Cross-Sectional Study

A Cross-Sectional, Multicenter Study Examining the Validation and Adaptation of the Chinese ROWAN Foot Pain Assessment Questionnaire

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Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 12-21-2021
Revised manuscript received: 01-03-2022
Accepted for publication: 02-25-2022

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Background: The 39-item ROwan Foot Pain Assessment Questionnaire (ROFPAQ) has affective, cognitive, and sensory dimensions to evaluate chronic foot pain. However, to date, the ROFPAQ has only been validated in English and Spanish versions. A simplified Chinese version of ROFPAQ is still not available, even though China has a large population of patients with foot pain.

Objective: This study's aim was to translate the ROFPAQ into a Chinese version and assess its reliability and validity in Chinese patients with chronic foot pain.

Study Design: A cross-sectional, multicenter descriptive study.

Setting: This study took place at the Chinese PLA General Hospital, PLA Strategic Support Force Characteristic Medical Center and Wenzhou integrated traditional Chinese and Western Medicine Hospital Affiliated to Zhejiang traditional Chinese Medicine University.

Methods: The ROFPAQ-C (Chinese) was developed by a forward/backward translation protocol and cross-cultural adaptation from the United Kingdom to China, and from English to Chinese Putonghua. A total of 194 patients from 3 centers with chronic foot pain were recruited for test-retest measures from July 2020 though September 2021.

Results: Adequate internal consistencies (Cronbach's α) in 3 domains ranged from 0.875 to 0.799 for the cognitive, from 0.795 to 0.629 for the affective, and from 0.801 to 0.811 for the sensory, as well as for the total score from 0.880 to 0.815. Adequate test-retest reliability by intraclass correlation coefficient (ICC) were shown in the cognitive 0.712 (95% CI 0.636 to 0.775), the affective 0.929 (95% CI 0.906 to 0.946), the sensory 0.753 (95% CI 0.685 to 0.808), and the total score 0.932 (95% CI 0.910 to 0.948). Adequate item-total correlations were shown for the cognitive from 0.848 to 0.825, the affective from 0.918 to 0.908, and the sensory from 0.943 to 0.855.

Limitations: The original ROFPAQ with 39 items was developed from a podiatry department of the health care national service of the United Kingdom.

Conclusions: The ROFPAQ-C can be used as a valid and reliable tool for chronic foot pain in the Chinese population.

Key words: Chronic pain foot, ROFPAQ, health impact assessment, validation studies

Pain Physician 2022: 25:401-408

Foot pain is common in the general population and among specific occupational groups. Almost 25% of the adult population and approximately 10% of adolescents aged from 12 to 19 years report having foot pain (1,2). Frequent foot pain is seen in up to 24% in adults aged 45

years and older (3). Almost 40% of runners sustain a foot or ankle injury each year (4,5). Pain prevalence appears to be higher in elderly people with specific foot diseases (6). Furthermore, consultation rates for foot and/or ankle musculoskeletal complaints rise to 8% in primary care (3,6). Foot pain is identified as an independent risk factor for impaired balance, increased risk of falling (7,8), locomotor disability (9), and functional activities of daily living among older people (10). Foot pain underlies the need for having an instrument capable of measuring the condition and evaluating the effect of treatment (11). Clinimetric tools such as the Manchester Foot Pain and Disability Index and the Foot Function Index have been validated and translated for measuring foot health (12-16). However, these tools lack adequate evaluation of the subjective measure of pain.

The ROwan Foot Pain Assessment Questionnaire (ROFPAQ) is designed for chronic foot pain with 3 domains about sense, affection, and cognition. The ROFPAQ is a patient-centered scale, incorporating the views and perspectives of patients with patient-reported outcome measures. The ROFPAQ was applied in the United Kingdom and Spain with an appropriate concurrent validity (17,18).

Excellent concordance was shown in previous studies between the ROFPAQ and Foot Function Index (13,18). Entailing 6 focus subscales and 2 semistructured interviews with patients, the ROFPAQ has good evidence of content validity and patient-reported outcome measures properties. Therefore, the ROFPAQ could effectively reflect a patient's perceptions of foot health and quality of life (17,18).

China has the largest population worldwide, however, only 17% report that their quality of life is affected by pain and discomfort. In terms of this proportion being far lower than those obtained in other studies, it may be inferred that foot complaints are being neglected by the Chinese population (19). Currently, the ROFPAQ has not been adapted or validated in China. Therefore, this study's aim was to carry out the adaptation and test-retest reliability of a Chinese Putonghua version of ROFPAQ (ROFPAQ-C).

Methods

Ethical Approval

This study was approved by the Human Ethics Committee of the Chinese PLA General Hospital. All patients were informed about the study and voluntarily signed a written consent. The study was carried out according to the Declaration of Helsinki.

Study Design

A cross-sectional and multicenter descriptive study was conducted according to the instructions of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) from July 2020 through September 2021 (Fig. 1) (20). Cross-cultural adaptation and test-retest reliability were carried out with the ROFPAQ (21).

Translation and Adaptation

The protocol recommended by the American Association of Orthopedic Surgeons was performed for the procedure of translation and cross-cultural adaptation of the original ROFPAQ from the United Kingdom to China (22,23). First, the original ROFPAQ was translated into a Chinese Putonghua version by 2 native Chinese who are bilingual in Chinese and English (forward), one of whom was blind to the purpose of this study. Second, the 2 versions of the ROFPAQ were reconciled into an integrated version. Third, 2 English speakers proficient at Chinese each translated the integrated version into English separately (backward). Fourth, an expert panel comprised of one pain physician, one orthopedic physician, one professor of statistics, and one English professor, evaluated all the translation results and reports and worked out a prefinal version of the ROFPAQ-C. Fifth, Chinese outpatients with chronic foot pain were recruited to test the acceptability of the prefinal ROFPAQ-C. The expert panel reached a decision on the final version of the ROFPAQ-C according to the feedback.

Test-Retest Reliability and Sample Size

The sample was purposely chosen to be heterogeneous to test the ROFPAQ-C for various types of foot conditions (13). The item scores were collected from the total and each domain: affective, cognitive, and sensory of the ROFPAQ-C (17). The data for age, gender, profession, study degree, and foot conditions were obtained by self-report. A preliminary test was conducted and indicated the ROFPAQ-C questionnaire was relatively practicable for patients. Furthermore, concerning sample sizes in other available studies (17,24), and an error α of 0.05, an error β of 20%, a 95% CI for a 2-tailed test, and an intraclass correlation coefficient (ICC) of 0.40, a final sample size of more than 60 for one center and 180 for 3 centers was deemed to be adequate (13,23,24).

Patients

Patients were recruited from the rehabilitation department of the First Medical Center of Chinese PLA General Hospital (Center 1), PLA Strategic Support Force Characteristic Medical Center (Center 2) and Wenzhou integrated traditional Chinese and Western Medicine Hospital Affiliated to Zhejiang traditional Chinese Medicine University (Center 3). patients were successive patients treated for chronic foot pain at the 3 centers from July 2020 through September 2021. The inclusion criteria were as follows: chronic foot pain for more than 3 months and the ability to read and write Chinese. The exclusion criteria were as follows: cognitive or psychiatric disorders; neuropathy; systemic disorders or painkiller abuser; or refusal to follow the study instructions. Before they completed test-retests of the ROFPAQ-C, patients did not receive any treatment.

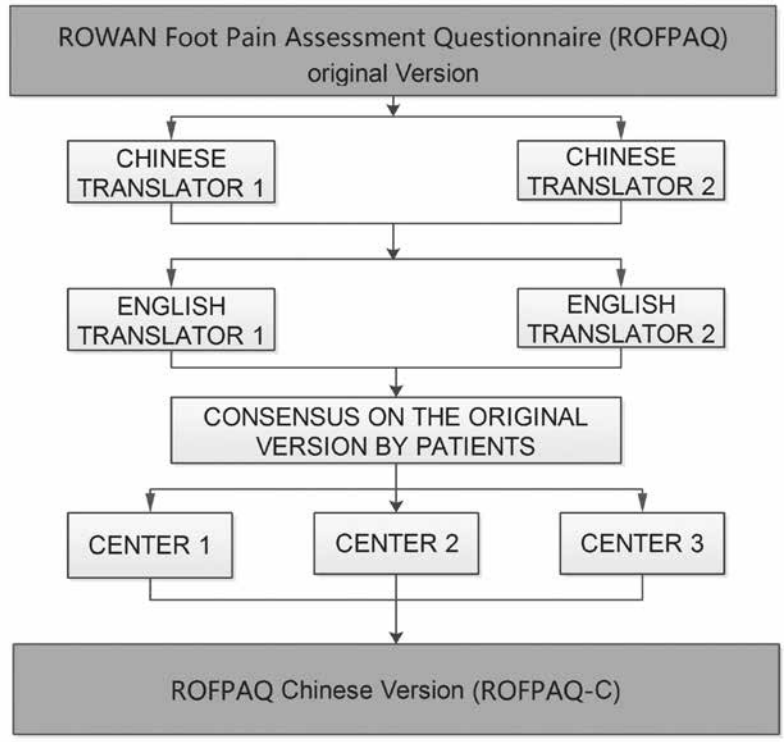

Fig. 1. *ROFPAQ-C cross-cultural adaptation process.*

Statistical Analysis

For statistical analyses, data were analyzed using SPSS version 26 (IBM). All variables were tested for normal distribution with the Kolmogorov–Smirnov test, and data were considered normally distributed if $P > 0.05$. All the data were $P < 0.05$ in overall and each domain during the test and retest studies, and were taken as a nonnormal distribution. Therefore, the nonparametric paired Wilcoxon's signed rank test was used to analyze the distribution to compare systematic differences between the test and retest. Independent Student's t tests were performed to test statistical significance of differences with data showing a normal distribution. Descriptive statistics were calculated for all variables and presented as mean (SD), minimum–maximum or frequency (percentage). Cronbach's α was used to describe the internal consistency of all items on a scale. The Cronbach's α and ICC were selected to analyze the internal consistency, correlation, and reliability of the overall score and each domain score, respectively.

Internal consistency was assessed using Cronbach's α. Cronbach's α from 0.70 to 0.95 was considered to be good (25). Correlations of all items with the total scores and Cronbach's α with the absence of each item was examined.

ICC and the Cronbach's α with a 95% CI were taken to analyze the reliability and internal consistency of the total score and each domain score. A two-way random effects model (2.1), single measures, absolute agreement, and ICC were used to describe concordance between the test and retest. ICC values were expressed with a Landis and Koch benchmark score: inferior (< 0.40), moderate (0.41-0.60), good (0.61-0.80), and excellent (> 0.80) (26,27), while Bland–Altman plots were created to assess agreement and heteroscedasticity (28).

Results

Patients

A total of 194 patients (102 men and 92 women) from 3 centers were selected according to the inclusion and exclusion criteria. The demographic and clinical data were collected, as shown in Table 1.

Translation

There was good agreement between ROFPAQ and ROFPAQ-C (Appendices S1, S2). The forward translations were carried out with only a few discrepancies and, similarly, the back translations showed the same result in most items between the 2 versions. Cognitive interviews with patients indicated good understanding and comprehension of the ROFPAQ-C.

Test-Retest Analyses

Each domain and total scores of test-retests, reliability, and systematic differences of the ROFPAQ-C in the 3 centers are listed from Table 2 to Table 4. For total results of the 3 centers (Table 5), the adequate item-total correlations were shown in the cognitive domain (0.742-0.619), the affective domain (0.809-0.793), and the sensory domain (0.834-0.638). Internal consistency of Cronbach's α was adequate from the 3 domains of cognitive (0.875-0.799), affective (0.795-0.629), and sensory (0.801-0.811) to the total domain (0.875-0.799). Test-retest reliability ICC was good for the total scores 0.932 (95% CI 0.910 to 0.948), and the 3 domains of cognitive 0.712 (95% CI 0.636 to 0.775), affective 0.929 (95% CI 0.906 to 0.946) and sensory 0.753 (95% CI 0.685 to 0.808). There was little possibility of systematic differences for each domain with $P > 0.05$, and the total with $P = 0.157$ between test 101.36 ± 22.77 (95% CI 98.14 to 104.58) and retest 102.38 ± 23.08 (95% CI 99.12 to 105.65). Bland and Altman plots showed no statistically significant or relevant differences between test

Table 1. *Demographic and clinical characteristics (n = 194).*

Variables	Center 1 (n = 66)	Center 2 (n = 65)	Center 3 (n = 63)	*P*
Women	30 (45.45%)	33 (50.77%)	29 (46.03%)	N/A
Age (years)	42.05 ± 12.12	42.15 ± 14.27	38.05 ± 12.61	0.080
Height (m)	1.69 ± 0.10	1.68 ± 0.09	1.68 ± 0.06	0.937
Weight (kg)	70.52 ± 10.61	69.65 ± 10.78	71.94 ± 12.09	0.594
BMI (kg/m^2)	24.89 ± 3.47	24.66 ± 3.66	25.41 ± 3.94	0.588
Educational level				
Primary schools	11 (16.67%)	13 (20.00%)	12 (19.05%)	N/A
Secondary School	30 (45.45%)	25 (38.46%)	29 (46.03%)	N/A
High school	13 (19.70%)	14 (21.54%)	12 (19.05%)	N/A
College degree	12 (18.18%)	13 (20.00%)	10 (15.87%)	N/A
Occupation				
Work	43 (65.15%)	41 (63.08%)	45 (71.43%)	N/A
Retired	19 (28.79%)	20 (30.77%)	15 (23.81%)	N/A
Unemployed	3 (4.55%)	4 (6.15%)	2 (3.17%)	N/A
Student	1 (1.52%)	0 (0.00 %)	1 (1.59%)	N/A
Pain Duration				
Between 3 and 6 months	22 (33.33%)	16 (24.62%)	23 (36.51%)	N/A
> 6 months	44 (66.67%)	49 (75.38%)	40 (63.49%)	N/A
Diagnosis				
Osteoarthritis	29 (43.94%)	27 (41.54%)	20 (31.75%)	N/A
Posttraumatic arthritis	12 (18.18%)	15 (23.08%)	17 (26.98%)	N/A
Impingement syndrome	7 (10.61%)	5 (7.69%)	9 (14.29%)	N/A
Malformation	6 (9.09%)	8 (12.31%)	5 (7.94%)	N/A
Rheumatoid arthritis	5 (7.58%)	3 (3.08%)	5 (7.94%)	N/A
Chron N/A ic fracture	4 (6.06%)	3 (4.62%)	1 (1.59%)	N/A
Spondyloarthritis	1 (1.56%)	0 (0%)	1 (1.59%)	N/A
Idiopathic pain	2 (3.03%)	4 (6.15%)	5 (7.94%)	N/A

Abbreviations: BMI; body mass index. $P < 0.05$ was considered statistically significant.

and retest from each domain scores to the total scores (Fig. 2). Similarly, of the ROFPAQ-C questionnaire in the 3 centers, an adequate internal consistency from the results of reliability, test-retest, and systematic differences by domains and total scores are shown in Table 2 and Table 4, respectively.

Discussion

This study applied standardized methods for cross-cultural adaptation and validation of outcome measures to develop a Chineseversion of the ROFPAQ. The original ROFPAQ and ROFPAQ-S were validated in the United Kingdom and Spain, respectively, with a high reliability (21,24). The ROFPAQ translated well into Chinese without needing significant changes. International recommended guidelines were implemented in this study (22,23). The procedure of translation and adaptation was conducted with rigorous methodology to ensure the content of the original ROFPAQ was reflected in the ROFPAQ-C without deviation.

Chinese cross-cultural adaptation and validation

Table 2. *Center 1 results of test-retest of the Chinese ROWAN Questionnaire (n = 66).*

Test Retest	Mean ± SD (95% CI)	Item-Total Correlation	α if Item Removed	Reliability ICC (95% CI)	Systematic Differences (*P* value*)
Cognitive	30.77 ± 7.25 (28.99 to 32.56)	0.887	0.925	0.781 (0.665 to 0.860)	0.406
CognitiveR	31.91 ± 8.91 (29.72 to 34.10)	0.641	0.740		
Affective	31.76 ± 8.01 (29.79 to 33.73)	0.907	0.898	0.940 (0.903 to 0.963)	0.441
AffectiveR	32.04 ± 8.16 (30.03 to 34.04)	0.776	0.632		
Sensory	44.85 ± 10.19 (42.34 to 47.35)	0.907	0.923	0.778 (0.662 to 0.858)	0.732
SensoryR	44.59 ± 11.79 (41.69 to 47.49)	0.592	0.839		
Total	107.38 ± 24.35 (101.39 to 113.36)	N/A	N/A	0.934 (0.894 to --0.959)	0.328
TotalR	108.54± 24.74 (102.46 to 114.62)	N/A	N/A		

Abbreviations: N/A, not applicable; SD, standard deviation; ICC, intraclass correlation coefficient. *Wilcoxon matched-pair signed-rank test. *P* value of < 0.05 is considered statistically significant.

Table 3. *Center 2 results of test-retest of the Chinese ROWAN Questionnaire (n = 65).*

Test Retest	Mean ± SD (95% CI)	Item-Total Correlation	α if Item Removed	Reliability ICC (95% CI)	Systematic Differences (*P* value*)
Cognitive	31.03 ± 5.73 (29.61 to 32.45)	0.727	0.682	0.527 (0.326 to 0.682)	0.221
CognitiveR	31.83 ± 6.89 (30.22 to 33.44)	0.673	0.738		
Affective	31.14 ± 6.72 (29.47 to 32.80)	0.661	0.728	0.767 (0.645 to 0.851)	0.251
AffectiveR	31.05± 5.54 (29.67 to 32.42)	0.801	0.610		
Sensory	42.54 ± 10.81 (39.86 to 45.22)	0.731	0.752	0.635 (0. 464 to 0.761)	0.184
SensoryR	43.98 ± 9.02 (41.75 to 46.22)	0.567	0.886		
Total	104.97 ± 19.06 (100.25 to 109.69)	N/A	N/A	0.866 (0.789 to 0.916)	0.121
TotalR	107.32 ± 20.30 (102.29 to 112.35)	N/A	N/A		

Abbreviations: N/A, not applicable; SD, standard deviation; ICC, intraclass correlation coefficient. *Wilcoxon matched-pair signed-rank test. *P* value of < 0.05 is considered statistically significant.

Table 4. *Center 3 results of test-retest of the Chinese ROWAN Questionnaire (n = 63).*

Test Retest	Mean ± SD (95% CI)	Item-Total Correlation	α if Item Removed	Reliability ICC (95% CI)	Systematic Differences (*P* value*)
Cognitive	29.30 ± 6.76 (27.60 to 31.00)	0.627	0.963	0.751 (0.619 to 0.842)	0.409
CognitiveR	28.86 ± 7.69 (26.92 to 30.79)	0.504	0.854		
Affective	22.95± 7.02 (21.18 to 24.71)	0.903	0.744	0.948 (0.915 to 0.968)	0.467
AffectiveR	23.19± 6.92 (21.45 to 24.93)	0.822	0.581		
Sensory	38.83 ± 8.87 (36.59 to 41.06)	0.873	0.771	0.809 (0.703 to 0.880)	0.555
SensoryR	39.17 ± 10.18 (36.61 to 41.74)	0.684	0.714		
Total	91.08 ± 20.62 (85.89 to 96.27)	N/A	N/A	0.908 (0.853 to 0.944)	0.916
TotalR	91.22 ± 20.20 (85.88 to 96.56)	N/A	N/A		

Abbreviations: N/A, not applicable; SD, standard deviation; ICC, intraclass correlation coefficient. *Wilcoxon matched-pair signed-rank test. *P* value of < 0.05 is considered statistically significant.

Table 5. *Total results of Centers 1-2-3 test-retest of the Chinese ROWAN Questionnaire (n = 194).*

Test Retest	Mean ± SD (95% CI)	Item-Total Correlation	α if Item Removed	Reliability ICC (95% CI)	Systematic Differences (*P* value*)
Cognitive	30.38 ± 6.62 (29.44 to 31.32)	0.742	0.875	0.712 (0.636 to 0.775)	0.332
CognitiveR	30.89 ± 7.85 (29.78 to 32.00)	0.619	0.799		
Affective	28.91 ± 8.12 (27.76 to 30.06)	0.809	0.795	0.929 (0.906 to 0.946)	0.888
AffectiveR	28.86 ± 8.27 (27.69 to 30.03)	0.793	0.629		
Sensory	42.12 ± 10.25 (40.67 to 43.57)	0.834	0.801	0.753 (0.685 to 0.808)	0.363
SensoryR	42.63 ± 10.63 (41.12 to 44.13)	0.638	0.811		
Total	101.36 ± 22.77 (98.14 to 104.58)	N/A	N/A	0.932 (0.910 to 0.948)	0.157
TotalR	102.38 ± 23.08 (99.12 to 105.65)	N/A	N/A		

Abbreviations: N/A, not applicable; SD, standard deviation; ICC, intraclass correlation coefficient. *Wilcoxon matched-pair signed-rank test. *P* value of < 0.05 is considered statistically significant.

of foot health-related questionnaires were previously carried out with impressive results (29,30). The Chinese version of the Foot Function Index is a reliable tool to evaluate foot disorders with a very good internal consistency (30). The Chinese version of the Manchester Foot Pain and Disability Index is a powerful tool to measure foot pain, impairment, and disability among Chinese-speaking people with inflammatory arthritis (29). As a large country with a population of more than 1.4 billion, there are great regional and cultural differences between the north and the south of China. Therefore, the ROFPAQ-C measurements were conducted in multiple centers in different geographical regions in China. The test-retest results of the ROFPAQ-C in the 3 centers (Table 5) showed good internal consistencies from domains (ICC from 0.712 to 0.925) and total scores (ICC = 0.932). Moreover, the independent analysis of the questionnaire test-retests of the three centers showed similar results (Table 2 to Table 4). This study indicated that the further research using the ROFPAQ-C will facilitate a better understanding of chronic foot pain involvement in China and will provide an opportunity for wider international culture exchanges.

This study has a number of limitations. First, successive enrollment was used to recruit patients from the departments of rehabilitation in large comprehensive tertiary hospitals in China, whereas the original ROFPAQ was developed from a podiatry department of the health care national service of the United Kingdom, thus these findings may not be generalizable to patients of the broader community

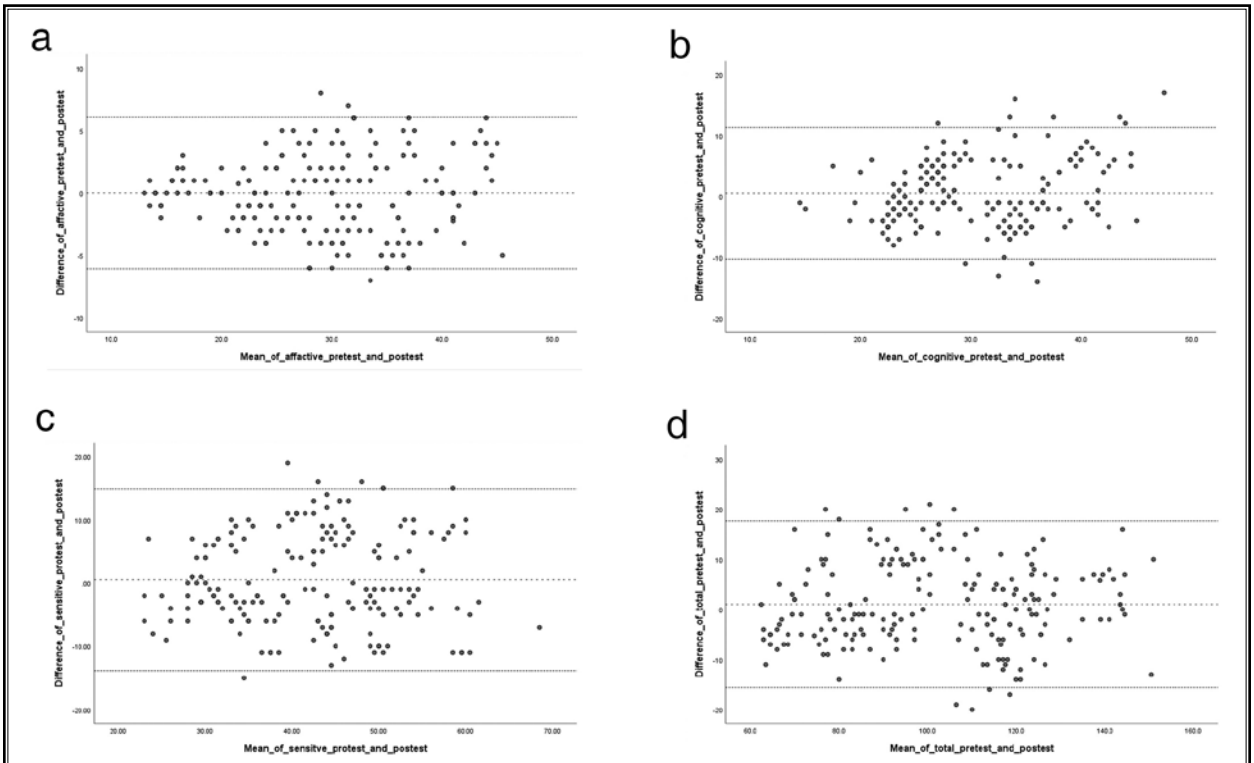

Fig. 2. *The agreement between test and retest for the individual subscales and the total score in Bland–Altman plots. No statistically significant differences from test to retest were shown (a, b, c and d).*

of medical institutions. Second, there were differences in the composition of patients between this study and the previous 2 studies. The patients we recruited had various types of chronic foot pain coexistent with various other diseases, whereas previous studies using the ROFPAQ focused on chronic foot pain in the health care service or at podiatry and physiotherapy institutions (17,24). Third, age distributions, such as less than 16, were not taken into account in this version's validation because the youngest patient in this study was 16 years old. Fourth, some patients with chronic foot pain were not included because of cognitive or psychiatric disorders, neuropathy, systemic disorders, painkiller abuser, or refusal to follow the study instructions; this may constitute a source of bias.

Conclusions

The internal consistency and test-retest reliability of the ROFPAQ-C embodied a faithful translation and localized adaptation of the original ROFPAQ. The ROFPAQ-C is shown to be valid and reliable for acceptable use in the Chinese population from the total to individual domains (cognitive, affective, and sensory).

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