

Validity and reliability of a self-administered foot evaluation questionnaire (SAFE-Q)

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Abstract

Background The Japanese Society for Surgery of the Foot (JSSF) is developing a QOL questionnaire instrument for use in pathological conditions related to the foot and ankle. The main body of the outcome instrument (the Self-Administered Foot Evaluation Questionnaire, SAFE-Q version 2) consists of 34 questionnaire items, which provide five subscale scores (1: Pain and Pain-Related; 2: Physical Functioning and Daily Living; 3: Social Functioning; 4: Shoe-Related; and 5: General Health and Well-

Being). In addition, the instrument has nine optional questionnaire items that provide a Sports Activity subscale score. The purpose of this study was to evaluate the test-retest reliability of the SAFE-Q.

Patients and methods Version 2 of the SAFE-Q was administered to 876 patients and 491 non-patients, and the test-retest reliability was evaluated for 131 patients. In addition, the SF-36 questionnaire and the JSSF Scale scoring form were administered to all of the participants. Subscale scores were scaled such that the final sum of scores ranged between zero (least healthy) to 100 (healthiest).

Results The intraclass correlation coefficients were larger than 0.7 for all of the scores. The means of the five subscale scores were between 60 and 75. The five subscales easily separated patients from non-patients. The coefficients for the correlations of the subscale scores with the scores on

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the JSSF Scale and the SF-36 subscales were all highly statistically significantly greater than zero ($p < 0.001$). The means for the five JSSF Scale classification groups fell within a relatively narrow range, indicating that the SAFE-Q labels are sufficiently similar to permit their use for all of the JSSF Scale classifications.

Conclusion The present study revealed that the test-retest reliability is high for each subscale. Consequently, the SAFE-Q is valid and reliable. In the future, it will be beneficial to test the responsiveness of the SAFE-Q.

Introduction

Patient-based outcome instruments, which are used to measure changes in health status over time, have become increasingly popular. The four basic types of patient-based outcome instruments are generic, disease-specific, region-specific, and patient-specific. A region-specific instrument contains items specific to only one body part and can be used with several different disease states affecting a specific region. The Japanese Society for Surgery of the Foot (JSSF) is developing a QOL questionnaire for use in individuals with pathological conditions related to the foot and ankle as a region-specific outcome instrument.

The questionnaire, named the Self-Administered Foot Evaluation Questionnaire (hereafter referred to as the “SAFE-Q”) version 1, was subjected to through an initial field test [1], after which it was revised to a second version [2]. The main body of the SAFE-Q version 2 consists of 34 questionnaire items, providing five subscale scores (1: Pain and Pain-Related; 2: Physical Functioning and Daily Living; 3: Social Functioning; 4: Shoe-Related; and 5: General Health and Well-Being). In addition, the instrument has nine optional questionnaire items that provide a Sports Activity score.

The SAFE-Q version 2 was subjected to a limited field test. Tentative scores for the five subscales were compared to their corresponding scales in the Short Form 36 Health Survey, version 2.0 (SF-36) [3] and the JSSF Scale score [4, 5], and the results obtained were reasonable [1]. Therefore, based upon its favorable performance in the previous field test [2], the JSSF decided to evaluate the second version of the SAFE-Q further by applying it to a larger sample of patients with foot and ankle disorders as well as a control sample of healthy teenagers and adults.

Because the factor structure of the responses to the instrument was valid in the former study, the primary aim of the present field survey was to evaluate the test-retest reliability. A secondary aim was to test the influence of background factors such as region-specific classification, age group, and gender on the subscale scores. This report provides an analysis of the data gathered in this second field test of the second version of the SAFE-Q.

Patients and methods

Study group

In the present field survey, the SAFE-Q version 2 was administered to 876 patients with pathological conditions related to the foot and ankle. A total of 491 non-patients consisting of healthy teenagers and adult volunteers were also analyzed. Both patients and non-patients had been registered in a total of 99 institutions in Japan.

Although the SAFE-Q version 1 has already been presented in a previous article [1], we have provided the SAFE-Q version 2 in “Appendix 1” for the sake of reader convenience. In addition, the manual for the SAFE-Q is shown in “Appendix 2.”

Among the 876 patients, 131 of them with stable pathological symptoms attended the test-retest reliability evaluation. The same questionnaire form was answered by these patients twice in succession. The interval between the first and second tests was a minimum of eight weeks. When the test was first administered, an SF-36 questionnaire form was also answered by the subjects, and the JSSF Scale scoring form was recorded by a physician.

Ethical issue

This study was approved by the Life Ethics Committee of St. Marianna University School of Medicine in 2007 (no. 1192). The elongation of the research period until 2014 was approved in 2012.

Statistical analysis

EFA and CFA

An exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were performed. These were done to determine whether the factor structure was stable, given that the patient population in this field test comprised a wide variety of pathologies. Response data from the patients during the first administration (but not the retest) of this field test were subjected to the same EFA and CFA as used in the first field test of the second version.

Computation of subscale scores

Subscale scores were computed for each of the five subscales. To compute the scores, for each subscale, the average non-missing values of items contributing to the subscale were computed for each respondent. Prior to averaging, VAS items were rescaled to conform to the ranges of the categorical items. Averages were then

rescaled so that the final sum of scores ranged between zero (least healthy) and 100 (healthiest), inclusive.

Test-retest reliability

Each subscale's scores were subjected to a random-effects linear regression with test-retest as a categorical predictor. The intraclass correlation coefficient (ICC) was computed as the index of reliability for each scale. Ninety-five percent confidence intervals (95 % CIs) for ICCs were computed by parametric bootstrapping [6] using 100 bootstrap samples of patients with scores for the scale for both test and retest administrations of the questionnaire.

Comparison with JSSF Scale scores

Spearman's rank correlation coefficients were computed between the scores for each of the five SAFE-Q subscales and the JSSF Scale scores (which were only taken from patient responders during the first administration of the questionnaire).

Comparison with SF-36 scores

Spearman's rank correlation coefficients were computed between the scores for each of the five SAFE-Q subscales and those for each of the eight SF-36 subscales. Scores for each of the eight SF-36 subscales were computed using the Japanese norm-based scoring method as prescribed in the commercial instrument's documentation [3]. Again, QOL scores were only taken from patient responders during the first administration of the questionnaire.

Comparison of scores for the Pain and Pain-Related subscale and the SF-36 Bodily Pain subscale

We compared the patients' scores for the Pain and Pain-Related subscale with the scores for the SF-36 Bodily Pain subscale. For this purpose, we extracted the values for the Pain subscale scores from the JSSF Scale scores. On the JSSF Pain subscale, 0, 20, 30, and 40 points are assigned to patients with diseases of the ankle and hindfoot, midfoot, hallux, and lesser toe, respectively; and 0, 10, 20, or 30 points are assigned to patients with rheumatoid arthritis. Thus, we computed the Spearman's rank correlation coefficient between the JSSF Pain score and the Pain and Pain-Related score or SF-36 Bodily Pain score for each of the patient groups.

Background factors

The following patient characteristics were assessed using scores from the first administration of the questionnaire: patient group in the JSSF Scale classification, age group, and

gender. Patient groups in the JSSF Scale classification were as follows: ankle and hindfoot, midfoot, hallux, lesser toe, and rheumatoid arthritis. Respondents were grouped by age as follows: 16–39, 40–64, and 65 and older, inclusive. For the patient groups and patient-age groups, each of the five subscales was assessed by means of one-way analysis of variance (ANOVA). Gender comparisons were made by means of Student's *t* test in each subgroup of patients classified by patient group and age group. Dunnett's multiple comparisons test was performed afterward to compare patient groups. In order to stabilize the variances in the presence of floor and ceiling effects, the data were arcsine square-root transformed prior to performing ANOVA or other tests.

Patient versus non-patient comparison

Scores for each of the five subscales were compared between patients (first administration of the questionnaire) and non-patients by means of the Mann–Whitney test. This nonparametric test was used for this comparison due to concern over the large proportion of ceiling responses in the healthy group.

Sports items

Sports-related questionnaire items were scored as above, taking into account the reversal of sense of the VAS item among them. EFA was applied to the responses of patients during the first administration of the questionnaire in order to confirm the unidimensionality of the scale. The test-retest reliability of the sum of these items' scores was assessed as above.

Statistical probability

In the statistical comparisons, a *p* value of less than 0.05 was considered statistically significant. Below, for all *p* values less than 0.001, we simply state $p < 0.001$, even when the exact value was obtained from the computation.

Results

Patient and non-patient classification and age

The classification of the subjects enrolled in the present field study is summarized in Table 1. A total of 876 patients and 491 non-patients were registered. The majority of the patients had diseases of the ankle and hindfoot (469). Numbers of patients in the lesser toe (45) and midfoot (68) groups were less than 100. The JSSF region-specific classification was not reported for eight patients. The mean age of the patients in each group and that of the non-patients

Table 1 Numbers of patients and non-patients

Patient-group by JSSF Scale classification	Gender	Number	Age Mean \pm SD
Patient			
Ankle and hindfoot	Male	232	47.0 \pm 18.6
	Female	237	52.6 \pm 18.1
	Total	469	49.8 \pm 18.5
Hallux	Male	43	54.9 \pm 19.1
	Female	126	59.5 \pm 15.6
	Total	169	58.3 \pm 16.6
Lesser toe	Male	15	43.7 \pm 19.2
	Female	30	52.7 \pm 17.4
	Total	45	49.7 \pm 18.3
Midfoot	Male	32	44.8 \pm 17.3
	Female	36	50.7 \pm 19.8
	Total	68	47.9 \pm 18.7
Rheumatoid arthritis	Male	30	61.0 \pm 14.3
	Female	87	59.3 \pm 12.1
	Total	117	59.8 \pm 12.6
Not reported	Male	4	31.5 \pm 16.9
	Female	4	67.8 \pm 7.5
	Total	8	49.6 \pm 22.8
All groups	Male	356	48.6 \pm 18.8
	Female	520	55.4 \pm 17.0
	Total	876	52.6 \pm 18.0
Non-patient			
	Male	225	45.0 \pm 17.0
	Female	266	44.2 \pm 16.4
	Total	491	44.6 \pm 16.6

are also indicated in Table 1. As a whole, the mean ages of the patients and non-patients were 52.6 ± 18.0 (mean \pm SD; $n = 876$) and 44.6 ± 16.6 ($n = 491$), respectively.

Factor analysis

The factor structure was remarkably stable, in that factor loadings and residual variances were essentially the same as those obtained in the previous field test of the SAFE-Q version 2 (data not shown). The factor correlation coefficients resulting from the CFA are summarized in Table 2. All of the correlations between different subscale factors were less than 0.9. The maximum coefficient was 0.841, for the correlation between the Physical Functioning and Daily Living subscale and the Social Functioning subscale.

Test-retest reliability

The value of the ICC for each of the five subscales is listed in Table 3. The ICC was always larger than 0.7; even the

minimum 95 % CI lower limit for the Social Functioning subscale was larger than 0.6. The ICC for the sum of the subscale scores was 0.85 (with a 95 % CI of 0.81 to 0.89), which is, as expected, higher than any of the individual components.

Distribution of subscale scores

The distributions of the subscale scores are illustrated in Fig. 1. The mean \pm SD and median for the five subscales were as follows: Pain and Pain-Related: 66.0 ± 23.8 , 70.1; Physical Functioning and Daily Living: 69.2 ± 26.2 , 75.0; Social Functioning: 66.3 ± 32.4 , 75.0; Shoe-Related: 62.7 ± 30.4 , 66.7; General Health and Well-Being: 66.8 ± 29.7 , 75.0. The width between the 25th percentile and the 75th percentile was broad in the Social Functioning, Shoe-Related, and General Health and Well-Being subscales, while smaller widths were observed in the Pain and Pain-Related and Physical Functioning and Daily Living subscales. The values of the means were very similar for the five subscales, ranging from 60 to 70.

Comparison with the JSSF Scale score

The distribution of the JSSF Scale score is illustrated in Fig. 2. The mean \pm SD and median were 69.4 ± 20.9 and 72 ($n = 864$), respectively. The JSSF score was correlated with each of the present subscale scores. The Spearman's rank correlation coefficients are summarized in Table 4, where the patients are classified into JSSF patient groups. The scores for the five subscales display statistically significant correlations ($p < 0.001$) with the JSSF Scale score, with rank correlation coefficients ranging from 0.51 to 0.61 (Table 4). This tendency was the same in each group of patients. However, slightly smaller correlation coefficients were observed in the lesser toe group containing 45 patients.

SF-36

The Spearman rank correlation coefficients between each of the five subscales of the SAFE-Q and each of the eight SF-36 subscales were all statistically significantly different from zero ($p < 0.001$), as summarized in Table 5. The correlation coefficient for the Pain and Pain-Related subscale was highest with Bodily Pain; the correlation coefficient for the Shoe-Related subscale was highest with Bodily Pain and Physical Functioning; the correlation coefficient for the Physical Functioning and Daily Living subscale was highest with Physical Functioning; the correlation coefficient for the Social Functioning subscale was highest with Role Physical and Bodily Pain (but nearly as high with Social Functioning and Physical Functioning);

Table 2 Factor correlation coefficients among five subscales resulting from confirmatory factor analysis

	Pain and Pain-Related (Q1–Q7, Q10, Q11) ^a	Physical Functioning and Daily Living (Q12–Q22)	Social Functioning (Q23–Q28)	Shoe-Related (Q8, Q9, Q34)	General Health and Well-Being (Q29–Q33)
Pain and Pain-Related		0.752 (0.016) ^b	0.647 (0.021)	0.721 (0.022)	0.785 (0.015)
Physical Functioning and Daily Living			0.841 (0.012)	0.737 (0.021)	0.808 (0.013)
Social Functioning				0.726 (0.023)	0.804 (0.014)
Shoe-Related					0.718 (0.022)

^a Q1–Q34 refers to question item numbers (used in “Appendix 1”) included in the corresponding subscales

^b Value in parentheses is the standard error in the factor correlation coefficient

Table 3 Values of ICC observed for the five subscales

Subscale	ICC	95 % CI
Pain and Pain-Related	0.78	0.74–0.83
Physical Functioning and Daily Living	0.83	0.77–0.89
Social Functioning	0.72	0.64–0.79
Shoe-Related	0.81	0.76–0.86
General Health and Well-Being	0.82	0.78–0.87
Sum of scores	0.85	0.81–0.89

the correlation coefficient for the General Health and Well-Being subscale was highest with Bodily Pain. In these particular patients, the scores obtained with these two instruments were largely driven by pain and difficulty with mobility. The mean \pm SD of each norm-based [3] SF-36 subscale score are also shown in Table 5. The mean of the norm-based SF-36 score ranged from 36 to 47 for these patients, indicating that the patients were somewhat below average in their health status.

Comparison of scores from the SAFE-Q Pain and Pain-Related subscale and SF-36 Bodily Pain subscale scores

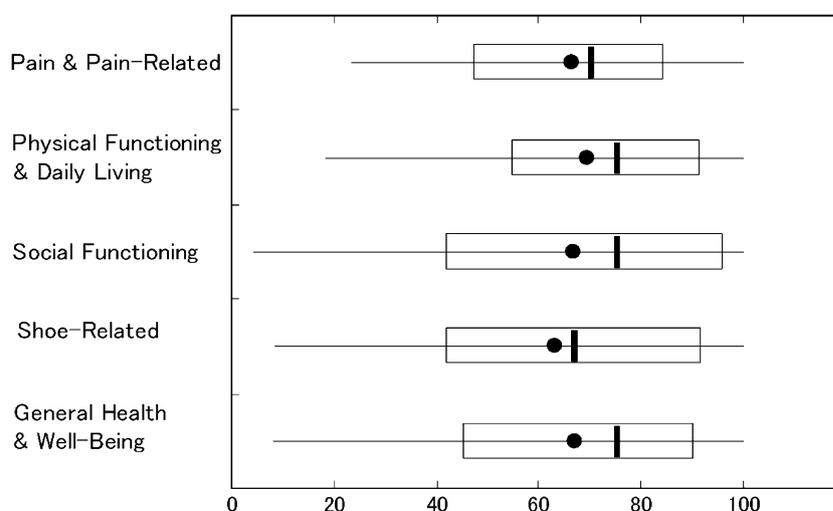
Results of comparisons of the Spearman rank correlation coefficients are summarized in Table 6. The Spearman’s rank correlation coefficients from the Pain and Pain-Related subscale were larger than those from the SF-36 Bodily Pain subscale in all groups of patients. Statistical significance ($p < 0.05$) was found in the ankle and hindfoot and the hallux groups.

Patient characteristics

Comparison among patient groups

A comparison of the mean subscale scores and SDs of the different JSSF patient groups is provided in Fig. 3. The scores for the five patient groups were statistically significantly different according to one-way ANOVA, for all subscales. The p values from ANOVA were smaller than 0.001 for the Physical Functioning and Daily Living and

Fig. 1 Subscale score distributions. Left and right rectangle edges indicate the 25th and 75th percentiles. Vertical lines within the rectangles show the medians. Bullet marks indicate the means. Left and right ends of the horizontal lines passing through the rectangles represent the 5th and 95th percentiles



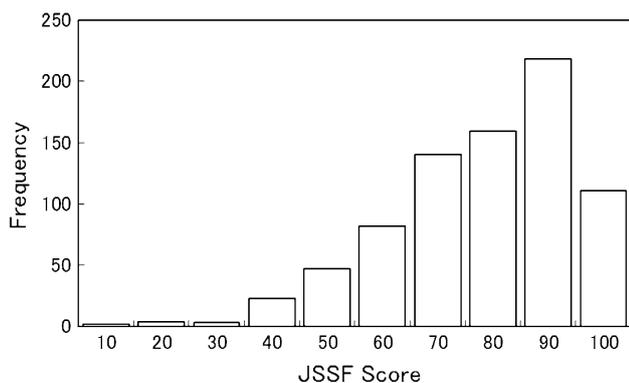


Fig. 2 Distribution of the JSSF Scale scores for the present patients

the Shoe-Related subscales, and were between 0.002 and 0.02 for the other subscales. Patients with rheumatoid arthritis showed the lowest mean values for the five subscales, and the differences between these mean values and those of other patient groups were sometimes found to be statistically significant upon performing Dunnett-type comparison tests, as shown in Fig. 3.

Age and gender

The subscale scores for male and female patients were compared for three age groups (ages 16–39, ages 40–64,

ages 65 and older, inclusive) in Fig. 4. The size of the sample analyzed in this work is large enough to allow subscale-specific comparisons of scores among age groups and genders. One-way ANOVA revealed that there were statistically significant differences ($p < 0.001$) among the age groups in all five subscales when only female patients were considered. When only male patients were considered, there were no statistical significant differences among the age groups for any of the subscales aside from the Physical Functioning and Daily Life subscale ($p < 0.001$). The scores of male and female patients are also compared in Fig. 4. In all subscales, the male scores were always higher than the female scores, whichever age group was considered; the differences between the male and female scores were sometimes significant, as shown in Fig. 4.

Comparison of the scores of patients and non-patients

As expected, patients scored lower (less healthy) on average than non-patients on each of the five subscales (Table 7). The p value from the Mann–Whitney test comparing patients and non-patients was less than 0.001 for all five subscales. The means and SDs of the five subscale scores for non-patients are summarized in Table 8. Older non-patients tended to present lower mean values than younger non-patients, and female non-patients

Table 4 Correlations with the JSSF score for the five patient groups

Patient group by JSSF Scale classification	<i>n</i>	Pain and Pain-Related	Physical Functioning and Daily Living	Social Functioning	Shoe-Related	General Health and Well-Being
Ankle and hindfoot	467	0.63 ($p < 0.001$)	0.65 ($p < 0.001$)	0.57 ($p < 0.001$)	0.49 ($p < 0.001$)	0.61 ($P < 0.001$)
Hallux	167	0.64 ($p < 0.001$)	0.50 ($p < 0.001$)	0.50 ($p < 0.001$)	0.46 ($p < 0.001$)	0.52 ($p < 0.001$)
Lesser toe	45	0.47 ($p = 0.002$)	0.52 ($p < 0.001$)	0.51 ($p = 0.001$)	0.48 ($p = 0.002$)	0.45 ($p = 0.004$)
Mid foot	68	0.61 ($p < 0.001$)	0.69 ($p < 0.001$)	0.63 ($p < 0.001$)	0.54 ($p < 0.001$)	0.58 ($p < 0.001$)
Rheumatoid arthritis	117	0.57 ($p < 0.001$)	0.64 ($p < 0.001$)	0.59 ($p < 0.001$)	0.55 ($p < 0.001$)	0.56 ($p < 0.001$)
All	864	0.61 ($p < 0.001$)	0.60 ($p < 0.001$)	0.55 ($p < 0.001$)	0.51 ($p < 0.001$)	0.56 ($p < 0.001$)

Table 5 Comparison of scores for subscales of the SAFE-Q version 2 with SF-36 subscale scores

SF-36 subscale (mean ± SD)	SAFE-Q subscale				
	Pain and Pain-Related	Physical Functioning and Daily Living	Social Functioning	Shoe-Related	General Health and Well-Being
Physical functioning (36.2 ± 18.4)	0.505 ($p < 0.001$)	0.771 ($p < 0.001$)	0.657 ($p < 0.001$)	0.520 ($p < 0.001$)	0.638 ($p < 0.001$)
Role physical (36.9 ± 17.1)	0.422 ($p < 0.001$)	0.625 ($p < 0.001$)	0.704 ($p < 0.001$)	0.436 ($p < 0.001$)	0.607 ($p < 0.001$)
Bodily pain (42.2 ± 11.8)	0.652 ($p < 0.001$)	0.634 ($p < 0.001$)	0.684 ($p < 0.001$)	0.532 ($p < 0.001$)	0.669 ($p < 0.001$)
Social Functioning (46.2 ± 14.9)	0.406 ($p < 0.001$)	0.579 ($p < 0.001$)	0.667 ($p < 0.001$)	0.446 ($p < 0.001$)	0.592 ($p < 0.001$)
General health (46.8 ± 11.5)	0.403 ($p < 0.001$)	0.461 ($p < 0.001$)	0.409 ($p < 0.001$)	0.399 ($p < 0.001$)	0.504 ($p < 0.001$)
Vitality (47.3 ± 10.5)	0.415 ($p < 0.001$)	0.400 ($p < 0.001$)	0.450 ($p < 0.001$)	0.375 ($p < 0.001$)	0.507 ($p < 0.001$)
Role emotional (42.3 ± 15.5)	0.442 ($p < 0.001$)	0.543 ($p < 0.001$)	0.600 ($p < 0.001$)	0.416 ($p < 0.001$)	0.610 ($p < 0.001$)
Mental health (47.7 ± 11.0)	0.408 ($p < 0.001$)	0.441 ($p < 0.001$)	0.484 ($p < 0.001$)	0.380 ($p < 0.001$)	0.566 ($p < 0.001$)

tended to present lower mean values than male non-patients.

Sports items

Optional sports items were responded to by 275 patients and 197 non-patients. EFA of the resulting patient data showed that these items contributed to a single major factor, as seen before (data not shown). The test-retest reliability for sports items was similar to that observed for the other sets of items: ICC = 0.76, with a 95 % CI of 0.64–0.87. The mean \pm SD of the Sports Activity score

was 45.3 ± 34.2 in patients, and it was 95.7 ± 10.9 in non-patients. The difference in the mean scores of patients and non-patients was statistically significant ($p < 0.001$).

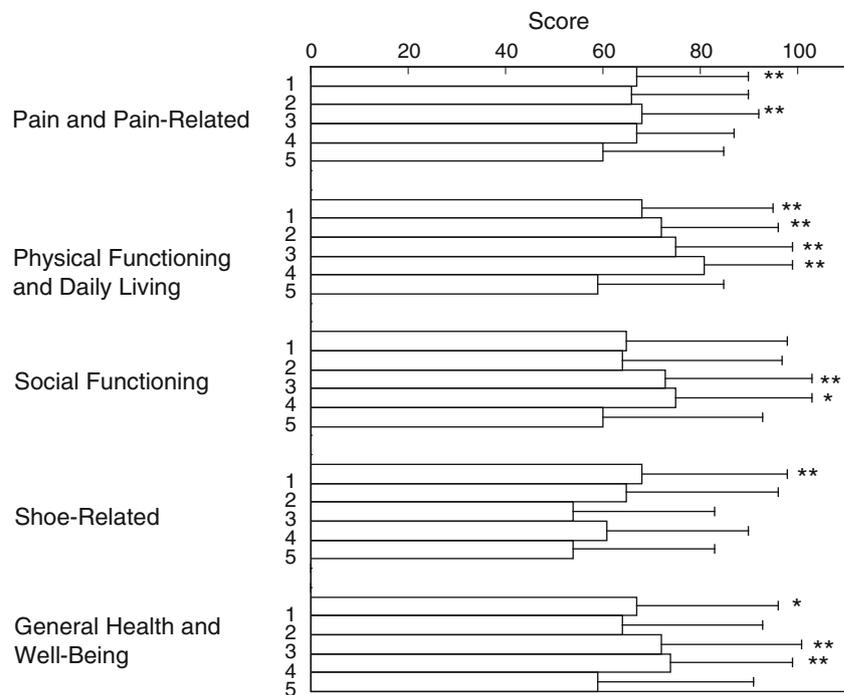
Discussion

Several patient-based and region-specific outcome instruments for patients with diseases or injuries of the foot and ankle region, such as the American Academy of Orthopaedic Surgeons lower limb outcomes assessment instruments (including the Foot and Ankle Module (AAOS-FA) [7], Foot and Ankle Ability Measure (FAAM) [8], Foot Health Status Questionnaire (FHSQ) [9], and Foot Function Index [10]), have been developed. Recently, a comparison of the responsiveness of the Manchester–Oxford foot questionnaire (MOXFQ) with those of the American Orthopaedic Foot Ankle Society [AOFAS] [11], SF-36 [12], and EuroQol (EQ-5D) [13] assessments following foot or ankle surgery was published [14]. Although the MOXFQ is a patient-based outcome measure, it was originally developed based on interviews with patients who had foot surgery. In the interviews, however, the Manchester Foot Pain and Disability Questionnaire (MFPDQ) [15] had been utilized as a template. In addition, the measurement properties of the MOXFQ were initially assessed in a specific group of patients undergoing surgery for hallux valgus [16, 17]. In this context, there is no new and original patient-based outcome instrument focusing only on the foot

Table 6 Comparisons of Spearman's rank correlation coefficients between the present Pain and Pain-Related subscale score and the SF-36 Bodily Pain subscale score

JSSF Scale classification	Rank correlation coefficients in comparisons of Pain scores by JSSF Scales		
	SAFE-Q Pain and Pain-Related	SF-36 Bodily Pain	Significance
Ankle and hindfoot	0.63 ($n = 409$)	0.51 ($n = 399$)	$p < 0.05$
Hallux	0.68 ($n = 163$)	0.47 ($n = 160$)	$p < 0.01$
Lesser toe	0.58 ($n = 44$)	0.32 ($n = 44$)	NS
Midfoot	0.66 ($n = 68$)	0.50 ($n = 67$)	NS
Rheumatoid arthritis	0.62 ($n = 116$)	0.47 ($n = 113$)	NS

Fig. 3 Comparison of the means and SDs of the five subscale scores among the five JSSF patient groups: 1 ankle and hindfoot; 2 midfoot; 3 hallux; 4 lesser toe; and 5 rheumatoid arthritis. Asterisks (* $p < 0.05$; ** $p < 0.01$) indicate p values from Dunnett-type comparisons with the rheumatoid arthritis group



1: Ankle-hindfoot; 2: Midfoot; 3: Hallux; 4: Lesser Toes; 5: Rheumatoid Arthritis

Fig. 4 Mean subscale scores (and their SDs) for each age group (1 ages 16–39, 2 ages 40–64, 3 ages 65 and older, inclusive) and gender (open column male; closed column female). ** $p < 0.01$ for comparisons between genders. Using ANOVA, the female-only scores were found to be significantly different among all age groups and subscales ($p < 0.001$), but when only males were considered, only the Physical Functioning and Daily Living subscale scores were only significantly different among the age groups

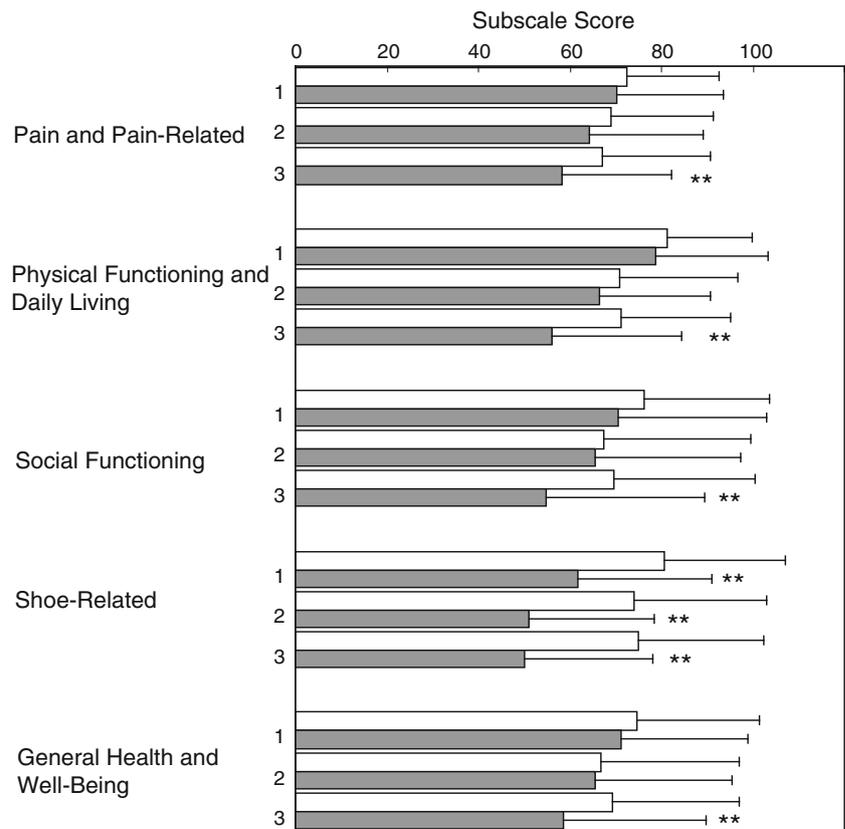


Table 7 Comparison of the subscale scores of patients and non-patients

Subscale	Patients			Non-patients		Comparison between patients and non-patients
	25th percentile	Median	75th percentile	25th percentile	Median	
Pain and Pain-Related	47	70	84	94	100	$p < 0.001$
Physical Functioning and Daily Living	55	75	92	98	100	$p < 0.001$
Social Functioning	42	75	96	100	100	$p < 0.001$
Shoe-Related	42	67	92	92	100	$p < 0.001$
General Health and Well-Being	45	75	90	100	100	$p < 0.001$
Sports Activity	11	34	75	97	100	$p < 0.001$

Table 8 Means and SDs of the five subscale scores for non-patients, classified by age and gender

Group		Pain and Pain-Related	Physical Functioning and Daily Living	Social Functioning	Shoe-Related	General Health and Well-Being
Age group ^a	1	96 ± 7 (n = 224)	99 ± 3 (n = 224)	99 ± 5 (n = 224)	94 ± 12 (n = 224)	99 ± 3 (n = 224)
	2	95 ± 10 (n = 178)	98 ± 6 (n = 178)	99 ± 7 (n = 177)	92 ± 13 (n = 178)	99 ± 5 (n = 178)
	3	94 ± 12 (n = 89)	93 ± 12 (n = 89)	95 ± 12 (n = 88)	91 ± 14 (n = 88)	94 ± 14 (n = 89)
Gender	Male	97 ± 7 (n = 225)	98 ± 6 (n = 241)	99 ± 6 (n = 224)	97 ± 7 (n = 224)	98 ± 7 (n = 225)
	Female	94 ± 11 (n = 266)	97 ± 7 (n = 266)	98 ± 9 (n = 265)	89 ± 15 (n = 266)	98 ± 7 (n = 266)

^a 1 16–39 years old, 2 40–64 years old, 3 65–88 years old

and ankle that is similar to the various instruments that have already been verified to be valid, repeatable, and reliable.

There are potential advantages and disadvantages associated with each of these instruments [18], and there is an ongoing process whereby evidence is collected to support

their use under various conditions. The usefulness of an outcome instrument is never completely established. There is currently an urgent need for scientific evaluation of foot and ankle surgery, which in turn requires the use of appropriate (patient-based) standard methods of outcome assessment. In this context, the Japanese Society for Surgery of the Foot (JSSF) is developing a QOL questionnaire for use in individuals with pathological conditions related to the foot and ankle as a region-specific outcome instrument.

The present field test of the second version of the SAFE-Q replicated the factor structure of the same version of the SAFE-Q in its first field test (which had a smaller patient sample). The test-retest reliability was high for each of the subscales and for the average of all subscales. Gender-related differences, observed in particular for the Shoe-Related subscale and Physical Functioning and Daily Living subscale, might reflect the well-known foot-health consequences of women wearing high-heeled footwear and women's more fashion-oriented attitude towards shoes. It is believed by many surgeons that age-related differences reflect a general decline in overall health and physical vigor, as well as a general reduced ability to recover quickly from health-related problems.

The differences between patient groups were also statistically significant according to ANOVA. In particular, patients with rheumatoid arthritis appeared to fare more poorly than patients in other region-specific categories (Fig. 3). Nevertheless, the averages for the patient groups fell in a relatively narrow range, indicating that the SAFE-Q labels are sufficiently similar to allow their use in all patient groups.

As expected, the SAFE-Q readily distinguished patients with foot and ankle disorders from non-patients. The mean scores on the subscales range between 60 and 75, which may lead to concern over the sensitivity or dynamic range of the QOL instrument in these patients. In contrast to this, the distribution of JSSF scores observed in the patients implies that most of the patients did not have severe symptoms (Fig. 2). This is a plausible reason for the scattered range of mean values observed in the present field test.

Given the large sample size, the coefficients for the correlation of the SAFE-Q subscale scores with the JSSF Scale score were all highly statistically significantly greater than zero. Likewise, the coefficients of the correlation of the SAFE-Q subscale scores and SF-36 subscale scores were statistically significantly greater than zero for the

same reason. Nevertheless, there was a qualitative alignment of the two QOL scales when the correlation coefficient values were examined. The lack of perfect alignment indicates that the SAFE-Q constructs measured in these patients are superior to those measured by the corresponding subscales in the more general SF-36 instrument. It does appear, however, that the scores obtained using both instruments are largely driven by pain and difficulty with mobility in these patients.

The nine items of the Sports Activity subscale of the SAFE-Q consist of questions about very basic performance of sports activities [8, 19, 20]. Regarding the Sports Activity subscale, the unidimensionality of the items remained stable and the difference between patients and non-patients was apparent. In addition, the test-retest reliability was adequate. Therefore, we will add these nine items to the responsiveness analysis without changing them.

As reviewed by Martin and Irrgang [18], validity testing of QOL outcome instruments should include assessments of content validity, construct validity, test-retest reliability, and responsiveness. In our process, content validity was confirmed for the SAFE-Q version 1 [1] and version 2 [2] through the various Cronbach α metrics. Regarding construct validity, we ascertained convergence by comparing the SAFE-Q subscales with the JSSF scales and SF-36 subscales. We also studied the convergence and divergence [21] by evaluating the results from CFA. That is, we observed that the factor loading of each questionnaire item was large for the intended subscale and small for the other subscales in the previous field study, and similar results were seen in the present study.

As described above, we were able to verify that the test-retest reliability was high for each subscale. The comparison of Spearman rank correlation coefficients shown in Table 6 suggests that the Pain and Pain-Related subscale is more responsive than the SF-36 Bodily Pain subscale. However, there is no other clear standard that could be used to gauge the responsiveness of the other subscales. Additionally, the responsiveness should be evaluated by performing a longitudinal study. In the future, it will be beneficial to test the responsiveness of the present outcome instrument.

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Appendix 1

Self-Administered Foot Evaluation Questionnaire (SAFE-Q)

Patient Name		Sex	Date of Birth
		1. Male 2. Female	(Month DD, YYYY)
Date When Answered			(Month DD, YYYY)

ID Number:

The following questionnaire is intended to ask about the condition of your feet, and what causes you difficulties and problems in your daily life. The questionnaire does not only contain questions on pain and physical function, but also emotion-related questions. It also asks about how your quality of life may be affected by foot disease and/or injury.

We believe that your honest opinion will benefit future foot treatment and footcare aids.

We would appreciate it if you would take the time to answer the questionnaire.

When we use the word “foot,” we here refer to the parts framed by the rectangle in the illustration below, that is, the entire part from the shank through the top of the toes; the **knees are not included.**



The word “foot” in this questionnaire refers to the parts framed by the rectangle in the left illustration. The knees are not included.

===== Precautions When Filling out the Questionnaire =====

- [1] Please think back about the last week or month, and then answer the questions.
- [2] Each question also gives you an explanation on how to answer the question; please read the explanation carefully and give your answer. It will take about 10 minutes to fill out the questionnaire although the time varies among individuals.
- [3] There are two ways of answering the questions in this questionnaire.
 - I. Put a tick (✓) in the appropriate box.
 - II. Put a cross (x) on the line.

Q1: Have you noticed any pain in your foot (feet) during the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q2: Have you had difficulty in sleeping due to foot pain in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q3: How intense was the most severe pain you experienced in your feet in the past week?

Place an “x” at the appropriate point on the line, with 0 indicating “no pain” and 10 indicating “worst pain imaginable”.



Q4: How intense was the foot pain you experienced while walking on flat ground in the past week?

(select the one that applies and place an “x” in the corresponding box)

No pain	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>				

Q5: Have you had foot pain in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q6: How intense was the foot pain you experienced when you woke up in the morning in the past week?

(select the one that applies and place an “x” in the corresponding box)

No pain	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>				

Q7: How intense was the foot pain you experienced at the end of each day in the past week?

(select the one that applies and place an “x” in the corresponding box)

No pain	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>				

Q8: Have you had difficulty in putting on your usual shoes due to foot pain in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q9: Do you find it difficult to find comfortable shoes due to your foot symptoms?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q10: How intense was the foot pain you experienced while walking barefoot in the past week?

(select the one that applies and place an “x” in the corresponding box)

No pain	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>				

Q11: How intense was the foot pain you experienced while walking in shoes in the past week?

(select the one that applies and place an “x” in the corresponding box)

No pain	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>				

Q12: Have you found it difficult to go upstairs due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q13: Have you found it difficult to go downstairs due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q14: Have you found it difficult to squat due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q15: Have you found it difficult to put on socks due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q16: How long have you been able to walk on flat ground in shoes without rest in the past week?

(select the one that applies and place an “x” in the corresponding box)

More than 30 min	about 15 min	about 5 min	about 1 min	less than 1 min
<input type="checkbox"/>				

Q17: Have you found it difficult to walk uphill due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q18: Have you found it difficult to walk downhill due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q19: Have you found it difficult to walk on uneven ground, such as rough or graveled roads, due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q20: Have you found it difficult to stand on your toes due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q21: Have you used a walking stick or handrails inside your house due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q22: Have you used a walking stick outside your house due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q23: Have you found it difficult to go out to an event or a department store due to your foot symptoms in the past month?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q24: Have you found it difficult to perform routine activities, such as lessons, socializing with friends or voluntary work, due to your foot symptoms in the past month?

(select the one that applies and place an “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q25: Have you had difficulty going to work, school, or shopping nearby due to your foot symptoms in the past month?

Not at all Slightly Moderately Considerably Extremely

Q26: Have you found it difficult to take a trip, such as a business trip or journey, due to your foot symptoms in the past month?

Not at all Slightly Moderately Considerably Extremely

Q27: Have you found it difficult to enjoy hobbies or leisure activities due to your foot symptoms in the past month?

(select the one that applies and place an “x” in the corresponding box)

Not at all Slightly Moderately Considerably Extremely

Q28: Have you had difficulty in doing work, school activities or household duties due to your foot symptoms in the past month?

(select the one that applies and place an “x” in the corresponding box)

Not at all Slightly Moderately Considerably Extremely

Q29: Have you felt anxious due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never Occasionally Sometimes Often Always

Q30: Have you felt depressed due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never Occasionally Sometimes Often Always

Q31: Have you felt frustrated due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q32: Have you felt that you were bothering people around you due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q33: Have you felt that you were handicapped due to your foot symptoms in the past week?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

Q34: Have you had difficulty in putting on high-fashion or formal shoes in the past month?

(select the one that applies and place an “x” in the corresponding box)

Never	Occasionally	Sometimes	Often	Always
<input type="checkbox"/>				

The following questions are for those who play sports on a routine basis.

Those who do not play sports do not have to answer Q35-43 below.

Sports Activity (Optional Item)

Please check one of the boxes below to indicate whether you play sports or not.

- I do not play sports.
 I play sports.

If you play one or more types of sports, please indicate the sport event that you consider is most important below:

The most important sport event is: _____

Q35: Have you found it difficult to run on flat ground due to your foot symptoms in the past month?

(select one that applies and place "x" in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q36: Have you found it difficult to run on uneven ground due to your foot symptoms in the past month?

(select one that applies and place "x" in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q37: Have you found it difficult to change direction suddenly while running fast due to your foot symptoms in the past month?

(select one that applies and place "x" in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q38: Have you found it difficult to hop on one foot due to your foot symptoms in the past month?

(select one that applies and place "x" in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q39: Have you found it difficult to do squat exercises due to your foot symptoms in the past month?

(select one that applies and place “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q40: Have you found it difficult to jump due to your foot symptoms in the past month?

(select one that applies and place “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q41: Have you found it difficult to pivot (turning your body around the axis of one foot) due to your foot symptoms in the past month?

(select one that applies and place “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q42: Have you found it difficult to run at full speed due to your foot symptoms in the past month?

(select one that applies and place “x” in the corresponding box)

Not at all	Slightly	Moderately	Considerably	Extremely
<input type="checkbox"/>				

Q43: What is your current sports activity level?

Place “x” at an appropriate point on the line, with 10 indicating “a state comparable to that before the occurrence of the foot problem” and 0 indicating “a state in which no sports-related activities can be performed”.

0	10

No sports-related activities can be performed	The same as before the occurrence of the foot problem

The Japanese Orthopaedic Association / Japanese Society for Surgery of the Foot, Self-Administered Foot Evaluation Questionnaire (SAFE-Q) can't be changed or modified without permission.

Appendix 2

Manual for the Self-Administered Foot Evaluation Questionnaire (SAFE-Q)

The Japanese Orthopaedic Association / Japanese Society for Surgery of the Foot, Self-Administered Foot Evaluation Questionnaire was created by The Clinical Outcomes Committee of the Japanese Orthopaedic Association as well as The Clinical Outcomes Committee of the Japanese Society for Surgery of the Foot. The title of the questionnaire and the scoring method are specified below. The Japanese Orthopaedic Association / Japanese Society for Surgery of the Foot, Self-Administered Foot Evaluation Questionnaire cannot be changed without permission.

I. Title of the Questionnaire

The title of this questionnaire, consisting of 34 mandatory items and 9 optional items (43 items in total), is “Japanese Orthopaedic Association / Japanese Society for Surgery of the Foot, Self-Administered Foot Evaluation Questionnaire.” The abbreviated form is SAFE-Q, and is pronounced “Seif-kju”.

II. Completion of the Questionnaire

1. This questionnaire is composed of patient-centered questions for assessment and should be filled out by the patients themselves or in cooperation with the caregiver. The healthcare staff should not help the patient answer the questions, because this may potentially guide the patient to give unintended answers. However, this does not apply in the following cases.
 - 1) The patient asks about the content of the questions.
 - 2) The patient is physically challenged and it is physically hard for him/her to write the answers accurately.
 - 3) The patient made a mistake when answering the questions (incorrect marking on VAS or multiple answers).
 - 4) Other cases in which a healthcare staff worker decides that it is necessary to help the patient fill out the questionnaire.
2. Healthcare staff workers must give consideration so that respondents do not learn the component name and score of the questions.

III. Questionnaire Items

1. Subscales of questions

The questions are comprised of the following subscales concerning the foot: [1] Pain and Pain-Related, [2] Physical Functioning and Daily Living, [3] Social Functioning, [4] Shoe-Related, [5] General Health and Well-Being, and [6] Sports Activity (optional).

Question items of each component are as follows:

- [1] Question 1 to Question 7, Question 10, and Question 11 (9 items) are “Pain and Pain-Related.”
- [2] Question 12 to Question 22 (11 items) concern “Physical Functioning and Daily Living.”
- [3] Question 23 to Question 28 (6 items) concern “Social Functioning.”
- [4] Question 8, Question 9, and Question 34 (3 items) are “Shoe-Related.”
- [5] Question 29 to Question 33 (5 items) concern “General Health and Well-Being.”
- [6] Question 35 to Question 43 (9 items) concern “Sports Activity,” and are listed as optional items.

2. Score of question items

- 1) For questions other than Questions 3 and 43, give a score of 4, 3, 2, 1, or 0 in order, from left to right.
- 2) For Questions 3 and 43, which should be answered using the Visual Analog Scale (VAS), read the value (to one decimal place) on the scale with the right end (full scale) as 10 cm. Calculate the score using the formula “ $(10 - \text{the Value}) \times 0.4$ ” for Question 3 and “ $\text{the Value} \times 0.4$ ” for Question 43.
- 3) Calculate the score of each subscale using the formula “[score calculated for each subscale] $\times 25 /$ [number of question items for each subscale].” For each subscale, the minimum score is 0 and the maximum score is 100.
- 4) The score of each subscale, and not the total score, is used for assessment.
- 5) The score of each subscale can be calculated using the “Scoring Table for the Japanese Orthopaedic Association / Japanese Society for Surgery of the Foot, Self-Administered Foot Evaluation Questionnaire (SAFE-Q)”.

**Scoring Table for the Japanese Orthopaedic Association /Japanese Society for Surgery of the
Foot, Self-Administered Foot Evaluation Questionnaire (SAFE-Q)**

Pain and Pain-Related (0 to 100 points)

Question 1	4, 3, 2, 1, 0
Question 2	4, 3, 2, 1, 0
Question 3	(10 – value) × 0.4
Question 4	4, 3, 2, 1, 0
Question 5	4, 3, 2, 1, 0
Question 6	4, 3, 2, 1, 0
Question 7	4, 3, 2, 1, 0
Question 10	4, 3, 2, 1, 0
Question 11	4, 3, 2, 1, 0

$$\boxed{\text{Calculated score}} \times \frac{25}{9} = \boxed{\text{“Pain and Pain-Related” score}} /100 \text{ points}$$

Physical Functioning and Daily Living (0 to 100 points)

Question 12	4, 3, 2, 1, 0
Question 13	4, 3, 2, 1, 0
Question 14	4, 3, 2, 1, 0
Question 15	4, 3, 2, 1, 0
Question 16	4, 3, 2, 1, 0
Question 17	4, 3, 2, 1, 0
Question 18	4, 3, 2, 1, 0
Question 19	4, 3, 2, 1, 0
Question 20	4, 3, 2, 1, 0
Question 21	4, 3, 2, 1, 0
Question 22	4, 3, 2, 1, 0

$$\boxed{\text{Calculated score}} \times \frac{25}{11} = \boxed{\text{“Physical Functioning and Daily Living” score}} /100 \text{ points}$$

Social Functioning (0 to 100 points)

Question 23	4, 3, 2, 1, 0
Question 24	4, 3, 2, 1, 0
Question 25	4, 3, 2, 1, 0
Question 26	4, 3, 2, 1, 0
Question 27	4, 3, 2, 1, 0
Question 28	4, 3, 2, 1, 0

$$\boxed{\text{Calculated score}} \times \frac{25}{6} = \boxed{\text{“Social Functioning” score}} /100 \text{ points}$$

Shoe-Related (0 to 100 points)

Question 8	4, 3, 2, 1, 0
Question 9	4, 3, 2, 1, 0
Question 34	4, 3, 2, 1, 0

$$\boxed{\text{Calculated score}} \times \frac{25}{3} = \boxed{\text{“Shoe-Related” score}} /100 \text{ points}$$

General Health and Well-Being (0 to 100 points)

Question 29	4, 3, 2, 1, 0
Question 30	4, 3, 2, 1, 0
Question 31	4, 3, 2, 1, 0
Question 32	4, 3, 2, 1, 0
Question 33	4, 3, 2, 1, 0

$$\boxed{\text{Calculated score}} \times \frac{25}{5} = \boxed{\text{“General Health and Well-Being” score}} /100 \text{ points}$$

Optional Item: Sports Activity (0 to 100 points)

Question 35	4, 3, 2, 1, 0
Question 36	4, 3, 2, 1, 0
Question 37	4, 3, 2, 1, 0
Question 38	4, 3, 2, 1, 0
Question 39	4, 3, 2, 1, 0
Question 40	4, 3, 2, 1, 0
Question 41	4, 3, 2, 1, 0
Question 42	4, 3, 2, 1, 0
Question 43	Value × 0.4

$$\boxed{\text{Calculated score}} \times \frac{25}{9} = \boxed{\text{“Sports Activity” score}} / 100 \text{ points}$$

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