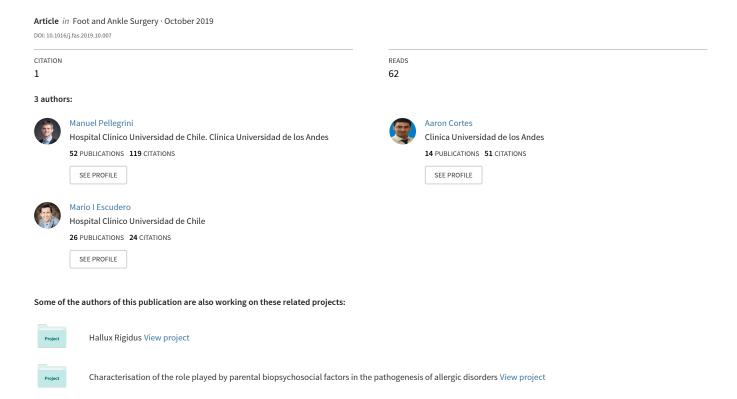
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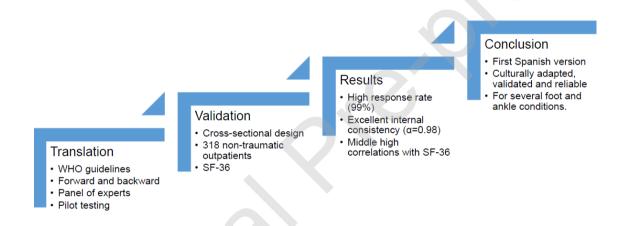
Cross-cultural Adaptation and Validation of the Foot and Ankle Outcome Score (FAOS) into Spanish (Chile).

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Graphical abstract



Highlights

- Validation based on data from a considerable sample size (318 participants)
- Excellent internal consistency (Cronbach' $\alpha = 0.98$)
- The first Spanish version of the FAOS
- A culturally adapted, validated and reliable version
- Capable of evaluating several foot and ankle conditions.

Abstract

Purpose: To adapt and validate the English version of the Foot and Ankle Outcome Score (FAOS) into

Spanish FAOS-CL, following the WHO guidelines.

Methods: A cross-sectional study including 318 outpatients with non-traumatic conditions. Validity, acceptability and internal consistency including correlations with the Medical Outcome Study Short Form

36 are reported.

Results: The preliminary version resulted from the forward and back-translation and a pilot administration. Validation response rate was 99.22%. Substantial ceiling effects were observed for Symptoms and ADL and floor effect for QoL sub-scales. The FAOS-CL had excellent internal consistency (Cronbach's $\alpha = 0.98$). The principal component analysis gave five factors explaining the 72.6% of the variance. The FAOS-CL items significantly correlate with their sub-scales. FAOS-CL subscales significantly correlated with SF-36 components and subcomponents.

Conclusion: The first Spanish version of the FAOS was generated. Culturally adapted and validated with high reliability capable of evaluating different foot and ankle conditions.

Keywords: PROMs · Orthopaedic condition · Cross-cultural adaptation · Psychometric Evaluation · Spanish.

1. Introduction

The primary goal when developing a scale is to achieve a quick and standardised evaluation of the patient to help classification, diagnostic and treatment. The instrument needs to be reliable, valid and adapted to the specific culture where it will be used. Patient report outcomes measures (PROMs) have increasingly gained support and importance on clinical practice and research; however, there is no agreement about "the preferred" instrument to use for each condition, making difficult to compare research results.[1]

Among the most commonly used scales to evaluate inferior extremity and specifically foot and ankle conditions is the Foot and Ankle Outcome Score (FAOS).[2]

The FAOS, an originally Swedish score, was developed by the same authors of the "Knee Injury and Osteoarthritis Outcome Score (KOOS)[3] which focuses on knee and others injuries produced by osteoarthritis; however, FAOS evaluates functional limitations related to foot and ankle issues.

The scale has been used worldwide, and translations and cultural adaptations have been validated in Portuguese (Portugal[4] and Brazil[5]), Turkish,[6] Persian[7], Korean,[8] German,[9] Dutch,[10] Danish,[11] Chinese.[12] Currently, several translations are ongoing. Except for the Korean (minimum Cronbach's α 0.615) and Persian (Iran) versions (minimum Cronbach's α 0.39), the FAOS have shown good to excellent reliability with Cronbach's α values varying from 0.76 to 0.98, showing that the scale is a reliable and valid instrument to measure the functional limitations related to foot and ankle across cultures and replicable for future populations[13]. However, no translation has been validated for its use within the Spanish speaking population.

The FAOS scale consist in 42 items that cover 5 dimensions: Symptoms (S: 7 items), Pain (P: 9 items), Activities of Daily Living (ADL: 17 items), Sport and Recreation Activities (SRA: 5 items), and foot and ankle related Quality of Life (QoL: 4 items). Items are scored in a 5-point Likert scale ranging from 0 to 4. It is a self-reported scale that can be answered in 10 minutes.[14] Raw scores of each subscales results of the sum of each item score. These raw scores are standardised into a 0 to 100 scale; higher scores mean higher dysfunction due to foot/ankle condition.

The original version focused on the reconstruction of the lateral ligament of the ankle; however, further research has shown applicability in a broader range of conditions and procedures related to foot and ankle; such us ankle arthroscopy, arthrodesis of the ankle and hallux valgus correction.[13]

Additionally, it is generally well accepted by the patients.[10]

Therefore, this original study pursuits the development of the first Spanish (Chile) translation, culturally adapted and validated version of the FAOS.

2. Material and methods

Consecutive outpatients attending a foot and ankle orthopaedic clinic were invited to participate.

Recruitment period run from October 2016 until May 2018. Participants included patients with foot or

ankle orthopaedic conditions, aged above 13 years old, fluent in Spanish, and capable of self-report their health status. Exclusion criteria were traumatic orthopaedic injury, neurological dysfunction, psychiatric or cognitive disorder and writing or reading disabilities. Socioeconomic data included age, sex, current activity/employment and educational level.

2.1. Translation and Cross-cultural adaptation

The first stage consisted of the translation and back-translation system where the guidelines of the World Health Organisation[15] were followed.

A professional native Spanish (Chile) speaker translator, with no health science background (blind to the original FAOS scale), translates the English version of FAOS into Spanish (Chile).

Afterwards, a panel of bilingual experts reviewed the translation and checked any discrepancies in medical expressions or concepts.

A second translator, a native English speaker with no previous knowledge of the FAOS scale, back-translate the resulting Spanish-Chile version. Like the first process, the emphasis was placed on the concepts, not on literal meaning. Discrepancies were discussed and resolved together, between the panel of experts and the translators.

The translated version of FAOS was applied to a sample of 14 participants with the same characteristics of the final population. This pilot application had the purpose of pre-testing the translated FAOS and assess the correct use of language by the target population.

2.2. Validation

The second stage used a cross-sectional design to test the reliability and validity of the translated Spanish version. Patients consulting due to an orthopaedic foot or ankle injuries answered the translated version of the FAOS and the Spanish version of the Health Survey Short Form (SF-36).[16]

2.2.1. Health Survey Short Form (SF-36)

The Medical Outcome Study (MOS) SF-36[17], It is a generic scale to evaluate health/disease status. The SF-36 has been translated and validates into Spanish (Chile).[16] It comprises 36 items divided into two components: Physical Health (PH) and Mental Health (MH). PH includes four subscales: Physical Function (PF), Role Physical (RP), Bodily Pain (BP), and General Health (GH). MH includes four subscales: Vitality (V), Social functioning (SF), Role Emotional (RE), and General Health (GH). The SF-36 User's Manual describes in detail the scoring system[18]. The scores are transformed into a 0-to-100 scale. Higher scores represent better health status

2.2.2. Data analysis

Data analyses included different levels of scrutinises:

- Data description: percentage, mean and standard deviation.
- Quality of the data was represented by percentages of missing data and the possibility of obtaining a scale or sub-scale score. Scale completeness cut-off was set at a minimum of 50% to be kept for further analyses.
- Acceptability was evaluated using item frequency distribution and central tendency measures:
 - o Score range: use of all the possible response choices for each item.
 - Mean, median scores and Standard Deviation: These parameters should be roughly equivalent within a scale or sub-scale
 - Floor and ceiling effects and skewness. Score distribution on the extreme scores was analysed; a
 high percentage (>20%) of floor or ceiling effect may compromise the discriminative ability of the
 scale.
 - Item-internal consistency: Expressed by the correlation between the specific item and its correspondent sub-scale. Coefficients (r) higher than 0.4 were considered acceptable.

- Item-discriminant validity: Expressed by the correlation between a specific item and its
 correspondent sub-scale compared with the correlation with the others sub-scales. It is expected
 higher correlations within the hypothesised scale.
- Very strong to perfect correlations (r>0.8) are not expected since indicates no addition of significant information; therefore, no difference between the items.
- Internal Construct Validity: Using Pearson's r among the five sub-scales. Since each sub-scale
 measures different aspects of the same construct, it is hypothesised moderate to strong correlations
 between all sub-scales.
 - Convergent Validity: Moderate to strong correlations between the sub-scales (r 0.3 to 0.7) indicates sufficient convergent validity.
 - Divergent Validity: Low correlations between the sub-scales (r <0.3) indicates sufficient divergent validity.
- Internal consistency Reliability: Cronbach's α and Guttman's split-half coefficients were calculated for internal consistency. Coefficients higher than 0.7 were interpreted as a cut-off criterion of reliability.
- External Validity:
 - Construct validity was assessed by comparing the final scores of the translated version of the FAOS and the SF-36, expecting a middle-high inverse correlation (Pearson's bivariate correlations).
 - Convergent: Moderate to strong inverse Pearson's correlation among FAOS-CL Symptoms,
 Pain, ADL and SRA and SF-36 Physical Health component and sub-components were expected.
 Moderate to low correlations were expected for FAOS-CL QoL and SF-36 Physical Health
 Component and Sub-components.
 - Divergent: Moderate to low inverse Pearson's correlation between FAOS-CL Symptoms, Pain,
 DLF and SRA and SF-36 Mental Health component and sub-components were expected.
 Moderate to strong correlations were expected for FAOS-CL QoL and SF-36 Mental Health
 Component and Sub-components.

o Discriminative validity of the FAOS-CL, a between-subjects t-tests and Pearson's correlations, were

calculated comparing demographic characteristics.

o Initially sampling Adequacy: Kaiser-Meyer-Olkin (KMO) test and Bartlett's sphericity test;

Exploratory Factor Analysis (EFA).

All analyses were performed using SPSS V.19. Results were considered significant with alpha

levels lower than 0.05 (two-tailed).

Results

A total sample of 318 eligible outpatients agreed to take part in the study, 17 of them (5.3%) did

not answer the questionnaire and 301 participants completed at least the 90% of the FAOS-CL. The final

sample included 301 subjects; 211 of them were women (70.1%); age ranged from 13 to 82 years-old

(media 44.1; median 44.5; SD 16.9); 93,8% had at least secondary studies; and 38,5% had a university

title. Sociodemographic data in Table 1.

A total of 43 non-traumatic conditions were diagnosed; the most frequent was Hallux Valgus

(28.9%), followed by Ankle instability (6.6%) and Osteomyelitis (6.3%). Three participants (0.9%) had

fractures evaluated after at least twelve months of their incident (Table 2).

3.1. First stage: Translation and cross-cultural adaptation (WHO guidelines [15]).

After the forward translation into Spanish, the bilingual panel of experts identify several but

minor words that need to be adapted to the clinical context and meaning of the original scale. After the

back-translation into English, the bilingual panel of experts compare both the Original and back-

translated English versions and no discrepancies were found. After the pilot language testing (N= 14)

meaningful adjustments were made to develop the preliminary FAOS-CL.

3.2. Second Stage: Validation process.

8

Questionnaire response rate achieves 99.22% of completion. The scale average missing data per items was 0.78% (range 0 to 2.99%); Sub-scale average missing data ranged from 0.44 to 1.41%. The 100% of the answered scales allowed computing a score and the 85.4% of the scales were fully completed. FAOS-CL scores ranged from 0 to 100, with higher scores meaning higher dysfunction or bother due to foot or ankle condition.

Descriptive statistics for each item are summarised in Table 3. Floor and ceiling effects were observed on the majority of the items. Substantial ceiling effects were seen for Symptoms (35.9%) and ADL (42,1%); Pain showed 26.2% of ceiling effect; QoL and SRA showed 29.2% and 21,5% of floor effect respectively (Table 3 and 4).

Differentiated analyses for age and sex were performed; younger participants (range 13-36 years old) showed a higher ceiling effect for Symptoms, Pain, ADL and SRA. No significant differences were seen for male compared to female participants (Table 4).

3.3. Validity

Inter-item consistency and discriminant validity. Items and its correspondent sub-scales showed, in general, significantly higher correlations when compared with the other sub-scales. A summary of these results is given in the next paragraph, and further details were placed in the Online Resource 1.

- **Symptoms**: Except for items S4 and S5, Pearson's coefficients between items showed moderate to strong correlations with r: ranging from 0.32 to 0.79. Items S4 and S5 concentrate all lower correlations.
- Pain: Pearson's coefficients between items showed moderate to strong correlations with r: ranging from 0.42 to 0.85. Items P3 and P4 had a very strong correlation (r: 0.85).
- Activities of Daily Living (ADL): Pearson's coefficients between items showed moderate to strong correlations with r: ranging from 0.54 to 0.91. Items A1, A2, A3, A4, A7, A9, A11, A14 and A15, had very strong correlations (from 0.83 to 0.91).
- Sport and Recreation Activities (SRA): Pearson's coefficients between items showed moderate to strong correlations with r: ranging from 0.68 to 0.90. Items SRA1 and 5 (r: 0.87) and items SRA2 and 3 had very strong correlations (r: 0.90).

• Quality of Life (QoL): Pearson's coefficients between items showed moderate to strong correlations with r: ranging from 0.56 to 0.76.

Correlations between the item and the sub-scales and the item and the total scale showed for the sub-scales Pain, ADL, SRA and QoL good adequacy of the item and its hypothesised sub-scale. On this regard Symptoms items (S1, 2, 3, 6 and 7) showed higher correlations with other sub-scales, especially Pain, ADL and SRA. Details in the repository (Table, Online Resource 2).

Internal construct validity: Pearson's correlation between the subscales ranged from r 0.59 to 0.87 (p <0.01). See Table 5 for details.

Regarding reliability, the FAOS-CL had excellent internal consistency with a total Cronbach's α of 0.98. Split-half Cronbach's α was 0.96 for both half 1 and half 2. The subscales had a similar excellent performance with 0.82 for Symptoms; 0.93 for Pain; 0.97 for ADL; 0.94 for SRA; and 0.88 for QoL.

Average and range of computed scores for each sub-scales were as follow: Symptoms: 38.1 (SD 24; range 0-100); Pain: 39.7 (SD 23.5; range 0-100); ADL: 28 (SD 24.1; range 0-100); SRA: 53.9 (SD 30.5; range 0-100); and QoL: 65.1 (SD 26.3; range 0-100). Frequency distribution showed that all possible response for every item of the scale was used.

As hypothesised, FAOS-CL subscales significantly and inversely correlated with the components and sub-components of the SF-36. For instance, SF-36 Physical Health Component significantly correlated with FAOS-CL subscales: Symptoms (r= -.53; p=.000); Pain (r= -.65; p=.000); ADL (r= -.70; p=.000); SRA (r= -.67; p=.000); and QoL (r= -.53; p=.000). Similarly, SF-36 Mental Health Component significantly and inversely correlated with FAOS-CL subscales: Symptoms (r= -.40; r=-.000); Pain (r= -.51; r=.000); ADL (r= -.58; r=.000); SRA (r= -.50; r=.000); and QoL (r= -.41; r=-.000). Details in Table 6.

The sub-component "General Health" of the Physical Health component of the SF-36 showed low correlations with all FAOS-CL subscales (range from r=.12 to .33). Unexpectedly, the subcomponent "Pain" of the "Physical Health" component and the sub-component "Social Function" of the "Mental Health" component of the SF-36 had direct and significant (but low) correlations with all FAOS-CL subscales (range from r=.20 to .34). All others correlations between FAOS-CL and SF-36 were

inverse, strong and statistically significant ranging from -.28 to -.74, these inverse middle-high and low correlations support cross-sectional construct validity meaning that the variation in one of the scales (or sub-scales) accounts from the 1% up to the 55% of the variation in the index of the other scale. In other words, they evaluate correlated but different variables.

3.3.1. Discriminative Validity

As expected, there were not significant differences when comparing male and female mean scores of the FAOS-CL sub-scales; Symptoms: male 39.2, female 37,6 (t(298)=0.540; p=0.59); Pain: male 38.9, female 39.9 (t(299)=-0.34; p=0.74); DLF: male 25.4, female 29.1 (t(299)=-1.23; p=0.22); SRA: male 54.9, female 53.4 (t(295)=0.39; p=0.66); and QoL: male 65.8 female 64.8 (t(296)=0.31; p=0.76).

Significant differences were seen when compared by age. In the sub-scales Pain, participants below the media of 44 years old scored a mean on 43 points (SD 24.5); meanwhile, participants above the age media scored a mean of 35.8 points (SD 22.3) (t(288)= 2.64; p= 0,009); ADL media scores for younger participants was 34.2 (SD 24.8) and 21.4 (SD 21.6) for older participant (t(288)= 4.69; p = 0,00); and SRA media scores for younger participants was 58.1 (SD 30) and 48.7 (SD 30.7) for older participant (t(284)= 2.61; p = 0,01). No significant differences were shown for Symptoms and QoL when compared by participants' age.

3.3.2. Exploratory Factor analysis

Data were adequate for factor analysis (Kaiser-Meyer-Olkin [KMO]= 0.969; Bartlett's test of sphericity p< 0.001). The Principal Component factor analysis gave five factors loading over 1 Eigenvalue. These factors explain the 72.6% of the variance, with factors loading range from 0.478 to 0.869. Only item 1 (S1) of the sub-scale Symptoms loaded lower than 0.5.

Based on the reported results the FAOS-CL comprises 42 items divided into five subscales evaluating performance during the last week (Appendix 1).

3.4. Scoring

Scoring strategy follows the indication of the original FAOS (Table 7). Raw scores result of summing items within each sub-scale. To obtain standardised sub-scales scores; the sum of each item is multiplied by 100, then divided by the highest possible score in that specific sub-scale, and the result is subtracted to 100.

4. Discussion

The reported results demonstrate the reliability, validity and responsivity of the FAOS-CL to evaluate patients suffering from foot or ankle conditions.

The final sample comprised 301 participants with high response rate and distribution implying good levels of acceptability and quality of the data. Therefore, the FAOS-CL can be self-administered.

Participants were outpatients consulting due to current orthopaedic symptoms; this may explain that the majority of the items and subscales, especially Symptoms and ADL showed floor and ceiling effects (stronger among younger participants).

Inter-item correlation showed middle to high Pearson's correlations between and within subscales meaning good construct validity and item-internal consistency. However, several within subscales inter-items correlations were very high (r > 0.8) meaning low information added by the item.

Higher correlations between item and its correspondent sub-scale comparing with the others subscales were seen for all sub-scales except for Symptoms, indicating good item-discriminant validity.

The FAOS-CL showed excellent internal consistency (α = 0.98) demonstrating the adequacy of the Spanish version, situating the FAOS-CL among the versions with the highest reported reliability. The FAOS-CL also included, so far, the highest number of participants for its cross-cultural adaptation and validation.

Construct validity was proven by significant middle to high correlations with the SF-36 components and sub-components.

- Convergent validity hypothesised moderate to strong inverse correlations among FAOS-CL Symptoms, Pain, ADL and SRA with the SF-36 Physical Health component and sub-components. This was seen for the Physical Health Component (p ranged from -.53 to -.70) and for two of the four SF-36 sub-components (Physical Function and Physical Role) but not for SF-36 Pain (with moderate to low direct correlations) nor SF-36 General Health (with low inverse correlations). Moderate correlations between FAOS-CL QoL and SF-36 Physical Health Component and sub-components were hypothesised and observed in the sample. Except for SF-36 Pain (r= 0.22) that showed a direct and low correlation.
- Divergent validity hypothesised moderate to low inverse correlations among FAOS-CL Symptoms,
 Pain, ADL and SRA with the SF-36 Mental Health component and sub-components. This was seen on three of the four SF-36 sub-components, but not for SF-36 Social Function, which showed low and direct correlations. Similarly, Moderate to strong correlations between FAOS-CL QoL and SF-36 Mental Health Component and sub-components were hypothesised and observed in the sample.
 Likewise, SF-36 Social Function sub-component sowed low and direct correlation.

FAOS-CL showed discriminative validity since, as expected, no significant differences were observed between male and female participants. Regarding validity, the principal component factor analysis revealed five factors explaining the 72.6% of the variance.

Among the weakness of this study is the lack of re-test. It is expected to report these data in future research. However, and based on preliminary data and previous validation processes a good quality data is expected for this scale.

As shown, several within sub-scales inter-items correlations were very high (r > 0.8). Meaning reduced information added to evaluate the variable. Nevertheless, if any item is eliminated the Cronbach's α would decrease.

5. Conclusion

The present study validated the first Spanish (Chile) version of the Foot and Ankle Outcome Score (FAOS-CL), showing excellent internal consistency, demonstrating its adequacy for the Spanish speaking population and is the versions among the highest reported reliability.

The FAOS-CL can be used to evaluate foot and ankle conditions; additionally, it can discriminate between ages.

Conflicts of Interest Statement

The authors declare that they have no conflict of interest. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article.

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Ethical Approval: The study protocol was approved by the Medical Ethics Committee of the Universidad de Chile Clinical Hospital.

Conflicts of Interest: The authors declare that they have no conflict of interest. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article.

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Table 1: Demographic data (N=301)

| | N(%) | |
|--------|----------------------|-----------|
| Sex | | |
| | Male | 90(29.9) |
| | Female | 211(70.1) |
| Age | Media: 43.8 (SD)16.8 | |
| | 13 - 36 | 104(34.6) |
| | 37 - 59 | 123(40.9) |
| | 60 - 82 | 63(20.9) |
| | Missing | 11(3,7) |
| Educa | ation | |
| | Primary | 17(5.6) |
| | Secondary | 66(21.9) |
| | Technic | 86(28.6) |
| | University | 85(28.2) |
| | Post Grade | 21(7.0) |
| | Missing | 26(8.6) |
| Activi | ity | |
| | Student | 49(16.3) |
| | Domestic activities | 28(9.3) |
| | Dependant worker | 141(46.8) |
| | Self-employed | 43(14.3) |

| Retired | 23(7.6) |
|------------|---------|
| Unemployed | 9(3.0) |
| Missing | 13(4.3) |

Table 2: Income Diagnosis (N=301)

| Table 2: Income Diagnosis (N=301) | | | | | | | | |
|-----------------------------------|----------------------------|-----------|------------|--|--|--|--|--|
| Diag | nostic | Frequency | Percentage | | | | | |
| 1 | Chronic osteomyelitis | 4 | 1.3 | | | | | |
| 2 | Ankle Arthrodesis | 5 | 1.7 | | | | | |
| 3 | Achilles tendinopathy | 10 | 3.3 | | | | | |
| 4 | Plantar Fasciitis | 18 | 6.0 | | | | | |
| 5 | Ankle Osteoarthritis | 15 | 5.0 | | | | | |
| 6 | Claw Toe | 16 | 5.3 | | | | | |
| 7 | Clubfoot | 1 | 0.3 | | | | | |
| 8 | Flatfoot | 18 | 6.0 | | | | | |
| 9 | Peroneal tendinopathy | 1 | 0.3 | | | | | |
| 10 | Hallux valgus | 87 | 28.9 | | | | | |
| 11 | Metatarsalgia | 5 | 1.7 | | | | | |
| 12 | Ankle Instability | 20 | 6.6 | | | | | |
| 13 | OLT | 19 | 6.3 | | | | | |
| 14 | Plantar Fibromatosis | 1 | 0.3 | | | | | |
| 15 | Flexible digging foot | 4 | 1.3 | | | | | |
| 16 | Hallux Rigidus | 17 | 5.6 | | | | | |
| 17 | Synovial cyst | 3 | 1.0 | | | | | |
| 18 | Anterior Ankle Impingement | 13 | 4.3 | | | | | |
| 19 | Arthrodesis | 2 | 0.7 | | | | | |
| 20 | Talocalcaneal Bar | 1 | 0.3 | | | | | |

| 21 | Posterior Ankle Impingement | 3 | 1.0 |
|----|--------------------------------|---|-----|
| 22 | Neurological Foot | 2 | 0.7 |
| 23 | Ankle prosthesis | 1 | 0.3 |
| 24 | Bad limb alignment | 1 | 0.3 |
| 25 | Bad union fracture leg | 1 | 0.3 |
| 26 | Calcaneal Osteomyelitis | 1 | 0.3 |
| 27 | Hernia | 2 | 0.7 |
| 28 | subtalar osteoarthritis | 2 | 0.7 |
| 29 | Cuneometatarsal osteoarthritis | 1 | 0.3 |
| 30 | Turf toe | 1 | 0.3 |
| 31 | Hallux, Cock-up | 1 | 0.3 |
| 32 | Buniounette | 2 | 0.7 |
| 33 | Subtalar Non-union | 3 | 1.0 |
| 34 | Rheumatic foot | 4 | 1.3 |
| 35 | Avascular talus necrosis | 2 | 0.7 |
| 36 | Exostosis | 2 | 0.7 |
| 37 | Syndesmosis instability | 1 | 0.3 |
| 38 | Rigid digging foot | 1 | 0.3 |
| 39 | Osteosynthesis | 1 | 0.3 |
| 40 | Navicular avascular necrosis | 1 | 0.3 |
| 41 | Defect / Bone loss | 1 | 0.3 |
| 42 | Osteochondroma | 1 | 0.3 |

| 43 | Villonodular synovitis | 1 | 0.3 |
|----|------------------------|---|-----|
| 44 | Peroneal break | 1 | 0.3 |
| 45 | Ankle Fracture | 1 | 0.3 |
| 46 | Tibia Fracture | 1 | 0.3 |
| | Lost data | 2 | 0.7 |

Table 3. Descriptive statistics and score distribution per item FAOS-CL

| Table 5. Des | scripuve s | tausues and | i score a | ISTLIDATIO | n per item FAO | S-CL |
|--------------|------------|-------------|-----------|------------|----------------|-----------------|
| Item | Media | Kurtosis | % | % | Item-total | Cronbach's α |
| ltem | Media | Kui tosis | Floor | Ceiling | correlation | if item deleted |
| S1 | 2.01 | -1.190 | 18.3 | 21.3* | .587 | .978 |
| S2 | 2.49 | -1.144 | 12 | 35.9* | .414 | .979 |
| S3 | 2.75 | 892 | 8 | 45.2* | .675 | .978 |
| S4 | 2.40 | -1.427 | 19.9 | 38.9* | .360 | .979 |
| S5 | 2.25 | -1.479 | 23.6* | 34.9* | .334 | .979 |
| S6 | 2.65 | -1.004 | 5.6 | 36.2* | .728 | .978 |
| S7 | 2.80 | 719 | 4 | 39.2* | .764 | .978 |
| P1 | 1.37 | 426 | 21.9* | 2.3 | .616 | .978 |
| P2 | 2.32 | -1.056 | 9.3 | 24.9* | .750 | .978 |
| Р3 | 2.62 | 677 | 7.6 | 32.6* | .812 | .978 |
| P4 | 2.50 | 989 | 7 | 29.2* | .783 | .978 |
| P5 | 2.57 | 837 | 3.3 | 26.9* | .704 | .978 |
| P6 | 2.29 | 950 | 6.6 | 21.6* | .830 | .977 |
| P7 | 2.82 | 567 | 2.3 | 33.9* | .693 | .978 |
| P8 | 3.09 | 068 | 2 | 48.8* | .760 | .978 |
| P9 | 2.16 | 826 | 8.3 | 15.3 | .767 | .978 |
| A1 | 2.45 | 959 | 7.6 | 28.2* | .864 | .977 |
| A2 | 2.44 | 889 | 8.3 | 26.9* | .834 | .977 |
| A3 | 2.74 | 560 | 5.6 | 35.9* | .843 | .977 |

| A4 | 2.74 | 569 | 5.6 | 35.9* | .844 | .977 |
|------|------|--------|-------|-------|------|------|
| A5 | 2.70 | 692 | 6.6 | 36.9* | .772 | .978 |
| A6 | 2.74 | 777 | 2.7 | 33.6* | .716 | .978 |
| A7 | 2.90 | 154 | 3.7 | 38.9* | .820 | .978 |
| A8 | 2.62 | 776 | 4.7 | 30.9* | .780 | .978 |
| A9 | 3.12 | .052 | 3 | 54.2* | .713 | .978 |
| A10 | 3.00 | 169 | 3.3 | 46.5* | .785 | .978 |
| A11 | 3.15 | .143 | 2 | 52.8* | .725 | .978 |
| A12 | 3.06 | 034 | 3 | 48.8* | .810 | .978 |
| A13 | 3.07 | .130 | 3.3 | 49.5* | .782 | .978 |
| A14 | 3.33 | 1.101 | 1.3 | 59.8* | .744 | .978 |
| A15 | 3.25 | .911 | 2.3 | 57.1* | .751 | .978 |
| A16 | 2.48 | -1.075 | 6.3 | 30.9* | .819 | .978 |
| A17 | 3.12 | .533 | 3 | 48.5* | .748 | .978 |
| SP1 | 2.14 | -1.210 | 14 | 22.9* | .789 | .978 |
| SP2 | 1.46 | 911 | 30.6* | 10.3 | .752 | .978 |
| SP3 | 1.46 | 964 | 31.2* | 11 | .766 | .978 |
| SP4 | 1.90 | -1.168 | 19.3 | 18.9 | .793 | .978 |
| SP5 | 2.25 | -1.204 | 12.6 | 25.6* | .831 | .977 |
| QoL1 | 1.03 | 1.379 | 33.6* | 5.6 | .513 | .978 |
| QoL2 | 1.56 | -1.286 | 34.2* | 12.6 | .633 | .978 |
| QoL3 | 1.47 | 881 | 28.2* | 8.6 | .655 | .978 |

| QoL4 | 1.55 | 711 | 20.6* | 4.3 | .738 | .978 |
|------|------|-----|-------|-----|------|------|
| | | | | | | |



Table 4: Subscale Floor and Ceiling effects by age and gender

| Ve | Variable | | ptoms | P | ain | AI | DL | SR. | A | Qo | L |
|-----|----------|-------|---------|-------|---------|-------|-------|---------|-------|---------|-------|
| V 2 | шаыс | Floor | Ceiling | Floor | Ceiling | Floor | Floor | Ceiling | Floor | Ceiling | Floor |
| | 13-36 | 12.2 | 42.5 | 5.9 | 35.0 | 3.0 | 55.6 | 17.7 | 26.9 | 27.7 | 8,7 |
| Age | 37-59 | 15.1 | 31.8 | 9.0 | 22.3 | 4.6 | 36.9 | 26.2 | 14.6 | 35.8 | 7,9 |
| | 60-82 | 11.1 | 33.1 | 8.3 | 20.8 | 6.0 | 29.9 | 18.7 | 10.5 | 20.3 | 7,5 |
| Sex | Male | 14.3 | 34.6 | 7.2 | 24.6 | 4.2 | 43.9 | 22.9 | 15.1 | 29.2 | 6,4 |
| | Female | 12.5 | 36.5 | 7.8 | 26.8 | 4.3 | 42.1 | 20.9 | 18.9 | 29.2 | 8,4 |
| 1 | otal | 13,1 | 35.9 | 7.6 | 26.2 | 4.3 | 42.1 | 21.5 | 17.7 | 29.2 | 7.8 |

Table 5: Correlations FAOS Sub-scales

| | Pain | ADL | SRA | QoL |
|----------|--------|--------|--------|--------|
| Symptoms | .761** | .703** | .716** | .593** |
| Pain | | .873** | .821** | .703** |
| ADL | | | .786** | .628** |
| SRA | | | | .714** |

all correlation p < 0.01 (bilateral)

Table 6: Pearson's Correlations FAOS versus SF-36

| SF-36 Components and | FAOS Sub-scales | | | | | | | |
|---------------------------|-----------------|--------|--------|--------|--------|--|--|--|
| Subcomponents | Symptoms | Pain | ADL | SRA | QoL | | | |
| Physical Health Component | 533** | 645** | 700** | 666** | 530** | | | |
| Physical Function | 569** | 693** | 738** | 688** | 506** | | | |
| Physical Role | 507** | 545** | 607** | 590** | 540** | | | |
| Pain | .234** | .285** | .334** | .265** | .204** | | | |
| General Health | 115* | 284** | 328** | 250** | 114 | | | |
| Mental Health Component | 402** | 513** | 575** | 499** | 411** | | | |
| Vitality | 276** | 459** | 484** | 422** | 359** | | | |
| Social Function | .220** | .299** | .321** | .289** | .274** | | | |
| Emotional Role | 440** | 496** | 572** | 492** | 417** | | | |
| Mental Health | 328** | 447** | 490** | 439** | 359** | | | |

^{**.} Significant correlation at 0.01 level (bilateral).

^{*.} Significant correlation at 0.05 level (bilateral).

Table 7: Scoring system per sub-scale

| Sub-Scale | oring system per si Items | Worst | Better | Formula |
|-----------|------------------------------|-------|--------|---|
| Sub-Scale | Items | worst | Detter | rormuia |
| Symptoms | S1, S2, S5, S6, S7 | 4 | 0 | $SScore = 100 - \frac{\sum i1 \ to \ i7 \times 100}{28}$ |
| | S3, S4 | 0 | 4 | |
| Pain | P1 to 9 | 4 | 0 | $PScore = 100 - \frac{\sum i1 \text{ to } i9 \times 100}{36}$ |
| ADL | DLF 1 to 17 | 4 | 0 | $ADL Score = 100 - \frac{\sum i1 to i17 \times 100}{68}$ |
| SRA | SRA 1 to 5 | 4 | 0 | $SRA Score = 100 - \frac{\sum i1 to i5 \times 100}{20}$ |
| QoL | QoL 1 to 4 | 4 | 0 | $QoL Score = 100 - \frac{\sum i1 \ to \ i4 \times 100}{16}$ |