Total Hip Arthroplasty: Psychometric Validation of the Italian Version of Forgotten Joint Score (FJS-12)

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Abstract

Background: Patient’s satisfaction after surgery was traditionally assessed by pre, and post-surgical scores and Patient-Reported Outcome Measures (PROMs) scales. Patients treated by Total hip arthroplasty (THA) usually perform well; therefore, it is useful to have a PROMs’ scale with a low ceiling effect as the Forgotten Joint Score-12 (FJS-12). PROMs have to be validated in the local language to be used. This study aims to perform a psychometric validation of the Italian version of FJS-12 in a group of consecutive patients treated by THA.

Methods: Each patient completed both the Italian version of FJS-12 and Western Ontario and McMaster University Osteoarthritis Index (WOMAC) in preoperative evaluation, after two weeks and 1 month, 3 months and 6 months postoperative follow-up. The reliability, internal consistency, test-retest reliability, and measurement error were evaluated.

Results: 53 patients were included. Cronbach’s α between 0.6 and 0.9 indicated good internal consistency for the FJS-12. The test-retest reliability was acceptable. The Pearson correlation coefficient between the FJS-12 and WOMAC was 0.238 ($P=0.087$) at baseline, $r = 0.637$ ($P < 0.001$) at 1 month, $r = 0.490$ ($P < 0.001$) at 3 months and $r = 0.572$ ($P < 0.001$) at 6 months. The ceiling effect was above the acceptable range (15%) for FJS-12 in 1 month (26.4%) and WOMAC in 6 months follow-up (24.5%).

Conclusions: An excellent test-retest reliability, a good internal consistency, and a good validity by medium-high correlation with the WOMAC were assessed for FJS-12. However, the responsiveness for the FJS-12 score was not assessed.

Background

Total hip arthroplasty (THA) is worldwide performed, with an estimated incidence of one million procedures per year [1]. In the United States, 370,000 THAs were performed both in 2014 and in 2017 [1]. In Italy, 91,428 THAs were performed in 2014, with an increased rate of 44.5% from 2001 to 2014 [2]. The annual increase in THA incidence was reported worldwide [3] mainly due to the ageing of the population [4].

Implant survival, pre and post x-ray imaging, medical checkup, and Patient-Reported Outcome Measures (PROMs) questionnaires were routinely used to assess patients' experience and satisfaction after surgery [5,6].

PROMs are useful for obtaining immediate feedback regarding a patient's perceptions that is not available with other approaches. Several validated scores evaluate outcomes after THA, as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [7]. Despite the excellent reliability and reproducibility, a high ceiling effect [8] has been reported with WOMAC, demonstrating some concerns in the capacity to distinguish between good and excellent results [9]. THA patients typically have good outcomes [10,11]; therefore, the capacity to recognize modest improvements amid high outcome results is beneficial in determining the true benefit of surgical treatment. Moreover, during the last decades, THA has evolved, and surgical outcomes have improved significantly, resulting in a higher ceiling effect in commonly used PROMs [12]. The most common PROMs cannot detect minor differences in patients treated by different implant design or surgical approaches. A variation in outcome results among high scores is poorly measured in the case of the ceiling effect. Furthermore, the scale's reactivity is reduced by the difficulty to properly evaluate the patient's progress in a ceiling group [13]. WOMAC is a traditional PROM scale used to assess THA outcomes. However, this score reported a high ceiling effect; to effectively detect modest THA population variations, further assessment techniques such as the Forgotten Joint Score – 12 (FJS-12) are required [13]. The ability to forget the replaced joint during daily activities should be the milestone for joint replacement surgery. The FJS-12 was initially developed by Behrend et al. in 2012, to evaluate joint awareness during daily life [14]. With a modest ceiling impact [14], this score reflects the degree of awareness of the prosthetic joint. The FJS-12 for THA has been translated and validated in a wide range of languages and is extensively used in medical usage and research [10,15,16]. However, PROMs must be verified in the local language before being deployed, and the Italian version of FJS-12 for THA had not yet been approved. The Italian version of FJS-12 was validated only in patients who underwent knee replacement (both Total or Unicompartmental) [17,18]. The Italian version of FJS-12 was already culturally adapted by Sansone et al. [17] for total knee replacement. As the questions of FJS-12 and the population (Italian patients) were the same, only validation was performed in patients who underwent THA. The goal of this study is to conduct a psychometric validation of the Italian version of FJS-12 in a sample of THA patients.

Methods

Validation study

This research was carried out in accordance with the Declaration of Helsinki's criteria. Institutional Review Board (IRB) approved the study before data collection. The patients and their families were notified that the case's data will be published and provided their permission. Severe hip osteoarthritis (Grade III-IV of Kellgren-Lawrence Classification) [19], severe and chronic pain, hip arthroplasty surgery and at least 6 months follow-up later surgery were the inclusion criteria. All the patients underwent THA with a postero-lateral approach and were treated by the same surgeon. Only unilateral implants were considered. All the patients used uncemented implants with Ceramic-on-Highly-Crosslinked-Polyethylene. Partial weight-bearing was allowed after the first 24 hours. All the patients were dismissed from the hospital after two days to continue rehabilitation in a specialized centre. Revision operation, Grade I-II of Kellgren-Lawrence Classification, concurrent bilateral hip arthroplasty, hip rising and patients with cognitive damage were excluded. Cognitive damage could affect the postoperative results, as patients with dementia reported a higher risk of falls and fractures, influencing the outcomes reporting [20]. The validity, reliability and responsiveness of the Italian version of the FJS-12 for THA were evaluated in this prospective, observational research. Between March to July 2019, 66 patients were enrolled. However, only 55 patients completed the 6 monthly follow-up questionnaires. Therefore, 55 patients were included in the study. In two preoperative evaluations (2 weeks apart and before surgery) and three postoperative follow-ups (1 month, 3 months and 6 months), each patient performed both the FJS-12 and the WOMAC Italian versions of the questionnaire. To carry out the test-retest, before surgery, the patients complete the FJS-12 and WOMAC surveys twice, two weeks apart.

Assessment instruments

FJS-12

The Forgotten Joint Score-12 is a self-administered outcome scale that assesses joint awareness throughout a variety of everyday activities [14]. The FJS-12 is a twelve-question survey with a one-to-five Likert answer scale. The item scores are added together for each patient, with a range of 12 (less awareness of the joint) to 60 (most awareness of the joint). The outcomes can be scaled from 0 (worse condition) to 100 (best condition). In comparison to other clinical scores, the FJS-12 achieved sufficient discriminating power and a limited ceiling effect [14]. The FJS-12 was utilized in its Italian version [21,22].

WOMAC

The WOMAC is a questionnaire with 24 questions in a 0 to 4-point Likert answer style, including five questions about pain, two questions about stiffness, and seventeen questions about function. The overall item scores, which range from 0 to 96, are added together. The findings can be standardized on a scale of 0 to 100, with 0 being the lowest and 100 being the highest functional status level. This score has been translated into 65 different languages, making it the most widely used in orthopaedic research [7]. In accordance with the consensus-based guidelines for the selection of health measuring instruments (COSMIN), Gandek et al. concluded in a systematic review that this score had good validity and internal consistency (Cronbach's $\alpha > 0.90$) [23]. For this reason, in this study, it was used as a comparative survey.

Reliability, validity and responsiveness

Internal consistency, test-retest reliability, and measurement error were determined to assess the reliability [24]. *Cronbach's α was used to evaluate the* internal consistency (value greater than 0.7 was considered appropriate) [25].

The retest was completed two weeks following the initial test, in accordance with the COSMIN procedure [24]. The intraclass correlation coefficient (ICC) between preoperative and two-week follow-up scores was used to assess test-retest reliability.

The formula $SD*\sqrt{(1 - \alpha)}$ (SD = standard deviation and α= Cronbach's α) was used to calculate the Standard error of measurement (SEM). $SEM*1.96*\sqrt{2}$ was used to calculate the Minimal Detectable Change (MDC, i.e., the smallest individual change in a score that may be considered significant). The SEM and the MDC were used to assess the measurement error [24].

To examine the validity, the Pearson correlation coefficient (r) between FJS-12 and WOMAC was computed at various follow-up points [24]. The correlation was defined as r values of at least 0.3.

To determine responsiveness, the effect size (ES) and MDC were calculated [24]. The ES was computed by comparing the scores at all different follow-ups times. ES was calculated as the ratio of mean difference and SD (Cohen's d). Furthermore, if MDC was lesser than the Minimal Important Change (MIC), an optimistic evaluation of responsiveness is supposed (MIC=0.5*SD).

Statistical analysis

A priori power analysis with Pearson's correlation coefficient of 0.522 between FJS-12 and WOMAC in patients who underwent THA[26], sig. level=0.05 (two-tailed) and power=0.80 have estimated a minimum sample of 26 patients.

Means and SD are used to report descriptive statistics. Ceiling effects are the frequencies for patients obtaining the highest (100) possible FJS-12 score and floor effects the lowest (0) possible score. Percentage of the ceiling and floor effects less than 15% were considered acceptable [25,27].

Statistical analysis was conducted with SPSS version 26.0 (Armonk, NY: IBM Corp) and power analysis with G*Power 3.1.9.4.

Results

Overall, 53 patients (25 females, 28 males; mean age of 74 ± 11 years old) were included in the study. The mean score of FJS-12 for the preoperative evaluation was 36.3 ± 14.2; for the 1-month postoperative follow-up was 82.7 ± 17.2; for the 3-months postoperative follow-up was 80.3 ± 13.2 and for the 6-months postoperative follow-up was 79.9 ± 15.7 (Table 1). Table 1 shows the WOMAC's average score.

In each follow-up period, Cronbach's alpha was calculated. Cronbach's coefficients between 0.6 and 0.9 suggested that the FJS-12 had acceptable internal consistency (Table 3).

The test-retest reliability was excellent for all cases, with an ICC of 0.99 (CI: 0.98, 0.99; p<0.001). There is a 2-weeks' period between the two preoperative tests.

The SEM for the preoperative FJS-12 was 8.9, and the MDC was 24.6. The SEM for the 6 months follow-up postoperative FJS-12 was 6.7, and the MDC was 18.5 (Table 3). The r coefficient between the FJS-12 and WOMAC was 0.238 (P=0.087) at preoperative evaluation, r = 0.637 (P < 0.001) at 1 month, r = 0.490 (P < 0.001) at 3 months and r = 0.572 (P < 0.001) at 6 months (Table 4).

In postoperative evaluation, the two surveys had a high-moderate correlation in construct validity.

At each follow-up period, the data were examined using pairwise comparisons to determine the FJS-12's response over time (Table 5). WOMAC was subjected to the same tests (Table 6).

From preoperatively to 6 months postoperative follow-up was calculated a mean difference of -46.4, with a huge ES (Cohen's d= 2.6, P<0.001). The WOMAC also showed a large ES (Cohen's d = 2.1, P<0.001), with a mean difference of -42.1. A large ES for FJS-12 between preoperative and 1- and 3-months follow-up was found (respectively, Cohen’s d = 2, P<0.001 and Cohen’s d = 1.8, P<0.001). There weren’t statistically significant changes across the other time points.

Lastly, the MDC of each follow-up were higher than the corresponding MIC; consequently, the Italian version of FSJ-12 is not a responsive measure.

At each time point, the floor effect was 0% for FJS-12. Also for the WOMAC questionnaire, the floor effect was 0%.

The ceiling effect was 0% for FJS-12 in preoperative evaluation and WOMAC in the preoperative and 1-month follow-up. The ceiling effect was under the acceptable range (15%) for FJS-12 in 3 months and 6 months (7.5% and 11.3%, respectively) and WOMAC in 3 months follow-up (3.8%). The ceiling effect was above the acceptable range (15%) for FJS-12 in 1 month (26.4%) and WOMAC in 6 months follow-up (24.5%) (Table 7).

Discussion

The validation of FJS-12 translated in Italian language consents to clinicians to use this scale in Italy. This is the first study that we are aware of that undertakes psychometric validation of the Italian version of FJS-12 for THA. The psychometric validation of the Italian version of FJS-12 for THA was performed, reporting an excellent test-retest reliability and a high-moderate correlation with the WOMAC. This is the first study to use the COSMIN checklist to psychometrically validate the Italian version of FJS-12 for THA [24].

Excellent reliability of the Italian version of FJS-12 for THA was observed. The internal consistency was found with Cronbach’s α, and the ICC was used to calculate the test-retest reliability between preoperative and two-week follow-up scores. The initial study on FJS-12 claimed a Cronbach's α of 0.95 and a good internal consistency rating. [14]. The results revealed a good internal consistency, except for the preoperatory time (Table 2) and an excellent ICC value (Cronbach’s α between 0.67 and 0.92, ICC of 0.99). These results are in line with the literature. Sethy et al. [28] studied the reliability and validity of α; they found a Cronbach’s α of 0.88 and an ICC of 0.94. Klouche et al. [16] assessed the reliability and validity of the FJS-12’s French version and calculated a Cronbach’s α of 0.96 and an ICC of 0.86. Hamilton et al. [15] validated the English version of FJS-12 and founded a Cronbach’s α of 0.98.

The Italian version of the WOMAC score is widely utilized in orthopaedic clinical trials, therefore it's a good benchmark for the FJS-12. With the exception of preoperative time, the results of this study conformed to the validity of FJS-12, with a high-moderate correlation between the two questionnaires (r between 0.238 and 0.637). This data is similar to the results of other studies [14,16,29] on THA. Hamilton et al. [15] and Klouche et al. [16] found a high correlation between FJS-12 and OHS (r=0.79 and r=0.86; respectively). Sethy et al. [28] and Klouche et al. [16] calculated a good correlation (r=0.8 and r=0.7; respectively) between FJS-12 and modified Harris Hip Score (m-HHS). In accordance with the reported results, Matsumoto et al. [30] found a moderate correlation between FJS-12 and WOMAC (r= 0.52).

In contrast, the correlation between FJS-12 and WOMAC for total knee arthroplasty was investigated in a study by Sansone et al., and only a modest correlation was found [17]. Further research is needed since the difference between FJS-12 and WOMAC might be attributable to the type of surgery performed.

In accordance with previous studies [17,18,31], the FJS-12 is not a responsive measure. The capability of a survey to find clinically significant changes over time has been termed as responsiveness. A smaller MDC implies a more sensitive measure since it reflects the smallest amount of change higher than within-subject variability and measurement error, which may be taken as a true change in an individual. The MIC represent the clinically important changes. According to Stipancic et al. [32], the MDC should be smaller than the clinically important change. Since the results of this study reported an MDC higher than MIC in the preoperatory, after 1, 3 and 6 months (Table 2), the Italian version of FJS-12 is not a responsive measure [25].

FJS-12 had a significant large ES (ES=2.6) between preoperative and 1-month post-operative. Comparing the same follow-ups, the WOMAC recorded a significant large ES (ES=2.1). In the time span between preoperative, 3 and 6 months postoperative, a high value of ES of FJS-12 was also recorded (ES= 2.0 and ES= 1.8, respectively).

A ceiling effect of 0% for FJS-12 in preoperative time and WOMAC in preoperative and after 1-month was reported. The ceiling effect was within the acceptable range for FJS-12 after 3 and 6 months. Instead, for WOMAC, it was acceptable only in the 3-month follow-up. The ceiling effect was above the acceptable range for FJS-12 in 1 month follow up and for WOMAC in 6 months follow-up (Table 6). The presence of ceiling effect at 1-month after surgery (25%) and the lack of it in further follow up (3 months 7.5% and 6 months 11.3%) is probably due to the use of painkillers and rehabilitation carried out in the first 4 postoperative weeks. However, there are no sufficient data to confirm this hypothesis. The ceiling effect was similar to what was seen in the initial study of FJS-12 [14]. At each follow-up, the floor effect for both FJS-12 and WOMAC was 0%. The floor had a similar impact as Behrend's [14] and is equal to Klouche [16]. Compared to WOMAC, FJS-12 had a higher ceiling effect at 1 and 3 months, and a lower ceiling effect at 6 months (Table 6). Therefore, an acceptable low ceiling and floor effect was demonstrated, and FJS-12 was more efficient for the stratification of upper ranges scores. However, the FJS-12 was initially designed for patients with a low symptom burden [14] and not for patients shortly after surgery with a high symptom burden.

Related to the paper by Hamilton et al.[15], the preoperative value of FJS-12 was higher. This data remains higher also at 6 months of follow up. Cross-cultural variability could have affected the differences between studies[33]. Furthermore, Hamilton et al. [15] did not culturally adapt the FJS-12 because the original questionnaire is already in the English language. As is our study, in the article of Hamilton et al. [15] only patients who underwent unilateral THA were included, patients with the second operation in cases of staged bilateral procedures were excluded. The mean age of patients in the Hamilton et al. [15] study was 67.6 ± 11.7 years old with 41.5% of males. In this study, the average age of patients was 74 ± 11 years old with 52.8% of males.

The study's main flaw is the brief follow-up period. According to Hamilton et al. [15], the most substantial differences in outcomes appear from 6 months to 1 year postoperatively. Furthermore, even though the number of patients comprised in the research is larger than that necessary by the power analysis, a small number of patients from a single centre might not represent the whole Italian population, given the substantial cultural differences within this country. Lastly, no responsiveness for FJS-12 was reported in the present study; however, this data is similar to other works [17,18,28]. Further studies are required to clarify the reason for this result.

Conclusions

The Italian version of FJS-12 is a valid and reliable tool to evaluate the improvement of outcomes in THA patients. However, no responsiveness in FJS-12 was assessed. In addition, a high ceiling effect at 1-month postoperative follow-up was found, however, no ceiling effect at preoperative, 3 months and 6 months postoperative were shown. Therefore, validating and translating this score in different languages might aid in the conduct of more accurate research on THA outcomes.

Abbreviations

Total hip arthroplasty (THA)

Patient-Reported Outcome Measures (PROMs)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Forgotten Joint Score – 12 (FJS-12)

Institutional Review Board (IRB)

Intraclass correlation coefficient (ICC)

Standard error of measurement (SEM)

Minimal Detectable Change (MDC)

Standard deviation (SD)

Pearson correlation coefficient (r)

Effect size (ES)

Minimal Important Change (MIC)

modified Harris Hip Score (m-HHS)

Declarations

Ethics approval and consent to participate: The study was conducted according to the guidelines of the Declaration of Helsinki. Institutional Review Board (IRB) of University Campus Bio-Medico of Rome approved the study before data collection. Informed consent was obtained from all individual participants included in the study.

Consent for publication: Not applicable.

Availability of data and material: The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Competing interests: UGL is a member of the Editorial Board of BMC Musculoskeletal Disorders. The remaining authors declare that they have no conflict of interest.

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Authors' contributions: Conceptualization, U.G.L. and S.D.S.; Data curation, A.I.; Formal analysis, I.P.; Methodology, S.D.S. and I.P.; Software, I.P.; Supervision, UGL and V.D.; Validation, G.S.; Visualization, M.G.D.M.; Writing—original draft, G.S. and I.P.; Writing—review and editing, S.D.S. and I.P. All authors have read and agreed to the published version of the manuscript.

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Tables

Table 1 – Summary of results of FJS-12

	FJS – 12 Preoperative	**FJS – 12 2 weeks**	**FJS – 12 1 month**	**FJS – 12 3 months**	**FJS – 12 6 months**
Mean	36.3	33.9	82.7	80.3	79.9
N	53	53	53	53	53
SD	14.2	14.0	17.2	13.2	15.7
0.5 SD (MIC)	7.1	7.0	8.6	6.6	7.9

N=Number of patients, SD= Standard Deviation, MIC= Minimally Important Change, FJS-12=Forgotten Joint Score 12

Table 2 – Summary of results of WOMAC

	WOMAC Preoperative	WOMAC 2 weeks	WOMAC 1 month	WOMAC 3 months	WOMAC 6 months
Mean	40.9	39.7	82.9	93.6	94.8
N	53	53	53	53	53
SD	18.6	18.5	8.7	5.4	6.4
0.5 SD (MIC)	9.3	9.3	4.4	2.7	3.2

N=Number of patients, SD= Standard Deviation, MIC= Minimally Important Change, WOMAC= Western Ontario and McMaster University Osteoarthritis Index

Table 3 – SEM, MDS and MIC of FJS-12 in different follow-up

	FJS – 12 Preoperative	FJS – 12 2 weeks	FJS – 12 1 month	FJS – 12 3 months	FJS – 12 6 months
Cronbach's α	0.6	0.7	0.9	0.7	0.8
SEM	8.9	7.9	5.2	7.0	6.7
MDC	24.6	21.9	14.3	19.5	18.5

SEM= Standard Error Measurement, MDC= Minimal Detectable Change, FJS-12=Forgotten Joint Score 12

Table 4 – Pearson correlation coefficient.

Follow-up	Pearson correlation coefficient	p-value
Preoperative	0.238	P=0.087
1 month	0.637	P<0.001*
3 months	0.490	P<0.001*
6 months	0.572	P<0.001*

*= statistically significant (P<0.05), P= p-value

Table 5 – Responsiveness of FJS-12 over time.

Time		Mean Difference	p-value	95% Confidence Interval for Difference		SD	ES
				Lower Bound	Upper Bound		
Preoperative	*1 month*	46.4	<0.001*	41.5	51.4	17.9	2.6
	3 months	44.0	<0.001*	38.0	50.0	21.8	2.0
	6 months	43.6	<0.001*	36.9	50.3	24.2	1.8
1 month	*3 months*	-2.4	0.445	-8.6	3.8	22.7	-0.1
	6 months	-2.8	0.406	-9.6	3.9	24.6	-0.1
3 months	*6 months*	-0.4	0.864	-5.5	4.6	18.2	-0.0

SD= Standard Deviation, ES= Effect Size, *= statistically significant (P<0.05)

Table 6 – Responsiveness of WOMAC over time.

Time		Mean Difference	p-value	95% Confidence Interval for Difference		SD	ES
				Lower Bound	Upper Bound		
Preoperative	*1 month*	42.1	<0.001*	36.5	47.6	20.3	2.1
	3 months	52.8	<0.001*	47.7	57.8	18.4	2.9
	6 months	53.9	<0.001*	48.7	59.0	18.7	2.9
1 month	*3 months*	10.7	<0.001*	8.0	13.4	9.9	1.1
	6 months	11.8	<0.001*	9.1	14.6	9.9	1.2
3 months	*6 months*	1.1	0.204	-0.6	2.9	6.4	0.2

SD= Standard Deviation, ES= Effect Size, *= statistically significant (P<0.05)

Table 7 – Ceiling and floor effects of FJS-12 and WOMAC

		Ceiling (%)	Floor (%)
FJS-12	Preoperative	0	0
	1 month	26.4	0
	3 months	7.5	0
	6 months	11.3	0
WOMAC	Preoperative	0	0
	1 month	0	0
	3 months	3.8	0
	6 months	24.5	0

FJS-12=Forgotten Joint Score 12, WOMAC= Western Ontario and McMaster University Osteoarthritis Index