structural equation models with unobservable variable and measurement error. *J Market Res*. 1981;18(1):39-50.
33. Pagano M, Gauvreau K. *Princípios de Bioestatística*. São Paulo, Brazil: Ed. Thomson; 2004.
34. Goodridge D, Trepman E, Embil JM. Health-related quality of life in diabetic patients with foot ulcers: literature review. *J Wound Ostomy Continence Nurs*. 2005;32:368-377.
35. Goodridge D, Trepman E, Sloan J, et al. Quality of life of adults with unhealed and healed diabetic foot ulcers. *Foot Ankle Int*. 2006;27:274-280.
36. Fejfarová V, Jirkovská A, Dragomirecká E, et al. Does the diabetic foot have a significant impact on selected psychological or social characteristics of patients with diabetes mellitus? *J Diabetes Res*. 2014;2014:371938. <https://doi.org/10.1155/2014/371938>.
37. Bresäter LE, Welin L, Romanus B. Foot pathology and risk factors for diabetic foot disease in elderly men. *Diabetes Res Clin Pract*. 1996;32:103-109.
38. Polit DF, Beck CT. *Nursing research: generating and assessing evidence for nursing practice*. Philadelphia, PA: Wolters Kluwer; 2016.
39. Heale R, Twycross A. Validity and reliability in quantitative studies. *Evid Based Nurs*. 2015;18(3):66-67.
40. Boulton AJ, Vinik AI, Arezzo JC, et al. Diabetic neuropathies. *Diabetes Care*. 2005;28(4):956-962.
41. International Working Group on the Diabetic Foot Guidelines Editorial Board. IWGDF Definitions and Criteria. 2019. <https://iwgdfguidelines.org/definitions-criteria/>. Accessed September 20, 2019.
42. Marôco J. *Análise de Equações Estruturais: Fundamentos Teóricos, Software e Aplicações*. Pêro Pinheiro; 2010.
43. Sibbald RG, Woo KY. The biology of chronic foot ulcers in persons with diabetes. *Diabetes/Metab Res Rev*. 2008;24(1):2S25-S30.
44. Lima MHM, Araujo E. Diabetes mellitus e o processo de cicatrização cutânea. *Cogitare enferm*. 2013;18:170-172.
45. Lima MHM et al. Topical insulin accelerates wound healing in diabetes by enhancing the AKT and ERK pathways: a double-blind placebo-controlled clinical trial. *PLoS ONE*. 2012;7(5):e36974.

How to cite this article: de Oliveira Kaizer UA, Alexandre NMC, Rodrigues RCM, Cornélio ME, de Melo Lima MH, São-João TM. Measurement properties and factor analysis of the Diabetic Foot Ulcer Scale-short form (DFS-SF). *Int Wound J*. 2020;17:670-682. <https://doi.org/10.1111/iwj.13310>