

## TRANSLATION, CROSS-CULTURAL ADAPTATION, AND PSYCHOMETRIC EVALUATION OF THE BOSNIA AND HERZEGOVINA VERSION OF THE FOOT AND ANKLE OUTCOME SCORE IN PATIENTS WITH ANKLE SPRAIN: A CROSS-SECTIONAL STUDY

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### ABSTRACT

**Objectives:** To translate, adapt, and evaluate the psychometric properties of the Bosnia and Herzegovina version of the Foot and Ankle Outcome Score (BH-FAOS) in patients with ankle sprain.

**Methods:** In this cross-sectional study, 55 patients with ankle sprains were included. Four psychometric measures were assessed: construct validity (correlation of FAOS and Short Form Quality of Life Questionnaire – SF-12), content validity (the patient's perception of the importance of FAOS questions), reliability (test-retest and internal consistency, Bland-Altman analysis), and responsiveness (after physical therapy intervention).

**Results:** Satisfactory construct validity was determined. All subscales of FAOS were in moderate correlation ( $r > 0.3$ ) with the physical and mental health components of the SF-12 ( $r > 0.30$ ). All FAOS subscales demonstrated excellent reliability [Interclass Correlation Coefficient (ICC) values  $> 0.90$ ; Cronbach's alpha values  $\geq 0.98$ ].

**Conclusions:** The BH-FAOS is a reliable and valid instrument for assessing outcomes in patients with ankle sprains. The acceptable reliability and construct validity make it suitable for research and clinical purposes. Future studies are needed to establish psychometric properties for patients with different foot and ankle problems.

**Keywords:** Translation; Cross-Cultural Comparison; Psychometrics; Outcome Assessment, Health Care; Ankle Injuries

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## INTRODUCTION

Ankle sprains are a common global health problem in the world's population, especially among athletes, physically active individuals, children, teenagers, young people, and women (1-3). Ankle sprain injury occurs due to awkward rolling, twisting, or turning of the ankle. This leads to stretching or tearing of the ligaments whose function is to keep the ankle bones together, stabilize the ankle joints, and prevent excessive range of motion of the foot (1, 4).

Clinically, ankle sprains are characterized by swelling, pain, loss of function, decreased postural control, strength deficit, and reduced range of motion in the foot (5). The intensity of these symptoms depends on the degree of damage to the ligaments and ankle joint. There are three grades of ankle sprain: a) Grade I, mild ankle sprain, b) Grade II, moderate sprain/micro ligament lesions and c) Grade III, severe sprain, complete ligament rupture. Depending on these grades presence of the symptoms of ankle sprain can vary from a few days to a few months (6, 7). However, the most important fact regarding ankle sprains is frequent re-injury and thereby the development of chronic ankle instability (CAI) (1, 8). The occurrence of CAI can lead to changes in motor patterns, impaired quality of life, and the development of osteoarthritis (1, 5, 9). Thus, insufficient treatment and outcome evaluation of initial ankle injuries often can cause CAI (10).

Patient-reported outcome measures (PROMs), either general or body region-specific, are a central part of investigating outcomes of foot and ankle disorders in

both clinical practice and research. Thus, the need for a validated patient outcome measurement tool is evident (11, 12). One of the most common PROMs for foot and ankle joint problems confirmed by the International Ankle Consortium is the Foot and Ankle Outcome Score (FAOS) (13). The FAOS was developed in 2001 to evaluate the patient's perception of their foot and ankle-related pain, symptoms, and functional limitations in daily life and sport, as well as quality of life (14, 15).

So far, FAOS has been translated and validated in most countries and regions worldwide for use in surgical and nonsurgical foot and ankle pathology (13, 14). However, there is no validated version for use in Bosnia and Herzegovina (BH), nor any of its official languages (Croatian, Serbian and Bosnian) (14).

This study aimed to translate, adapt, and evaluate the psychometric properties of the BH version of the Foot and Ankle Outcome Score (FAOS) in patients with ankle sprain. This includes assessing the reliability, validity, and usability of the adapted version in accurately measuring functional outcomes in this patient population.

## METHODS AND PARTICIPANTS

### Study design

This was a cross-sectional study. The study was approved by the Ethics Committee of the Rehabilitation Center "Život", Mostar, Bosnia and Herzegovina (ID: 002/2024, 24.1.2024). All the study methods were in line with the Declaration of Helsinki. Participants signed the written informed consent. Consolidated Standards of Reporting Cross-sectional Study

(STROBE), as well as Consensus-based Standards for the selection of Health Measurement Instruments (COSMIN) guidelines were followed in the design and reporting of the study. This study was conducted from February to October 2024.

### Participants

The convenience sample was used. Inclusion criteria were: diagnosis of acute ankle sprain made by a specialist physician, all genders, age >18 years, and willingness to participate in the study. Exclusion criteria were: ankle sprain with fractures of bones, other foot and ankle pathology, other musculoskeletal problems and previous surgical interventions that can affect the patient's perception, neurologic, cardiac, vascular and metabolic disease, as well as mental disorders and conditions that make it impossible to understand the questionnaire.

### Instruments

The participants were asked to fill out FAOS and Short Form Quality of Life Questionnaire (SF-12). All participants self-completed the questionnaires in paper format.

### The FAOS

The original English version and scoring system of the FAOS were downloaded from Mapi Research Trust (14). The FAOS consists of 42 questions divided into five subscales: Symptoms (seven questions), Pain (nine questions), Activities of Daily Living (ADL) (17 questions), Sports and Recreational Activities (Sports & Rec) (five questions), and Foot and Ankle-Related Quality of Life (QOL) (four

questions). Each question is answered on a five-point Likert scale. For each item, the recall period is the past week. This self-administered questionnaire is scored from 0 (extreme symptoms) to 100 (no symptoms or limitations) for each subscale. FAOS scores are reported by subscale only; the total score is not calculated (15, 16). The average time to complete the FAOS is 10 minutes (17, 18).

### Translation procedure

The translation of the BH version of FAOS was carried out according to the instructions for Cross-Cultural Adaptation of Self-Report Measures (19). The English version of the FAOS was translated by two native translators and English language experts, one of whom is a healthcare professional. The three versions were compared and a consensus was reached for the prefinal version by two translators and an investigator. The prefinal version was used in a back-translation (Croatian to English) by an English translator with no prior knowledge of the FAOS original version. In the presence of all translators, the first translation version (synthesis), the back translation version, and the original English version of FAOS were compared; the result of this meeting created new a pre-final version of the BH FAOS. A pilot study with a random selection of participants with an ankle and foot injury (n=22) was conducted to exclude the possibility of misunderstanding the question. All participants reported that the questions were understandable and that there were no ambiguities; moreover regardless of native language BH. After a discussion of the results of the pilot study,

the final version of the BH FAOS was created.

### Short Form Quality of Life Questionnaire (SF-12)

SF-12 is a shortened version of the most commonly used questionnaire for assessing quality of life and subjective general health. It was often used in foot and ankle-related studies (17, 18, 20). This questionnaire is self-administered and consists of 12 questions that assess eight domains: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. Finally, the results are summarized into two components: a physical component (PCS QOL) and a mental component (MCS QOL), which were generated using standardized scoring guidelines (21). Both measures of health can be quantitatively compared, the scores for each question are converted to standard values and placed on a scale from 0 to 100 (higher score means better physical and mental health).

### Floor and ceiling effects

The presence of floor and ceiling effects may influence the reliability and validity of an instrument. Floor and ceiling effects are identified when more than 15% of participants achieve the highest or lowest possible scores on the FAOS subscales (22).

### Psychometric procedures

Psychometric procedures included checking: construct and content validity, reliability and internal consistency, as responsiveness.

### Construct validity

Construct validity was assessed by analyzing the relationship between the FAOS subscales and the two components of the SF-12 questionnaire using Spearman's correlation coefficient ( $r$ ). A coefficient between 0.30 and 0.70 indicates a moderate correlation, while a coefficient below 0.30 indicates a poor correlation (18). According to previous validation studies, we hypothesized that all FAOS subscales would be moderately correlated with SF-12 PCS and weakly correlated with SF-12 MCS (17, 20). Construct validity is considered satisfactory if at least 75% of the priory hypotheses were confirmed (22).

### Content validity

Content validity is the patient's perception of the importance of each FAOS question for their condition. All participants filled out the questionnaire for all 42 questions with the following answers: 1 = not important, 2 = somewhat important, and 3 = very important. A mean score of  $\geq 2$  was considered acceptable content validity (17, 18).

### Reliability

The reliability of the test implies the ability to assess a condition in the same way at two different points in time. In this study, reliability was assessed using test-retest reliability and internal consistency. The retest was conducted 48 hours after the test on the same participants (23). The intraclass correlation coefficient (ICC), two-way random effect model, and absolute agreement were used to evaluate test-retest reliability. An ICC values  $\geq 0.7$

indicate acceptable reliability (17). Internal consistency was assessed by calculating Cronbach's alpha; values  $\geq 0.7$  were considered satisfactory (17). Bland and Altman's plots were calculated to estimate acceptance and heteroscedasticity (24).

### Responsiveness

Responsiveness means the ability of the instrument to determine changes in health status after medical intervention (17). After baseline and retest assessment, all participants were included in physical therapy treatment (Protection, Rest, Ice, Compression and Elevation protocol - PRICE, exercise therapy, and manual therapy) for four weeks.

The questionnaire was re-administered two weeks after the intervention was completed; all participants completed the intervention and completed the questionnaires. The analysis was performed with the Paired Student t-test, and Cohen's effect size was calculated, where 0.2 was considered a small effect, 0.5 a moderate effect, and  $\geq 0.8$  a large effect.

### Statistical analysis

Sample size calculation was determined with GPower software (Version 3.1.9.7) and an analytical approach (hypothesis testing). Regarding correspondence ICC for the alternative hypothesis was 0.5 ( $\rho H1$ ), a null hypothesis ( $\rho H0=0$ ), a 95% confidence interval, an error  $\alpha$  of 0.05, and a desired analysis power of 95%, the program calculated that a minimum of 46 participants is required. Thus, assuming that the minimum dropout rate will be around 15%, the sample size calculation

was 55 participants (25, 26). The ICC for the sample size was determined during a pilot project of understanding the prefinal version of the FAOS according to instructions of COSMIN Recommendations for sample size in reliability studies (27).

The normality of data distribution was measured by the Kolmogorov-Smirnov test. The descriptive data were presented with absolute and relative frequencies, means, and standard deviations. In all tests, statistical significance was  $p < 0.05$ . Statistical analysis was performed using SPSS for Windows, Version 23.0 (SPSS Inc., Chicago, IL, USA).

### RESULTS

The total sample in this study consisted of 55 participants, 54.5% men and 45.5% women. The average age range of the participants was 42 years (range: 20 to 71 years). Presentation of the demographic and clinical characteristics of the participants is shown in Table 1.

**Table 1.** *Participants' characteristics*

Variables	Total (N=55)	Male (N=30)	Female (N=25)
	N (%)	N (%)	N (%)
Age (years)*	42.1 ± 15.2	43.13±14.96	40.92±15.71
Height (cm) *	179.4 ± 8.6	85.53±12.73	66.32±5.73
Weight (kg) *	76.8 ±13.9	185.43±6.11	172.28±4.94
BMI (kg/m <sup>2</sup> ) *	23.7 ±2.6	24.79±2.80	22.33±1.46
Marital status			
Single	25 (45.5)	12 (40)	13 (52)
Married	27 (49.1)	15 (50)	12 (48)
Divorced	- (-)	- (-)	- (-)
Widow/er	3 (5.5)	3 (10)	- (-)
Education level			
High School	21 (38.2)	11 (36.7)	10 (40)
College degree	5 (9.1)	3 (10)	2 (8)
Post-graduate degree	25 (45.5)	12 (40)	13 (52)
Doctoral Degree	4 (7.3)	4 (13.3)	- (-)
Employment status			
Student	1 (1.8)	1 (3.3)	- (-)
Employment	44 (80)	23 (76.7)	21 (84)
Unemployment	4 (7.3)	2 (6.7)	2 (8)
Retired	6 (10.9)	4 (13.3)	2 (8)
Types of ankle sprains			
Lateral (inversion)	48 (87.3)	26 (86.7)	22 (88)
Medial (eversion)	7 (12.7)	4 (13.3)	3 (12)
Grades of sprains			
Grade I	5 (9.1)	2 (6.7)	3 (12)
Grade II	28 (50.9)	15 (50)	13 (52)
Grade III	22 (40)	13 (43.3)	9 (36)
*Data are expressed as mean (standard deviation);			

### Floor and ceiling effect

The overall distribution of the item's responses on the BH-FAOS was acceptable (the range of means was from 0 to 94.1). The effect of the floor and ceiling was not determined in any FAOS subscale. The minimal score was found in one participant (1.8%) in the Sport & Recreation Activities subscale.

### Time spent completing the questionnaire

All participants answered all questions. The average time to complete the questionnaire was 10.50 minutes (ranging from 5.52 to 14.10 minutes).

### Construct validity

In all subscales of the BH-FAOS, a moderately significant correlation with the physical (PCS) and mental components of the SF 12 questionnaire was determined (Table 2).



**Table 2.** Construct validity of Bosnia and Herzegovina version of Foot and Ankle Outcome Score (XY-FAOS) and 12-item Short Form Health Survey version 2 (SF 12v2)

FAOS subscale	PCS		MCS	
	r	P value	r	P value
Symptom	0.326	0.015*	0.487	<0.001*
Pain	0.404	0.002*	0.563	<0.001*
ADL	0.399	0.033*	0.589	<0.001*
Sport & Rec	0.331	0.014*	0.476	<0.001*
QOL	0.609	0.017*	0.446	0.001*

**Acronyms:** PCS – Physical component of SF 12; MCS – Mental component of SF 12; ADL – Activity of Daily Life; Sport&Rec – Sport and Recreation Activity; QOL – Quality of Life  
r (rho)– Correlation coefficient of Spearman correlation  
\* Significant value

## Content validity

Satisfactory importance was determined in four subscales of FAOS, except subscale Activity of Daily Living (*Table 3*).

**Table 3.** A mean score of the importance of the Bosnia and Herzegovina version of Foot and Ankle Outcome Score (BH-FAOS) questions.

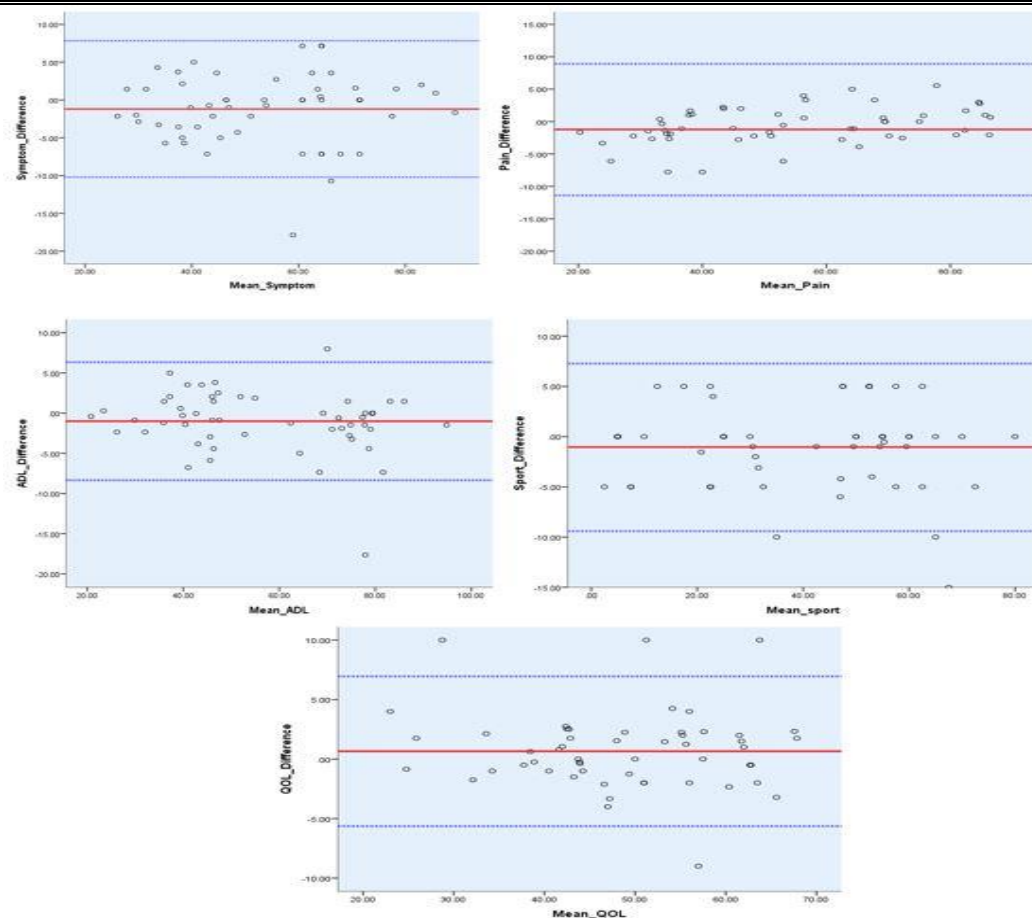
FAOS subscales	Mean ± Standard Deviation*
Symptom	2.08 ± 0.65
Pain	2 ± 0.98
ADL	1.86 ± 0.94
Sport & Rec	2.61 ± 0.99
QOL	2.51 ± 0.89

**Acronyms:** ADL – Activity of Daily Life; Sport&Rec – Sport and Recreation Activity; QOL – Quality of Life  
\* Mean score ≥ 2 considered satisfactory importance.

## Reliability

There was no systematic difference in the BH-FAOS test/retest analysis. Moreover, excellent test/retest reliability and internal consistency were determined for each BH-

FAOS subscale (*Table 4*). Bland-Altman plots of difference test/retest for each subscale of BH-FAOS suggest absolute agreement and without consistent bias (*Figure 1*).



**Figure 1.** Bland-Altman plot test and retest of the Bosnia and Herzegovina version of the Foot and Ankle Outcome Score (BH-FAOS).

## Responsiveness

In all BH-FAOS subscales, a statistically significant difference with a large effect size was found in the comparison of BH-FAOS baseline and post-intervention scores (Table 4).

**Table 4.** Reliability and the internal consistency of the XY version of the Foot and Ankle Outcome Score (XY-FAOS)

	FAOS_test N=55 M±SD	FAOS_retest N=55 M±SD	MD (95%CI)	P value*	ICC (95%CI)	Cronbach alpha
Symptom	53.30±16.40	54.50±16.22	-1.19 (-2.43 to -1.03)	0.061	0.98 (0.96 to 0.99)	0.980
Pain	53.99±19.72	55.21±19.15	-1.21 (-2.61 to 0.18)	0.086	0.98 (0.97 to 0.99)	0.982
ADL	57.10±19.06	58.10±19.75	-1 (-2 to 0.01)	0.053	0.99 (0.98 to 0.99)	0.990
Sport & Rec	39.16±21.18	40.20±21.37	-1.04 (-2.19 to -0.78)	0.074	0.99 (0.98 to 0.99)	0.990
QOL	49.50±11.40	48.83±11.67	0.65 (-0.21 to 1.52)	0.136	0.98 (0.96 to 0.99)	0.980

**Acronyms:** ADL – Activity Daily Living; Sport & Rec – Sport and Recreation Activity; QOL – Quality of Life; M±SD – Mean±Standard Deviation; MD (95%CI) - Mean Difference (95% Confidence Interval); ICC (95% CI) - Interclass Correlation Coefficient (95% Confidence Interval);

\*Paired Student t-test: statistical significance  $p < 0.05$



## DISCUSSION

The results of this study indicated that the BH version of the FAOS is a valid and reliable questionnaire for assessing symptoms and functional limitations in patients with ankle sprains. Moreover, the established high values of the psychometric characteristics of the BH-FAOS suggest that this instrument was properly adapted for the BH population with an ankle sprain.

Regarding construct validity, following the results of available similar studies, the hypothesis was that the FAOS subscales would have a moderate correlation with the PCS component of the SF-12 and a weak correlation with the MCS component of the SF-12 (15, 17, 20). In our study we found a moderate positive significant correlation with both components of the SF-12, thus only partially confirming the hypothesis. A moderate correlation with both components of the SF-12 questionnaire was determined in the validation study by Joshi et al (18). Finally, our results suggest that the BH-FAOS and SF-12 can be used together and that they will provide similar results.

The importance of the FAOS questions from the patient's perspective is also an essential step for the validity of the instrument. In our study, all questions within the BH-FAOS subscales were of acceptable importance, except for the ADL subscale. A possible reason may be that the original FAOS was developed from KOOS and that some issues related to functional limitations in everyday life are more related to knee and osteoarthritis disorders, as stated by Whittaker et al, 2020 (28).

The consistency of the BH-FAOS was very high (ICC and Cronbach values range from 0.98 to 0.99). The highest values of both measures were determined for the ADL and Sport&Rec subscales, and a significant difference was found in the two subscales in test-retest analysis. Compared to other FAOS validation studies, the reliability and internal consistency measures in our study are somewhat higher. However, in all studies, the determined values indicate very high to excellent reliability of FAOS. A possible reason for the slight diversity in the determined values of ICC and Cronbach's alpha in our and similar studies can certainly be the diversity of foot and ankle disorders and injuries. Our study included participants with ankle sprains, while other studies included a variety of disorders, from Acquired Flatfoot Deformity, Infracalcaneal Heel Pain, Hallux Rigidus and Valgus, and others (16-18, 20, 29). In addition, Bland-Altman's analysis showed absolute agreement and a lack of consistent bias in BH-FAOS reliability.

Also, the BH-FAOS is useful for evaluating the effectiveness of ankle sprain treatment. In this study, the physical therapy intervention consisted of the PRICE protocol (first week), immobilization and manual therapy (second week), and exercise therapy and manual therapy (third and fourth week). The difference of determined values in all subscales had a large significant effect size. The usefulness of FAOS in determining the prognostic values of clinical and anthropometric parameters after physical therapy intervention in lateral ankle sprains was confirmed in the

study by Khazaei et al (30). Also, the study by Goulart Neto et al confirmed the validity of FAOS and FAAM in assessing postural control and muscle strength in CAI, highlighting the need for future validation studies for determining the monitor the efficacy of rehabilitation and postoperative care of both instruments (31).

Despite some stated shortcomings in the literature review and studies of poor quality, recent systematic reviews stated that FAOS is one of the two most commonly used outcome measures for foot and ankle pathology and it is in first place in the bibliometric weighted average of the impact factors of included original publications (13, 32, 33). This is the main reason for the choice of this outcome instrument for the validation purpose in our population.

The strengths of this study include a robust psychometric evaluation, as it comprehensively assesses four key psychometric properties. The FAOS demonstrated high reliability, indicating consistent and reproducible results. By correlating the FAOS with the widely used SF-12 questionnaire, the study strengthens its construct validity findings, linking FAOS scores with both physical and mental health outcomes. The inclusion of responsiveness testing after physical therapy highlights the FAOS's sensitivity to changes in patient condition, enhancing its clinical applicability. Additionally, the study demonstrates that the BH-FAOS is both valid and reliable, making it suitable for use in clinical practice and research within the targeted patient population. These strengths contribute to the

reliability, validity, and practical utility of the BH-FAOS for assessing outcomes in patients with ankle sprains.

This study had several limitations. We did not use objective outcome measurements, such as the range of motion in the foot and ankle. Also, the findings of this study may not be generalizable for children and teenagers since these age groups were not included in our sample. Moreover, we did not have a follow-up period (up to a year) to more clearly determine responsiveness. A limitation may also be the sample size, regarding the calculation. According to the COSMIN Study Design checklist for Patient-reported outcome measurement instruments, the sample size in this study falls into the category „adequate“ for assessing construct validity, reliability, criterion validity and construct validity. To have the highest ranked category (very good), the sample size needs to be  $\geq 100$ . However, our sample size falls into the „very good“ category in terms of responsiveness (34). Finally, the limitation is the influence of the timing of the second survey in the assessment of responsiveness.

## CONCLUSION

This study has translated and validated the BH version of FAOS with acceptable construct and content validity, reliability, and responsiveness. The use of this questionnaire as an outcome measure is acceptable for clinical and scientific purposes in ankle sprain injuries.

Future studies are needed to establish psychometric properties for patients with different foot and ankle problems.

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## **PRIJEVOD, MEĐUKULTURALNA PRILAGODBA I EVALUACIJA PSIHOMETRIJSKIH SVOJSTAVA BOSANSKOHERCEGOVAČKE VERZIJE UPITNIKA ZA PROCJENU ISHODA STOPALA I GLEŽNJA KOD PACIJENATA S UGANUĆEM GLEŽNJA; STUDIJA PRESJEKA**

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### **SAŽETAK**

**Cilj:** Prilagoditi i potvrditi bosanskohercegovačku verziju upitnika procjene ishoda stopala i gležnja (FAOS) kod pacijenata s uganućem gležnja.

**Metode:** Uključeno je ukupno 55 bolesnika s uganućem gležnja. Procijenjene su četiri psihometrijske mjere: konstruktivna valjanost (korelacija FAOS-a i upitnika o zdravlju – SF12), sadržajna valjanost (pacijentova percepcija važnosti FAOS pitanja), pouzdanost (test-retest i unutarnja dosljednost, Bland-Altmanova analiza) i odgovornost (nakon intervencije fizioterapije).

**Rezultati:** Utvrđena je zadovoljavajuća konstruktivna valjanost; sve podljestvice FAOS bile su u umjerenoj korelaciji ( $r > 0,3$ ) s komponentama fizičkog i mentalnog zdravlja SF-12 ( $r > 0,30$ ). Također, sve FAOS podljestvice pokazale su izvrsnu pouzdanost (vrijednosti koeficijenta međuklasne korelacije (ICC)  $> 0,90$ ; Cronbachove alfa vrijednosti  $\geq 0,98$ ).

**Zaključak:** BiH verzija FAOS-a je pouzdan i validan instrument za procjenu ishoda kod pacijenata sa uganućem gležnja. Izvrsna pouzdanost i konstruktivna valjanost čine ga prikladnim za znanstvene i kliničke svrhe.

**Ključne riječi:** FAOS, PROM, uganuće gležnja, valjanost, pouzdanost

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