Original Article

Reliability and Validity of Foot Function Index Thai Version [FFI-TH]

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Objective: To assess the reliability and validity of Foot Function Index Thai version [FFI-TH].

Materials and Methods: The cross-sectional descriptive study was conducted in patients with painful foot/ankle problems at Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand. Foot Function Index [FFI] is a self-administered patient-reported outcomes [PRO] measure for evaluating foot/ankle problems. It comprises three domains including pain, disability, and activity limitation. It was translated into Thai language using internationally recognized translation standards. Internal consistency reliability coefficients and coefficient of stability were calculated to test for reliability. The average test-retest interval was 3.90 days. Construct validity was evaluated by the Pain Visual Analogue Score [VAS-pain], the Visual Analogue Scale Foot and Ankle Thai version [VASFA-TH], and the Medical Outcomes Study [MOS] 36-item short form Thai version [SF36-TH].

Results: Ninety-seven patients were enrolled. Most participants were female (80.47%), with an average age of 45.74 years and an education level of at least bachelor's degree (81.40%). The most common diagnoses were plantar fasciitis, ankle sprain, and hallux valgus. Median time to onset of problem was 5.5 months. Three domains revealed Cronbach's alpha coefficient values, as follows, pain subscale (0.94), disability subscale (0.96), and activity limitation subscale (0.72). Intraclass correlation coefficient as 0.92 indicated high stability. Construct validity demonstrated significant correlation between the total and subscale of FFI-TH scores when compared to VAS-pain and SF36-TH for bodily pain, as determined by moderate correlation from Pearson's correlation coefficients that ranged from 0.5 to 0.7. Average time to complete the FFI-TH was 4.67 minutes. A higher level of impairment will correspond with and result in a higher FFI score.

Conclusion: FFI-TH demonstrated good reliability and validity with appropriate completing time. FFI-TH is suitable to be one of the Thai PRO measures that provide clinical benefit for patients with painful foot/ankle problems.

Keywords: FFI-TH, Foot Function Index, Patient-reported outcome questionnaire, Foot pain, Ankle pain, Validity, Reliability

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Painful foot and ankle problems are commonly seen in clinical practice[1,2]. These conditions lead to activity limitation, falls, and disability, especially among elderly and obese patients[3,4]. Foot Function Index [FFI] is a disease-specific questionnaire for evaluating painful foot/ankle problems. Patients can complete this questionnaire in approximately 5 to 10 minutes. The original FFI comprises 23 items that are categorized into three domains, as follows, pain, disability, and activity limitation. A higher the level of impairment will correspond with and result in a higher FFI score[5].

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The Visual Analogue Scale Foot and Ankle [VAS-FA] and Foot and Ankle Ability Measure [FAAM] are the patient-reported outcome [PRO] questionnaires that, to date, have been translated into Thai[6,7]. As compared to VAS-FA and FAAM, FFI is a foot-specific PRO measure that has been widely translated into several different languages with satisfactory validity and reliability[8-16]. FFI has been one of the five most common measures related to clinical outcome in the orthopedic literature[17]. While the original FFI has been studied mainly in patients with foot problems, the more recently translated versions of FFI have been studied among patients with foot and/or ankle problems[5,9,13,15]. The aim of the present study was to translate the original FFI into Thai and to determine if the Foot Function Index Thai version [FFI-TH] can assess patients with painful foot/ankle problems.

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Materials and Methods

Development and translation process

A literature review was conducted within the PubMed database to confirm whether the FFI had already been translated into Thai and tested for validity and reliability. This review of the PubMed literature revealed no Thai translation of the FFI. In response to a request to officially translate the FFI, Professor Dr. Elly Budiman-Mak, the developer of the original FFI, granted the authors of this study formal and official permission to translate the original FFI into Thai language.

The original FFI was translated into Thai language according to International Society for Pharmacoeconomics and Outcomes Research [ISPOR] guidelines for translation and cultural adaptation[18]. The ISPOR translation protocol consists of seven mandatory steps, as follows:

Step 1 (forward translation): The original English version of the FFI was independently translated into Thai language by two bilingual Thai-English translators, one of whom was an ordinary person (naïve translator) and the other an orthopedic surgeon.

Step 2 (forward translation reconciliation): The two forward translations were combined into one version by one rehabilitation physician (physiatrist) to create a reconciled version of the forward translation. This version was consistent in all content-related regards with the original version, but was culturally adapted to Thai people.

Step 3 (back translation): The reconciled version was translated back into English by two bilingual Thai-English native speakers.

Step 4 (back translation review): Discrepancies in meaning and terminology between back translations and source version were reviewed by a Thai-English language professional to identify the best possible language option or solution.

Step 5 (pilot testing): The translated version was tested in 10 native Thai speaking patients with painful foot and/or ankle problem.

Step 6 (pilot testing review): The authors reviewed the comments received from patients and arrived at conclusions via discussion and consensus.

Step 7 (proofreading): The final version of the translation was then sent to two other Thai physiatrists and to a Thai-English language specialist who specializes in semantics and pragmatics. The translated version was finalized after receiving three professional recommendations attesting to the accuracy of the translation.

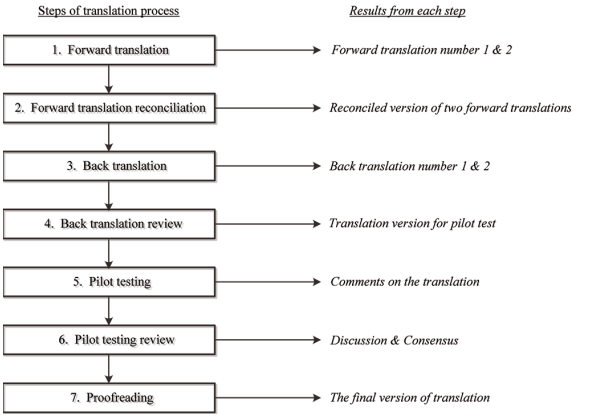

Figure 1. Illustration of the translation process.

A simple illustration of the translation process is shown in Figure 1.

Thai version of FFI [FFI-TH]

Cultural adaptation: The distance referred to in the original English version of the FFI described as "4 blocks" is a distance or measurement phrase that is not generally used in normal communication among Thai people. The Thai-English language specialist in semantics and pragmatics that we retained and consulted for this study recommended using "500 meters" as an alternative to "4 blocks".

Questionnaire format: Although the original English language version of the FFI uses a horizontal line for scoring (similar to the original VAS) as Figure 2, some translated versions of the FFI use a horizontal numeric block rating scale with 10 equal sized boxes ranging from 0 to 9 as[9,10]. Both scoring formats were presented to 10 patients during pilot testing to determine patient preference. Eight of 10 patients preferred the horizontal numeric block rating scale format, indicating that it was easier to comprehend and complete. Hence the FFI-TH is presented as horizontal numeric block rating scale as Figure 3. Both formats have the same scoring system.

Study design, setting, and ethical considerations

This cross-sectional descriptive study was conducted at the Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The protocol for the present study was approved by the Institutional Review Board [IRB], Faculty of Medicine, Chulalongkorn University (IRB No.220/57).

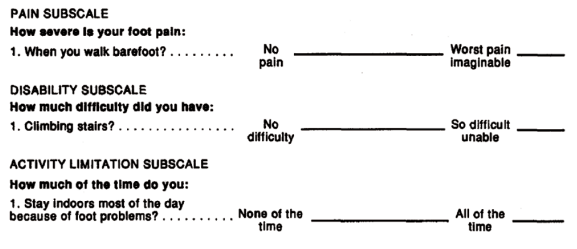
PAIN SUBSCALE
How severe is your foot pain:
1. When you walk barefoot? ..... No pain ——— Worst pain imaginable ———
DISABILITY SUBSCALE
How much difficulty did you have:
1. Climbing stairs? ..... No difficulty ——— So difficult unable ———
ACTIVITY LIMITATION SUBSCALE
How much of the time do you:
1. Stay indoors most of the day because of foot problems? ..... None of the time ——— All of the time ———

Figure 2. Original FFI.


ระดับความปวด: ท่านเจ็บปวดเท้ามากแค่ไหน
เมื่อเดินเท้าเปล่า
ไม่ปวดเลย 0 1 2 3 4 5 6 7 8 9 ปวดมากที่สุด ☐ ไม่สามารถตอบได้
ระดับความลำบากในการทำสิ่งต่างๆ: ท่านทำสิ่งเหล่านี้ได้อย่างลำบากมากเพียงใด
ขณะเดินขึ้นบันได
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ระดับข้อจำกัดในการทำสิ่งต่างๆ: ท่านทำสิ่งเหล่านี้บ่อยเพียงใด
ต้องอยู่บ้านทั้งวัน เพราะมีปัญหาเรื่องเท้า
ไม่เคยเลย 0 1 2 3 4 5 6 7 8 9 ตลอดเวลา ☐ ไม่สามารถตอบได้

Figure 3. FFI-TH.

Participants

Inclusion criteria were as follows, patients with acute or chronic painful foot and/or ankle problems, age greater than 18 years, and ability to read and fully understand Thai language. Painful foot/ankle problems were evaluated by physiatrist to establish a provisional diagnosis. Exclusion criteria included loss of sensation at foot, infection as the cause of pain, foot/ankle deformity or painful knee/hip problems that affect walking ability, and underlying psychiatric illness. Patients that could not attend the retest at seven days were released from further participation in the study. Patients that had developed significant clinical change such as immediately using orthotic after first response, as determined by a physiatrist, at the time of the retest on day 7 were also excused from further participation in the study. For consideration as statistically acceptable, minimum number of 100 participants for internal consistency analysis and at least 50 participants for construct validity were recommended[19]. All participants were recruited from the department of King Chulalongkorn Memorial Hospital which is University Hospital.

Statistical analysis

Data were analyzed using SPSS Statistics version 22.0 (SPSS Inc., Chicago, IL, USA). The maximum allowable percentage of missing data was 5%. The maximum allowable percentage of floor and ceiling thresholds was 15%[19]. Asymmetry of score distribution was determined by absolute z-value of skewness and kurtosis, which conclude of the sample is non-normal if z-value over 3.29[20].

Reliability

Reliability was evaluated using internal consistency and test-retest method. Internal consistency was determined by Cronbach's alpha, with an acceptable minimum value of 0.70[21]. The test-retest method was used to indicate intraclass correlation coefficient [ICC], with a satisfactory value being greater than 0.70[22,23]. The test-retest time interval was pre-specified to be between two and seven days. The minimum test-retest interval was set as to at least two days for prevention of memory effect. The maximum test-retest interval was set as seven days for prevention of significant clinical change.

Validity

Construct validity was assessed by Visual Analogue Scale for Pain [VAS-pain], Thai version of Visual Analogue Scale Foot and Ankle [VASFA-TH], and Thai version 2.0 of the Medical Outcomes Study [MOS] Short Form-36 [SF36-TH]. The VASFA-TH and SF36-TH were studied and were found to be both valid and reliable[6,24]. The VASFA-TH comprises 20 items that are categorized into three domains, including pain (4 items), function deficits (11 items), and other complaints (5 items). For VASFA-TH, a lower score corresponds with or represents a higher level of impairment[6]. The SF36-TH comprises 36 items that are categorized into two domains: physical composite score [PCS] and mental composite score [MCS]. The SF36-TH has eight subscales that fall within the two aforementioned domains, as follows: physical functioning [PF], physical role functioning [RP], bodily pain [BP], general health perceptions [GH], vitality [VE], social role functioning [SF], emotional role functioning [RE], and mental health [MH]. A lower SF36-TH score indicates an overall lower level of patient health status[24,25]. Pearson's correlation coefficient was used to assess the construct validity between these measures. The size of correlation was interpreted as follows: 0.90 to 1.00 (-0.90 to -1.00) = very high positive (negative) correlation; 0.70 to 0.90 (-0.70 to -0.90) = high positive (negative) correlation; 0.50 to 0.70 (-0.50 to -0.70) = moderate positive (negative) correlation; 0.30 to 0.50 (-0.30 to -0.50) = low positive (negative correlation); 0.00 to 0.30 (0.00 to -0.30) = negligible correlation[26].

Results

Ninety-seven native Thai speaking patients were enrolled between April 1, 2014 and January 11, 2016. Most participants were female (80.47%), average age of 45.74 years old, and education level of at a least bachelor's degree (81.40%). Most participants (79.38%) were aged less than 60-years-old. Patient pain was caused by foot problem in 69% of patients and ankle problem in 31% of patients. The diagnoses were plantar fasciitis (41.24%), ankle sprain (27.84%), hallux valgus (16.49%), Pes planus (6.19%), Metatarsalgia (5.15%), and Achilles tendinitis (3.09%). Median onset of symptoms was 5.5 months. Pain severity of participants was classified by VAS-pain, as follows, mild pain (VAS ≤39 mm; n = 45), moderate pain (VAS 40 to 60 mm; n = 34), and severe pain (VAS >60 mm; n = 18). Demographic and clinical data of the study population was shown in Table 1. Details relating to the quality and acceptability of data were presented in Table 2. The FFI-TH score in total and each domain demonstrated the normal distribution according to z-value less than 3.29. Average time to complete the FFI-TH was significantly lower than average time needed by patients to complete the VASFA-TH (4.67 minutes vs. 6.63 minutes, 95% CI -2.58 to -1.25). The median time (interquartile range) to complete FFI-TH and VASFA-TH were 3.62 minutes (2.57 to 5) and 3.46 minutes (4.20 to 8.58).

Eighty-eight study subjects were eligible for participation in the retest. Six subjects were implied as having potentially clinical change because they did not complete the retest within seven days. Three subjects had significantly clinical change at the retest date because they immediately used the orthotic after the first response. Reliability test revealed a Cronbach's alpha of 0.96, with details for each subscale described in Table 3. The average test-retest interval was 3.90 days. Test-retest reliability revealed an ICC of 0.92, with details for each subscale also described in Table 3. Construct validity testing revealed that FFI-TH was significantly positively correlated with VAS-pain, VASFA-TH, and SF36-TH (Table 4). Unlike the FFI-TH activity limitation subscale, the FFI-TH total and

Table 1. Demographic and clinical data of the study population (n = 97)

Age (years), mean ± SD	45.74±14.39
Sex (female)	80 (80.47)
Education	
Secondary	18 (18.56)
Bachelor	79 (81.44)
BMI (kg/m^2), mean ± SD	24.20±4.21
Category	
Painful foot problem	67 (69.07)
Painful ankle problem	30 (30.93)
Diagnosis	
Plantar fasciitis	40 (41.24)
Ankle sprain	27 (27.84)
Hallux valgus	16 (16.49)
Metatarsalgia	5 (5.15)
Pes planus	6 (6.19)
Achilles tendinitis	3 (3.09)
Onset (months), median (IQR range)	5.5 (1 to 12)
Daily walking time (hours), median (IQR range)	4.0 (3 to 6)

BMI = body mass index; IQR = interquartile range; SD = standard deviation
Values are numbers (percentages) unless stated otherwise

Table 2. Quality and acceptability of Foot Function Index Thai version [FFI-TH] data

	Mean	SD	Skewness	Kurtosis	Median	IQR range	Min	Max	Floor effect (%)	Ceiling effect (%)
Total	32.57	17.71	0.46	-0.66	31.11	17.99 to 43.96	6.57	79.71	1.00	1.00
Pain	42.64	21.23	0.39	-0.75	39.51	25.40 to 58.38	9.88	93.83	2.10	1.00
Disability	38.39	23.82	0.41	-0.85	33.33	16.67 to 57.41	3.70	96.30	3.10	1.00
Activity limitation	5.71	9.49	2.42	7.20	0.00	0.00 to 8.15	0.00	53.33	51.50	1.00

IQR = interquartile range; SD = standard deviation

Table 3. Internal consistency [Cronbach's α] and intraclass correlation coefficient [ICC] of FFI total and subscales

	Cronbach's α (n = 97)				ICC (n = 88)			
	Cronbach's α	95% CI		*p*-value	ICC	95% CI		*p*-value
		Lower	Upper			Lower	Upper	
Total	0.96	0.95	0.98	<0.0001	0.92	0.87	0.95	<0.0001
Pain	0.94	0.91	0.96	<0.0001	0.88	0.82	0.92	<0.0001
Disability	0.96	0.94	0.97	<0.0001	0.91	0.86	0.94	<0.0001
Activity limitation	0.72	0.61	0.78	<0.0001	0.72	0.57	0.82	<0.0001

CI = confidence interval

other subscales demonstrated moderate correlation with VAS-pain and the SF36-TH BP subscale. Pearson's correlation coefficients were shown in Table 4. Regarding non-applicable questionnaire responses, questions relating to orthotics had a high percentage, with 40% non-applicable responses for pain walking with orthotics and 41% non-applicable responses for pain standing with orthotics. A list of non-applicable answers to questionnaire questions was presented in Table 5.

Table 4. Pearson's correlation coefficient for FFI-TH score to Pain Visual Analogue Score [VAS-pain], Visual Analogue Scale Foot and Ankle Thai version [VASFA-TH], and 36-item short form Thai version [SF36-TH]

	Total	Pain	Disability	Activity limitation
VAS-pain	0.532**	0.526**	0.520**	0.239*
VASFA-TH	-0.447**	-0.420**	-0.432**	-0.291**
SF-36				
PCS	-0.411**	-0.412**	-0.344**	-0.374**
- PF	-0.275**	-0.225*	-0.217*	-0.461**
- RP	-0.273**	-0.185	-0.255*	-0.436**
- BP	-0.584**	-0.540**	-0.568**	-0.318**
- GH	-0.345**	-0.368**	-0.260*	-0.276**
MCS	-0.290**	-0.159	-0.291**	-0.434**
- VT	-0.283**	-0.217*	-0.265**	-0.359**
- SF	-0.338**	-0.253*	-0.338**	-0.388**
- RE	-0.269**	-0.110	-0.277**	-0.487**
- MH	-0.322**	-0.230*	-0.290**	-0.426**

BP = bodily pain; GH = general health perceptions; MCS = mental component summary score; MH = mental health; PCS = physical component summary score; PF = physical functioning; RE = emotional role functioning; RP = physical role functioning; SF = social role functioning; VT = vitality

* Correlation is significant at the 0.05 level (2-tailed)

** Correlation is significant at the 0.01 level (2-tailed)

Table 5. Percentage of non-applicable responses (n = 97)

Domain		Questions	Percentage
Pain	1.	Foot pain at worst	3
	2.	Foot pain in morning	1
	3.	Pain walking barefoot	0
	4.	Pain standing barefoot	0
	5.	Pain walking with shoes	0
	6.	Pain standing with shoes	0
	7.	Pain walking with orthotics	40
	8.	Pain standing with orthotics	41
	9.	Foot pain at end of day	4
Disability	10.	Difficulty walking in house	1
	11.	Difficulty walking outside	1
	12.	Difficulty walking 4 blocks	0
	13.	Difficulty climbing stairs	1
	14.	Difficulty descending stairs	2
	15.	Difficulty standing tip toe	6
	16.	Difficulty getting up from chair	0
	17.	Difficulty climbing curbs	2
	18.	Difficulty walking fast	2
Activity limitation	19.	Stay inside all day because of feet	1
	20.	Stay in bed because of feet	2
	21.	Limit activities because of feet	2
	22.	Use assistive device indoors	3
	23.	Use assistive device outdoors	3

Discussion

Various translated versions of the original FFI have been widely studied for reliability and validity and have been included among the list of PRO questionnaires[8-12,14-16]. In the present study, FFI-TH was translated and developed according to the recognized international standards[18]. In comparison to previous studies, the present study recruited a large number of participants to ensure accurate and reliable results[8-12,14-16]. Both acute and chronic painful foot/ankle conditions were enrolled to ensure a wide variety of patient problems. The design of the FFI-TH scoring scale was changed to a horizontal numeric block rating scale (similar to some previous studies), because the authors found that most participants preferred the adapted scale to the original FFI scale during pilot testing[10,11]. Pilot study participants (8 of 10) declared the horizontal numeric block rating scale to be easier to comprehend and complete. The time it took to complete the FFI-TH was significantly shorter than the time needed to complete the VASFA-TH. The shorter times usage of this PRO will encourage the physiatrists and physical therapists routinely use it as key indicator for assessment and following up patients with painful foot/ankle. This internationally recognized indicator is currently required for hospital accreditation. Our findings confirm that FFI-TH could be qualified for applying in clinical practice, with anticipated results similar to those of VASFA-TH. Unlike the other FFI-TH subscale scores, the FFI-TH subscale activity limitation scores were asymmetrical and had lower reliability. This may be explained by two findings from our data. First, most participants were not elderly, with 79.38% of patients having an age of less than 60 years. Second, most participants had mild to moderate severity of pain as a result of their foot/ankle problem. None of our patients had fracture or recently underwent operation. As such, most participants in the present study did not require assistive device, nor did they have to limit their activities during the study. These participant groups were considered as the future target population that FFI-TH should be explored and analyzed the correlation between each domain. Finally, the clinical implication is that a high total score of FFI-TH indicates a higher clinical impairment.

The authors postulated that the differences in the correlation matrix regarding construct validity were due to the pathological nature of the foot and ankle of those study participants. VASFA was initially focusing

on patients recently received the foot/ankle operation and patients with previous medical history of foot/ankle trauma[6]. Moreover, the differences could be caused from dissimilarity of detail questions described in each questionnaire. FFI was generally used with patients with painful foot/ankle problem[17]. Recent studies usually used VAS-pain and SF36 for validation[9,10,12,15]. In addition, few studies use another PRO measure related to either foot/ankle problem or disease such as Lower Extremity Functional Scale and McMaster Toronto Arthritis questionnaire[12,13]. The present study is the only study using VASFA-TH for validation in view of two reasons. First, the authors would like to validate FFI-TH with another PRO measure related to foot/ankle problem apart from the VAS-pain and SF36-TH. Second, VASFA-TH is the translated PRO measure related to foot/ankle problem only available at the beginning of the present study. While FFI-TH was comparable to VAS-pain and VASFA-TH, the Activity Limitation subscale of FFI-TH revealed a Pearson's correlation coefficient lower than the total scale and the other subscales of FFI-TH due to asymmetrical data. Study participant activities were not limited by their painful foot and/or painful ankle problems.

While FFI-TH was comparable to SF36-TH, the Activity Limitation subscale of the FFI-TH was more closely related to the psychological domain [MCS] of the SF36-TH, than to the physical domain [PCS]. The authors observed that FFI-TH activity limitation subscale was correlated to SF, RE, and MH subscales of the MCS domain, which reflected the perceived frustration, embarrassment, and inability to participate in normal social functioning that were experienced by the participants. The low to moderate correlation have been demonstrated between FFI-TH and SF36-TH. These findings have been similar to Taiwan and Italian studies[9,15]. Moreover, the SF36-TH is the PRO representing the general health well-being whereas FFI-TH is the PRO specific to foot/ankle problems. The subjects with surgical condition had tendency for reporting SF36 closed to FFI. In authors' view point, the PRO specific disease is required for conducting clinical trials among subjects with either non-surgical condition or serious illness, hence some subscales of SF36-TH is more important than overall if it could represent related issue.

Some previous studies disregarded the questions relating to orthotics because these questions were not relevant to their subjects[10,13,15]. The present study did not eliminate the orthotic-related questions, although a high percentage of non-applicable answers were received. The orthotic questions were not eliminated for two reasons. First, the FFI-TH score can still be calculated, even when non-applicable responses are given for orthotic-related questions. Second, the authors concluded that both questions were important for assessment patients who require orthotic for relief of pain. As a result, both questions were included and considered mandatory for patients receiving orthotic prescription, especially for score comparison between before and after treatment.

Limitation

Two main limitations were demonstrated regarding the present study. First the generalizability issue, the participants were recruited from University Hospital. The majority of participants were female with at least a bachelor's degree. In the meantime, FFI-TH could be applicable in the routine practice or clinical trials with instruction and supervision focusing on participants with education level under bachelor degree. Second the test-retest interval issue, although the fixed test-retest interval is at least 1 to 2 weeks to prevent memorization of prior score is generally recommended for best reliability result, the present study preferred flexible test-retest interval within one week to allow more feasibility[19].

Conclusion

FFI-TH demonstrated good reliability and validity with appropriate completing time. FFI-TH is suitable to be included as one of the Thai PRO measures that provide clinical benefit in musculoskeletal medicine, especially in patients with painful foot/ankle problems. Higher total score reflects higher impairment. In rehabilitation medicine, FFI-TH can be used as a clinical tool for evaluation of disease severity and outcome of treatment.

What is already known on this topic?

FFI is a disease-specific questionnaire for evaluating painful foot/ankle problems. Patients can complete this questionnaire in approximately 5 to 10 minutes. The original FFI comprises 23 items that are categorized into three domains, pain, disability, and activities limitation. A higher the level of impairment will correspond with and result in a higher FFI score.

What this study adds?

FFI-TH was translated into Thai language using internationally recognized translation standards. FFI-TH demonstrated good reliability and validity with

appropriate completing time. FFI-TH is suitable to be included as one of the Thai PRO measures that provide clinical benefit in musculoskeletal medicine, especially in patients with painful foot/ankle problems. Higher total score reflects higher impairment. In rehabilitation medicine, FFI-TH can be used as a clinical tool for evaluation of disease severity and outcome of treatment.

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The authors gratefully acknowledge Professor Dr. Elly Budiman-Mak for granting us permission to translate the original FFI questionnaire into Thai language. The authors also express their appreciation to Assistant Professor Dr. Jiranthara Srioutai, Department of English, Faculty of Arts, Chulalongkorn University, for her translation guidance given as a specialist in semantics and pragmatics. This process is considered most important in translating the FFI into Thai.

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Potential conflicts of interest

None.

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