Journal of Plastic, Reconstructive & Aesthetic Surgery (2020) 000, 1–8

"Validation of a spanish version of the 'Unité Rhumatologique Des Affections De La Main' (URAM) scale"

Diego Gómez-Herrero[a,b,*], Francisco J. Carrera-Hueso[c], Rafael Sanjuan-Cerveró[d], Daniel Montaner-Alonso[e], Luis Aguilella-Fernandez[f], Pedro Vazquez-Ferreiro[g], Jaime E. Poquet-Jornet[h], Emilio García-Jiménez[b]

[a] *Pharmacy Department. Vithas Hospital 9 de Octubre. Valle de la Ballestera, 59. 46015, Valencia. Spain*
[b] *Pharmacy Program. University of Granada. Faculty of Pharmacy. 18011, Granada. Spain*
[c] *Pharmacy Department. Hospital Universitario La Plana. Ctra. Vila Real-Burriana Km 0.5. 12540, Vila-Real, Castellón. Spain*
[d] *Orthopedics and Traumatology Surgery Department. Hospital de Denia. Marina Alta s/n. 03700, Denia, Alicante. Spain*
[e] *Orthopedics and Traumatology Surgery Department. Hospital Doctor Peset. Gaspar Aguilar, 90. 46017, Valencia. Spain*
[f] *Orthopedics and Traumatology Surgery Department. Hospital de la Ribera. Ctra. Corbera Km 1. 46600, Alzira, Valencia. Spain*
[g] *Ophtalmologic Department. Hospital Virxe da Xunqueira. Paseo do Alcalde Pepe Sánchez, 7. 15270, Cee, A Coruña. Spain*
[h] *Pharmacy Department. Hospital de Denia. Marina Alta s/n. 03700,Denia, Alicante. Spain*

Received 20 November 2019; accepted 22 November 2020
Available online xxx

KEYWORDS
Carpal tunnel syndrome;
Dupuytren's contracture;
Quality of life;
Reliability and validity;
URAM

Summary *Background:* In health care, quality-of-life surveys and questionnaires related to care are becoming increasingly important as a measure of its quality. There is currently no Spanish version of the Unité Rhumatologique des Affections de la Main (URAM) scale, which makes it suitable for hand pathology. The purposes of this study are to develop a Spanish version of the URAM and perform a transcultural adaptation of it, analyzing the result for reliability, validity, and sensitivity to changes.
Methods: The questionnaire was evaluated for patients with Dupuytren's disease and Carpal Tunnel Syndrome. The cohort study subjects were interviewed at three points in time (baseline,

* Corresponding author.
E-mail address: gomezhd@vithas.es (D. Gómez-Herrero).

https://doi.org/10.1016/j.bjps.2020.11.024

Please cite this article as: D. Gómez-Herrero, F.J. Carrera-Hueso and R. Sanjuan-Cerveró et al., "Validation of a spanish version of the 'Unité Rhumatologique Des Affections De La Main' (URAM) scale", Journal of Plastic, Reconstructive & Aesthetic Surgery, https://doi.org/10.1016/j.bjps.2020.11.024

three days after intervention, and one month after), administering the QuickDASH, URAM, and SF-12 (CF12 = physical component, CM12 = mental component) questionnaires at baseline and after intervention; and only the URAM at 3 days. Content validity was evaluated using Cronbach's α. The distribution of the factorial loads of the items and the pattern of the answers were checked. Responsiveness was evaluated by the size of the effect and the reliable rate of change. Convergent and divergent validity was performed using Spearman's r between the different questionnaires.

Results: The study was conducted with 106 patients. The mean baseline scores were: URAM = 14.8, *QuickDASH* = 41.6, CF12 = 39.3 and CM12 = 49.4. Ceiling or floor effects were not observed in the Spanish URAM. The Cronbach $\alpha = 0.853$ explains 49.6% of the variance. The study had a high reproducibility (*intraclass correlation coefficient (ICC)* = 0.939). Size effect, measured as differences in scores, was moderate for URAM (-0.69) and *QuickDASH* (-0.51); and low for CF12 and CM12. The correlation of URAM with *QuickDASH* was high ($r = 0.716$), and moderate with DD and CTS.

Conclusion: The Spanish version of the URAM is a valid and reliable tool for use in assessing hand pathology.

Introduction

In health care, quality-of-life surveys and questionnaires related to care are becoming increasingly important as a quality measure. In this regard, research on patient-reported outcome measures (PROMs) includes health-related quality-of-life studies, which help track the results of treatment[1].

In hand pathology, this type of PROM results has been used for clinical decision-making for quite some time[2]. Usually, generic quality-of-life questionnaires are used, such as the Short-Form 36[3] or Euroqol[4], or more specific tools such as the Disability of the Arm, Shoulder and Hand[5] (DASH) or the Michigan Hand Outcomes Questionnaire[6] (MHQ). These types of surveys have been refined by developing shorter versions that increase their rate of acceptance by patients without diminishing their validity or reliability with respect to the originals, such as Short-Form 12[7], QuickDASH[8], or briefMHQ[9].

Recently, more specific rating scales have been designed for specific diseases, such as Southampton Dupuytren's Scoring System[10] (SDSS) or the Unité Rhumatologique des Affections de la Main[11] (URAM) scale for Dupuytren's disease (DD). They are quicker and easier to fill out because they contain fewer questions and are more understandable to patients[12,13].

In order to apply any PROM questionnaire to a given population differing in native tongue from that of the questionnaire, a previous transcultural adaptation must be performed[14,15]. Currently, there is no Spanish version of the URAM scale, a quick and simple questionnaire, which makes it suitable for hand pathologies such as DD or Carpal Tunnel Syndrome (CTS).

The objective of this research was to develop the Spanish version of the URAM and to conduct a cross-cultural adaptation. Moreover, its reliability, validity, and sensitivity to changes are analyzed in such a way that it serves as a useful tool in the clinical assessment of patients with different hand pathologies.

Methods

Design

This study had been previously approved by the Ethics Committee and the Spanish Agency of Medicines and Medical Devices (JPJ-COL-2015-01). Patients were added only if they met the inclusion criteria and gave their express consent to participate in the study. The inclusion criteria differed according to the disease. For DD, patients had to present a contracture $\geq 20°$ in the metacarpophalangeal (MCP) and/or interphalangeal (PIP) joints of one finger (except thumb finger), ≥ 18 years of age, have one or two fingers affected per hand, and have one or both hands affected. Inclusion criteria for patients with primary CTS were established according to Rempel et al.[16] including a positive attitude to examination, nocturnal symptoms, and diagnosis confirmation by electromyography (EMG). Exclusion criteria for both pathologies were the following: patients with cancer or diabetes, pregnant or lactating women, history of serious bleeding episodes and those who had undergone surgery on that same hand during the prior year (regardless of the reason).

We calculated the required sample size for conducting the study, a two-sided test for two-independent simple factors; based on a clinically significant difference of 2.9 points between two URAM administrations and a standard deviation (SD) of 2.7 with an 80% power and a 5% alpha error[11], obtaining for paired groups a total of 28. Considering foreseen losses of 15%, a sample of 33 patients would be needed.

The patients with DD were treated with 0.58 mg of collagenase clostridium histolyticum (CCH) in the affected joint following previous criteria[17]. The degree of contracture was measured using a validated digital goniometer. Patients with CTS were classified by their surgeon according to EMG criteria in one of the three categories: first stage or mild, second stage or moderate, and third stage or severe[18]. Treatment was considered effective in CTS patients if they

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were asymptomatic, or else symptoms were mild after one month[19].

Instruments and measures

The URAM is a questionnaire validated for DD by the Rheumatology Service of the Lariboisere Hospital (Paris, France). It is a self-administered questionnaire, consisting of a central body of nine items designed to measure the impact of hand injury on the ability to normally perform daily activities. Each item has six response values along a Likert scale ranging from 0 to 5, with increasing values based on symptom intensity, from "without difficulty" (0) to "impossible" (5). The score for each item is then summed to obtain a total, which can range between 0 (best possible score) and 45 points (worst possible score). The URAM allows assessing the degree of disability perceived by the patient in performing various activities, including daily chores and symptoms such as stiffness or strength loss[20,21].

The Spanish version of SF-12 version 2 used is a generic self-administered tool that measures health-related quality-of-life. This version allows only two summary scores: one for the physical component and another for the mental component. It consists of 12 items from the 8 sections of the SF-36 questionnaire. To facilitate interpretation, the scores are standardized with the values from population norms, such that 50 (SD = 10) is the average for the general population. Values greater or less than 50 should be interpreted as better or worse than the reference population. In a similar reference population[22], the average physical component was 48.6 (SD = 10.6) and the mental component was 53.6 (SD = 10.7).

QuickDASH is an abbreviated version of the DASH designed to measure "upper extremities disability". There is a validated Spanish version for patients with CTS that contains 11 items[23]. In order to calculate the QuickDASH score, at least 10 of the 11 questions must be answered. The numerical value of the responses given to each of the completed answers is summed and the average calculated, obtaining a score from one to five. To express this score on a scale of 0 to 100, 1 is subtracted and then multiplied by 25: the higher the score, the greater the disability[24].

Translation and transcultural adaptation of the URAM

We conducted the translation-retranslation procedure in the following phases: first, two bilingual translators whose mother tongue was Spanish independently translated the questionnaire. The translators and the research team jointly reviewed both translations until settling by consensus on an initial Spanish version. Next, this initial version was translated back into English by two different bilingual translators whose mother tongue was English, which resulted in two reverse translations that the research team, in consultation with the translators, compared with the original version to assess conceptual equivalence, resulting in a preliminary final version.

With this second version, a test pilot was conducted with the first 15 DD patients included in the study. After completing the questionnaire, an open interview was held with the patients to identify any difficulties regarding question comprehension, and to assess whether any wording required modification. Finally, the definitive Spanish version of the URAM was drawn up, which was used in the subsequent validation study (Appendix S-1).

Validation

For the validation study, between May 2016 and June 2017 patients who met inclusion criteria were selected from three different Orthopedic and Trauma Surgery hospital unit. Of the 113 patients who were asked to participate in the study, seven did not attend or did not fill out the questionnaires; hence, a total of 106 patients remained. Main demographic and clinical data were collected from each patient (Table S-2). A group of 45 patients returned for an appointment in a period of three to five days after the first questionnaire administration to perform the reproducibility analysis, all of whom had to fulfill the questionnaires again one month after their treatment. Of the 106 patients who completed the first visit, 12 patients did not complete the last administration, such that 94 valid cases remained for sensitivity to changes analysis (11.2% loss).

There were no data missing on the questionnaires or in the demographic and clinical information from the patients. The results were entered securely into a database designed for this purpose with MS Access 2007 for further analysis.

Statistical analysis

Continuous variables were expressed as a mean (SD); and categorical ones as numbers and percentages. Variables were compared with the Student *t*-test if they were continuous or with the chi-square test, or Fisher's exact test, for the qualitative variables. If there were several categories, the Mantel–Haenszel test for trend was used. Nonparametric tests were used for the variables whose distributions were not normal.

To assess the internal consistency of the URAM scale, we carried out a principal component analysis (PCA) using single-factor analysis, as in the original questionnaire. First, it was determined whether or not it was possible to perform the analysis (using Bartlett's test of sphericity chi-square and the Kaiser–Meyer–Olkin measure of sampling adequacy, KMO). The scale's consistency was evaluated with Cronbach's α: the values were greater than 0.8, indicating a high internal consistency. The content validity of the URAM on first administration was checked by distributing the responses to the items, comparing the percentage of cases that were assigned minimum (floor effect) and maximum values (ceiling effect).

The test–retest reliability was evaluated with the intraclass correlation coefficient (ICC), two-way random effect model and absolute agreement definition, which were expected to be significant and with a value exceeding 0.70[25].The means of each of the two survey administrations were also compared using the *t*-test for paired samples.

To analyze URAM sensitivity to changes, the presence of significant differences between baseline and end-of-

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Table 1 Baseline scores of the items on the URAM scale and the QuickDASH and SF-12v2 questionnaires.

Questionnaire*	Median	Median (SD)	n (%) of Extremes† ($n = 106$)	
			Low	High
item 1 (URAM)	1.0	1.5 (0.14)	0 (0.0)	8 (7.5)
item 2 (URAM)	1.0	1.2 (0.12)	0 (0.0)	3 (2.8)
item 3 (URAM)	1.0	1.5 (0.14)	0 (0.0)	4 (3.8)
item 4 (URAM)	1.0	1.2 (0.12)	0 (0.0)	2 (1.9)
item 5 (URAM)	1.0	1.1 (0.12)	0 (0.0)	1 (0.9)
item 6 (URAM)	2.0	1.9 (0.16)	0 (0.0)	0 (0.0)
item 7 (URAM)	2.0	2.4 (0.17)	0 (0.0)	0 (0.0)
item 8 (URAM)	2.0	2.3 (0.16)	0 (0.0)	0 (0.0)
item 9 (URAM)	1.0	1.7 (0.16)	0 (0.0)	0 (0.0)
URAM	13.5	14.8 (0.88)	0 (0.0)	2 (1.9)
QuickDASH	43.2	41.6 (2.52)	0 (0.0)	0 (0.0)
SF-12 physical component	37.5	39.3 (1.00)	0 (0.0)	0 (0.0)
SF-12 mental component	52.4	49.4 (1.13)	3 (2.8)	1 (0.0)

* URAM, *UnitéRhumatologique des Affections de la Main*; QuickDASH, Quick version of Disabilities of the Arm; SF-12, Short-Form version 2.†Number of cases outside the range (Q1- 1.5*IQR, Q3+1.5*IQR); Q1, first quartile; Q3, third quartile; IQR, interval quartile range; SD, standard deviation.

treatment assessments was evaluated, and the effect size was estimated (differences between scores obtained divided by the initial SD). For interpretation of these statistics, criteria proposed by Cohen[26] for the size of the typified effect were followed: values below 0.20 represent a change of approximately one-fifth from the baseline SD and are considered small; a 0.50 value represents a change of at least half the baseline SD and is considered moderate, and values above 0.80 represent a change of at least four times the baseline SD and are considered high. The standard error of measurement (SEM) and the reliability change index (RCI) were also calculated to determine whether differences were clinically significant: they were considered to be so whenever they exceed 1.96*SEM or 1.96*RCI[27].

To verify convergent and divergent validity, correlation of the differences of URAM scores between final and baseline interviews was compared to those obtained by the QuickDASH, the physical and mental components of the SF-12; as well as with the effectiveness of the treatments. We hypothesized that there would be a correlation of $r \geq 0.5$ with QuickDASH, the physical component SF-12, while in the case of treatment effectiveness; however, there would be no correlation with the mental component of the SF-12, as this was not affected in these pathologies of the hand.

The minimal important change (MIC), which is the optimal cut-off point, derived from the receiver operating curve at the score having the largest sensitivity and specificity. Previous logistic regression was performed with the differences between the questionnaire scores for visits after treatment and the baseline[28].

A significant alpha value of 0.05 was obtained in all tests. SPSS Statistics for Windows, Version 19.0 Release 2010 application software (IBM Corp. Armonk, NY) was used to conduct data analysis.

Results

The total duration of the cohort study was 14 months, encompassing from the first to last interview. The second interview using the URAM was conducted on average (SD) at 4.3 (3.0) days, and the post-intervention interview was performed at 43.5 (12.2) days after the administration of CCH.

Patients with DD had on average a 57.0° of contracture (95%CI: 48.0-66.1) (MCP + PIP) at the beginning. The distribution of the 51 patients according to Tubiana classification was: grade I: 24 (47.1%); grade II: 19 (37.7%); grade III: 7 (13.7%); and grade IV: 1 (2.0%).Patients with CTS presented moderate symptoms in 21 (38.2%) and severe symptoms in 34 (61.8%) cases.

The mean baseline scores of the questionnaires are shown in Table 1 for QuickDASH and SF-12; as well as for each of the nine items from the URAM scale. The response rankings on the URAM were distributed mainly among the lower scores; those falling into the "no difficulty" category ranged from 39.6% for item 4 to 16.0% for item 9; while those falling into the "with very little difficulty" category ranged from 34.9% (item 5) to 8.5% (item 8). No ceiling or floor effect was detected in the response pattern to any of the nine items. In the case of item 1, 7.5% of patients deviated from the norm.

The factorial loads obtained for each item with factor solution from the PCA are shown in Table 2. Scale reliability was high, with a Cronbachś $\alpha = 0.853$ (95%CI: 0.807-0.891, $p > 0.001$). The SD of the alpha coefficient was small, SE = 0.03426, indicating both that correlation between items is homogeneous, and one-dimensionality of the items. The sample size of our study is adequate for analyzing the URAM scale: KMO = 0.779, meaning that the sphericity of the covariance matrix can be rejected, and a factor

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Table 2 Principal Component Analysis in a factor solution of URAM.

Items	Factor loading
item 1	0.759
item 2	0.837
item 3	0.537
item 4	0.799
item 5	0.836
item 6	0.736
item 7	0.574
item 8	0.731
item 9	0.349

analysis may be performed (Bartlett's test of sphericity chi-square = 529.753; $p < 0.001$).

The one-factor solution explains 49.6% of the variance. There are two factors with a loading value greater than 1, which would suggest a two-factor solution, as well as in the scree plot.

The mean difference between scores for the second and first interviews for the 45 patients who completed the URAM was not significant: 0.36 points (95%CI: −1.69-0.98, $p = 0.595$). The reproducibility of the Spanish version of the URAM was very high, with reliability measure for the ICC test-retest = 0.939 (95%CI: 0.888-0.966, $p < 0.001$).

The change sensitivity or responsiveness of all questionnaires is shown in Table 3. The values for both components of the SF-12 are below those of the reference population and only the difference in physical component was significant. The negative sign of effect size tells us that we are measuring an effect that decreases with treatment, meaning that we are dealing with inverse scales; hence, lower values indicate better quality-of-life. The effect size was moderate for the URAM and QuickDASH scales; however, it was low for both SF-12 components according to Cohen's criteria.

To verify convergent or divergent validity, we checked URAM results at post-intervention visit with other surveys and treatment effectiveness (Table 4). There was a moderate significant correlation with the QuickDASH scale, indicating that they measure the same construct, and a low significant correlation with the physical component of the SF-12. The relationship between differences between the URAM scores and the differences in degrees of contracture in DD after administration of CCH was significant ($p < 0.01$). The correlation with the effectiveness of the CTS surgical intervention was also significant ($r = 0.300$, $p < 0.05$).

The main results of questionnaire interpretability are shown in Table 5. All regressions performed have a decent goodness fit, although with low explanatory capacity. Prediction degree is moderate for the questionnaires, except for SF-12 physical component, which was high and showed high specificity.

Discussion

The final Spanish version of the URAM has shown high content validity, and high Cronbach's α value. The factorial loads and the component analysis solution suggest that a two-factor solution could be used, given the greater variance shown in our patient sample.

All our data suggest eliminating item 9 from the questionnaire because of its lowest factorial load. Should this be done, there would be an increase in Cronbach's α. These results differ from the original scale[11,20] possibly because it was applied to two different types of pathology, DD and CTS, whose patients have differing appreciations of their disease. In the case of DD, the disease more commonly affects the ulnar side of the hand, which would also argue for the elimination of this item in this specific pathology. In CTS, involvement of the lateral three and a half fingers on the anterior surface of the hand (palmar) in the form of loss of fine sensitivity could affect the ability to grip and pinch to a greater or lesser extent; in fact, some affected patients

Table 3 Responsiveness of questionnaires: URAM, QuickDASH, and SF-12 ($n = 94$).

Questionnaire*	Baseline, mean (SD)	After intervention, mean (SD)	Differences (S. Error)†	Effect size	Pearson correlation (SEM)	Reliable change index	P value‡
URAM score (range: 0-45)	15.20 (9.02)	8.96 (8.63)	−6.25 (0.946)	−0.69	0.885 (3.06)	6.0	<0.001
QuickDASH score (range: 0-100)	41.08 (25.99)	27.93 (22.11)	−13.15 (2236)	−0.51	0.604 (16.36)	32.1	<0.001
SF-12 physical component (range: 48.6 ± 10.6)	39.50 (10.02)	41.63 (9.88)	2.12 (1012)	0.21	0.485 (7.19)	14.1	0.044
SF-12 mental component (range: 53.6 ± 10.7)	50.34 (10.59)	51.34 (11.20)	1.13 (1088)	0.11	0.532 (7.25)	14.2	0.303

SD, standard deviation; SEM, Standard Error of the Measurement.
* URAM, *UnitéRhumatologique des Affections de la Main*; QuickDASH, Quick version of Disabilities of the Arm; SF-12, Short-Form version 2.†Absolute value.‡T-test for paired samples.

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Table 4 Construct (divergent or convergent) validity study of the URAM scale by Spearman's correlation coefficients at post-intervention visit.

Comparator*	URAM scale	P value	Effectiveness†	
			Dupuytren's ($n=49$)	Carpal Tunnel ($n=45$)
QuickDASH	0.716	<0.01	−0.142	0.057
SF-12 physical component	−0.385	<0.01	0.244	−0.229
SF-12 mental component	0.013	0.9	−0.088	0.087
URAM	—-	—-	−0.453	0.300

* URAM, *UnitéRhumatologique des Affections de la Main*; QuickDASH, Quick version of Disabilities of the Arm; SF-12, Short-Form 12 version 2.†Effectiveness: In Dupuytren's disease, the differences in degrees of contracture are compared; in carpal tunnel syndrome, the comparison is to the final efficacy with respect to the level of symptomatology.

Table 5 Interpretability of questionnaires.

Questionnaire*	Logistic regression†			Receiver operating curve‡					
	−2 Log likelihood	Nagelkerke R^2	P value	AUC (95%CI)	MIC	Se (%)	Sp(%)	PV+ (%)	PV- (%)
URAM	47.69	0.06	0.132	0.66 (0.56-0.76)	0.93	70.1	57.1	95.3	13.3
QuickDASH	49.66	0.01	0.405	0.48 (0.37-0.58)	0.92	72.4	42.9	94.0	11.1
SF-12 physical component	45.54	0.11	0.258	0.78 (0.68-0.86)	0.92	71.3	71.4	96.9	16.7
SF-12 mental component	49.78	0.01	0.239	0.50 (0.40-0.61)	0.93	51.7	42.9	91.8	6.7

* URAM, *UnitéRhumatologique des Affections de la Main*; QuickDASH, Quick version of Disabilities of the Arm; SF-12, Short-Form 12 version 2.†Logistic regression of the differences between the mean scores of the questionnaires from the total sample ($n=94$) was used in comparison with the total efficacy of the treatment, P-value of the Hosmer-Lemeshow test.‡Sample prevalence = 92.6%; AUC, area under curve; 95%CI, 95% confidence interval; MIC, optimal cut-off point; Se, sensitivity; Sp, specificity; PV+, predictive value positive; PV-, predictive value negative.

of this pathology report "that things fall from their hands". This information is not reflected in our results, showing item 9 disparity. In spite of these considerations, a PCA of the Spanish version of the URAM can be performed.

The URAM has proved to be a valid and reproducible tool for hand pathology in our sample, with small differences in average scores obtained between two administrations spaced closely in time, also showing a high test-retest reliability with a high ICC.

As we had initially hypothesized, the Spanish version of the URAM shows convergent validity with the QuickDASH and with the physical component of the SF-12. This is due to the fact that patients with advanced hand pathology, treated either by surgical intervention or DD medication, have evident physical limitations when they cannot use their hands. It also correlates significantly with treatment effectiveness, both for DD and CTS, showing good responsiveness. It was also shown that there is no correlation – divergent validity – with the mental component of the SF-12, although the relation was not significant possibly because there was no change in the score on this scale between the two administrations.

The use of this tool with Spanish patients with hand pathologies will allow clinicians to make more accurate decisions by considering patient opinion, as well as to assess the treatment outcomes[12,13] since angular deformity has limited value in the valuation of DD outcomes. The URAM test provides the clinician a quick and easy-to-fill questionnaire, which can be self-administered by patients or provided by the clinician, with very understandable questions for the patients and a quick and visual valuation of the results. All these advantages make the questionnaire a useful tool for overstuffed clinics, having some limitations for research purposes.

This study has several limitations. First, the age and sex distribution of our population sample and the initial severity of patient disease may not be adequate for other clinical scenarios. Additionally, as any observational study, even when significant correlations between variables were obtained, conclusions about causality cannot be drawn. Moreover, it was impossible to limit the information bias caused by other concurrent processes that affect hand mobility, as this was an observational study.

Nevertheless, scores were consistent over time, as indicated by the good reproducibility index, and high internal consistency of the final Spanish version of the URAM that resulted after translation-retranslation of the original version. Finally, we can say that the tool has shown to be reliable and valid for use with the Spanish population. From our study, it can be concluded that the Spanish version of the URAM is a suitable tool for the Spanish population and is valid and reliable for use in the treatment and care of hand pathologies.

Declaration of Competing Interest

The authors hereby declare to have no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Acknowledgements

This article is part of the Doctoral Thesis of Diego Gómez-Herrero within the Doctoral Program in Pharmacy at Granada University, Spain.

Funding

Our research did not receive any specific grant from any funding agency in the public, private, or non-profit sectors.

Author's contribution

Francisco Javier Carrera-Hueso conceived the study and Diego Gómez-Herrero designed the study and drafted the manuscript. Rafael Sanjuan-Cerveró, Daniel Montaner-Alonso, and Luis Aguilella-Fernandez collected the data and Pedro Vazquez-Ferreiro analyzed the data. Jaime Eduardo Poquet-Jornet, and Emilio Garcia-Jimenez put forward the concept of the study and reviewed the manuscript. All authors read and approved the final manuscript.

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Please cite this article as: D. Gómez-Herrero, F.J. Carrera-Hueso and R. Sanjuan-Cerveró et al., "Validation of a spanish version of the 'Unité Rhumatologique Des Affections De La Main' (URAM) scale", Journal of Plastic, Reconstructive & Aesthetic Surgery, https://doi.org/10.1016/j.bjps.2020.11.024