Unité Rhumatologique des Affections de la Main (URAM) Scale: Development and Validation of a Tool to Assess Dupuytren's Disease–Specific Disability

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Objective. To our knowledge, no functional outcome measure has been developed and validated for Dupuytren's disease. We aimed to develop and validate a patient-reported functional outcome measure for Dupuytren's disease.

Methods. Patients with Dupuytren's disease (n = 9) and medical experts (n = 7) provided input and opinions about limiting activities that were difficult to perform because of Dupuytren's disease for item generation. The provisional scale was studied in an independent sample of patients (n = 85) for item reduction according to response distribution, reliability, redundancy, and loading in a 1-factor solution. The final scale was evaluated as follows: reliability using Cronbach's alpha coefficient and test-retest intraclass correlation coefficient from the previous 85-patient population, and construct validity and responsiveness after needle aponeurotomy in another independent 53-patient sample. For construct validity, convergent validity and divergent validity were tested. The clinically important change was estimated relative to a 1-point categorical change on the Tubiana scale.

Results. A 52-item provisional scale was generated and reduced to the final 9-item scale called the Unité Rhumatologique des Affections de la Main (URAM) scale (total score 0-45). The scale showed good to excellent reliability and suitable construct validity. The URAM score improved after needle aponeurotomy: the standardized effect size was 0.56. The estimated clinically important change of the URAM scale was 2.9 points.

Conclusion. We provide the first patient-reported functional measure for Dupuytren's disease. The URAM scale demonstrated suitable psychometric properties, and is short and convenient enough for easy use in daily practice and in clinical studies.

INTRODUCTION

Dupuytren's disease is a worldwide disorder (1). Its incidence has been estimated at approximately 34 per 100,000 people in the UK (2). Its prevalence varies between 3% and 13% according to country, age, sex, and other well-known risk factors such as heredity, diabetes mellitus, tobacco and alcohol consumption, and heavy manual work (1). Because of aging and the mixing of populations, a high burden of Dupuytren's disease is expected for future de-

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cades. Therefore, research in the fields of epidemiology, pathology, and therapy (including needle aponeurotomy, collagenase, and surgery) is of crucial importance, but needs suitable outcome measures.

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Significance & Innovations

- No functional outcome measure has been developed and validated for Dupuytren's disease.
- The Unité Rhumatologique des Affections de la Main (URAM) scale is the first patient-reported functional measure for Dupuytren's disease.
- The URAM scale demonstrated suitable psychometric properties, and is short and convenient enough for easy use in daily practice and in clinical studies.

Dupuytren's disease is a progressive fibrosis disorder that consists in pathologic production and deposition of collagen in the palmar fascia (3). The tissue consequences consist in the formation of nodules and cords that induce flexion contracture of the metacarpophalangeal and interphalangeal joints. Therefore, Dupuytren's disease is a potentially disabling physical condition. Objective hand function measures for affected patients, i.e., flexion contracture of the joints or fingers, extension deficit, and range of motion (4–8), are assessed by a clinician and directly relate to physical and functional impairments due to the disease.

Subjective functional outcome measures, either patient or clinician reported, assess the consequences of impairments in daily activities that define the disability (6,9-14). Because of the diversity of limitations and differences between Dupuytren's disease and other hand conditions, such as arthritis or fractures, no standard measure exists to assess specific hand function in Dupuytren's disease. Functional measures are available for hand and upper extremity conditions in general, but data supporting the validation of the measures in Dupuytren's disease are limited. The Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) is a patient-reported measure that assesses symptoms and functional status for a wide range of upper extremity musculoskeletal conditions, and has been used in Dupuytren's disease (6,11-14). The Michigan Health Outcomes Questionnaire (MHQ) measures outcomes of patients with conditions of, or injury to, the hand or wrist (15,16). The MHQ is not specific to Dupuytren's disease because the measure was intended to be used as a broad-based measure for many different hand conditions.

In patients with Dupuytren's disease, hand activity limitations and functional impairment are diverse. Therefore, physicians must assess all patients on an individual basis about the nature of the disability, especially noting the use of the hands at work and at home (17). When asked to define the most disabling activities experienced as a consequence of Dupuytren's disease, patients have reported a wide range of problems, such as putting on a glove, washing and grooming, doing carpentry, shaking hands, placing hand in pocket, typing, recreational activities such as golf or tennis, using a computer, baking, playing the piano or the trumpet, gardening, doing gymnastics, and gripping a bicycle handlebar (18,19).

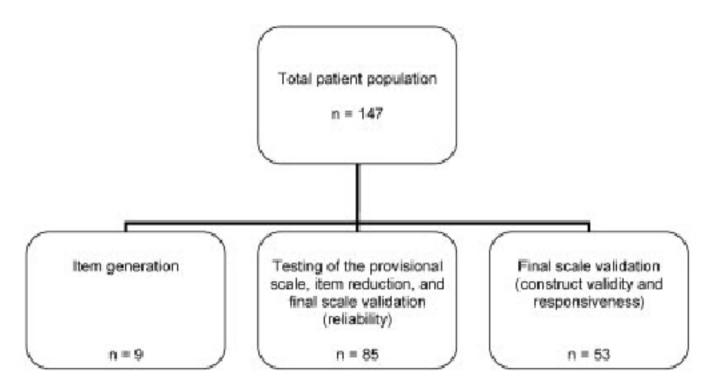


Figure 1. Flow diagram of patients used in the scale development and validation.

Functioning and functional outcome measures of the hand are complementary (20). Clinician and patient perspectives are both considered for suitable assessment. Given that the patients are the most intimate about their disability, physical function or disability should be included as a patient-reported outcome for assessing the severity of the disease and efficacy of treatments and for treatment decisions. However, to our knowledge, no functional outcome measure has been developed and validated to assess disability specific to Dupuytren's disease.

We aimed to develop and validate a patient-reported measure for hand function, called the Unité Rhumatologique des Affections de la Main (URAM) scale, assessing physical disability associated with Dupuytren's disease in daily clinical practice, observational studies, and clinical trials.

MATERIALS AND METHODS

Patients and experts. A total of 147 French adult patients consulting for ascertained Dupuytren's disease were recruited in our Rheumatology Unit for Hand Conditions in Lariboisière Hospital. These patients were used for instrument development or validation (Figure 1). Seven experts (6 rheumatologists and 1 hand surgeon) from our unit were also invited to participate in the study for instrument development.

Instrument development and validation. The scale was constructed in 3 steps using standard methodology (21–23). A list of activities that were difficult to perform because of Dupuytren's disease was compiled for item generation. A provisional scale was tested in patients and reduced. If both hands were affected by Dupuytren's disease, the hand with greater structural severity (based on the Tubiana scale) (4) was assessed. The final scale, the URAM scale, was then validated (22–24).

Item generation. Items were generated by interviewing 9 patients and 7 medical experts about functional restriction due to Dupuytren's disease. For each interview, up to 10 activities were recorded. For patients, activities were collected during a one-on-one interview. Expert opinions were provided during a one-on-one interview or by mail. Patients and experts were asked, "What are the activities

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mainly restricted because of Dupuytren's disease?" All items (questions) were accepted as a provisional scale if related to usual daily activities or living. We excluded specific activities not represented in the general population of patients with Dupuytren's disease, such as music playing, sports, and do-it-yourself home improvements. For question formulation, each item was preceded by "Are you able to?" Responses were scored on a 6-point scale, where 0 = yes, without difficulty; 1 = yes, with little difficulty; 2 = yes, with some difficulty; 3 = yes, with much difficulty; 4 = nearly impossible to do; and 5 = impossible. Respondents could indicate whether the activity was never done.

Testing of the provisional scale and item reduction. The questionnaire was administered twice with a 1-week interval to 85 patients with Dupuytren's disease with no interval treatment. The provisional scale then underwent a 5-step reduction to exclude less psychometrically desirable items. All of the 5 steps of reduction involved the baseline questionnaire results. The test—retest reliability involved both baseline and 1-week results.

First, for item reduction, items answered "never done" by more than 5% of patients were eliminated. Second, the remaining items for which a pattern of responses involved fewer than 4 grades on the 6-point rating scale were also excluded. Third, items with test-retest reliability of <0.8 by an intraclass correlation coefficient (ICC) were excluded. Fourth, if several item scores showed a Spearman's correlation of >0.7, the one with better results on the basis of the previous criteria, specifically response distribution and test-retest reliability, was retained. Finally, an exploratory factor analysis was conducted to remove items with factor loading (standardized regression coefficients) of <0.4 in a 1-factor solution, prespecified to represent the singular concept of physical disability. The final scale was developed to explore 1 domain corresponding to physical disability.

Final scale validation. The final scale that became the URAM scale was then validated with the sum of its item responses (total score). Reliability of the measure was assessed with the study population of 85 patients. It included internal consistency that was assessed with Cronbach's alpha coefficient, and test—retest reliability assessed by the ICC.

Construct validity and responsiveness were assessed in an independent population of 53 patients undergoing needle aponeurotomy. For construct validity, convergent and divergent validities at baseline were analyzed by Spearman's correlation. Moderate and high convergences were accepted with r=>0.35 and r=>0.5, respectively. Divergence corresponded to r=<0.35. Convergent validity was assessed by correlating the URAM score with scores of other scales assessing a similar or a linked concept: the Tubiana scale (4), self-assessed disability on a 0-100 visual analog scale (VAS), the Cochin Hand Function Scale (CHFS) (21), and the DASH (25,26). The Tubiana scale and self-assessed disability on a 0-100 VAS were considered a primary standard. The Tubiana scale we used is based on goniometry (4). It grades the severity of Dupuytren's dis-

ease. Divergent validity was assessed by correlating the URAM score with scores of variables known to be unrelated to disability in Dupuytren's disease: self-assessed pain on a 0–100 VAS and the Hospital Anxiety and Depression Scale (HADS), including subscales for anxiety and depression (27,28).

Responsiveness was assessed with changes in score and standardized effect size (ES), the difference between baseline and 1-month followup after needle aponeurotomy divided by the baseline SD of scale scores. Responsiveness assessment and comparison involved the URAM scale, the Tubiana scale, the self-assessed disability VAS, the CHFS, and the DASH. To assess a clinically important change, we considered the mean change in the URAM score (the target measure) according to the variation in the Tubiana score (the anchor), expressed as a continuous variable. Responder status was also examined and corresponded to the change in Tubiana score that was categorized (in discrete categorical levels) as no variation, 1-point variation, 2-point variation, and 3-point or more variation, after 1 month following needle aponeurotomy.

English translation and adaptation of the original French version of the URAM scale. The URAM scale was then translated and adapted for English populations according to a back-translation method. This involved 2 translators for English translation, 2 translators for back-translation, and 1 translator to control the final result of the translation process.

Statistical analysis. Quantitative variables were described with mean \pm SD and 95% confidence intervals (95% CIs). Qualitative variables were described with numbers and percentages. ES of 0.20, 0.50, and 0.80 indicated small, moderate, and large degrees of responsiveness, respectively (29). For responder status, at least a 1-point categorical change (increase or decrease) in Tubiana score was empirically considered to be clinically relevant. Comparisons involved use of Wilcoxon's signed rank tests for 2 related samples and the Kruskal-Wallis test for independent samples, with statistical significance set at P values less than 0.05.

RESULTS

Provisional scale. We recorded 68 items: 33 were from patients alone, 21 were from the experts alone, and 14 were from both. Sixteen items related to specific activities (such as music playing, sports, and do-it-yourself home improvements) were excluded. The provisional scale therefore constituted 52 items.

Item reduction. For further item reduction, the provisional scale was administered to the 85-patient population sample. The mean \pm SD age was 69.8 \pm 8.9 years in this population sample. There were 20 women and 65 men. The patients had flexion contracture of the fingers for which needle aponeurotomy was indicated. Patients with a Tubiana score ranging from 1–10 were included in order

Table 1. Exploratory factorial analysis in a 1-factor solution of 12 selected items			
Codes of items	Factor loading		
SP3	0.58		
SP6	0.65		
SP9	0.26		
C3	0.66		
C11	0.33		
VS1	0.76		
VS2	0.72		
VS3	0.71		
GM1	0.53		
GM3	0.50		
GM4	0.23		
GM7	0.53		

to have severe and nonsevere forms of Dupuytren's disease in the sample. We eliminated 12 items answered "never done" by more than 5% of patients, 15 items because of a pattern of responses involving fewer than 4 grades on the 6-point rating scale, 3 items because of test—retest reliability of <0.8, and 10 items because of redundancy, with a Spearman's correlation coefficient of >0.7. The remaining 12 items underwent exploratory factor analysis in a 1-factor solution (Table 1). Three items with factor loading of <0.4 were finally eliminated.

Final scale. The final 9-item scale (Supplementary Appendix A, available in the online version of this article at http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658) has a total possible score ranging from 0-45. Three of the 9 items were provided by the patients only, 2 by the experts, and 4 by both. The reliability of the URAM scale was assessed with the 85-patient sample used for the reduction process. The Cronbach's alpha coefficient was 0.81 (95% CI 0.67-0.88) and the ICC on the total score for test-retest reliability was 0.97 (95% CI 0.94-0.98).

The characteristics of the sample of 53 patients used to assess the scale's construct validity and the responsiveness are shown in Table 2. The results of the construct validity study, including convergent and divergent validity, are shown in Table 3. Convergent validity was shown by a high correlation with the Tubiana scale (r=0.61), the self-assessed disability on a VAS (r=0.67), the CHFS (r=0.63), and the DASH (r=0.55). Divergent validity was shown by a considerably smaller correlation with self-assessed pain and the HADS anxiety subscale and HADS depression subscale.

The results for the responsiveness of the URAM scale are in Table 4 and Figure 2. Scores for the URAM scale, Tubiana scale, self-assessed disability on a VAS, DASH, and CHFS showed significant improvement after needle aponeurotomy (Table 4). The highest ES was achieved with the Tubiana scale. The URAM scale and self-assessed disability on a VAS had a moderate ES of 0.56, and the DASH and CHFS had smaller ES (0.31 and 0.26, respectively). URAM score change after needle aponeurotomy was then analyzed according to Tubiana score variation to assess its clinical relevance and to estimate a clinically important

Table 2. Characteristics of included patients to assess construct validity and responsiveness of the URAM scale*

	Value (n = 53)
Age, mean ± SD years F/M, no. (%) Right handed, no. (%) Disease on the dominant side, no. (%) Tubiana score (range 0–20), mean ± SD Disability VAS score (range 0–100), mean ± SD URAM score (range 0–45), mean ± SD DASH score (range 0–100), mean ± SD CHFS score (range 0–90), mean ± SD	63.2 ± 8.9 $9 (17)/44 (83)$ $42 (79)$ $29 (55)$ 4.8 ± 2.8 29.9 ± 23.5 13.2 ± 10.0 13.3 ± 13.7 13.0 ± 12.8

* URAM = Unité Rhumatologique des Affections de la Main; VAS = visual analog scale; DASH = Disabilities of the Arm, Shoulder, and Hand questionnaire; CHFS = Cochin Hand Function Scale.

change (Figure 2). No patient showed worse scores on the Tubiana scale after needle aponeurotomy. Results demonstrated the clinical relevance of variation in the URAM score after needle aponeurotomy because mean score changes differed according to the Tubiana responder status. These findings were reinforced by the Spearman's correlation coefficient indicating a significant and moderate relationship between changes in the URAM and the Tubiana scores (r = 0.47, P = 0.0007). The mean \pm SD clinically important change for the URAM, on the basis of a 1-point variation of the Tubiana score, was 2.9 \pm 2.6.

Finally, the original version of the URAM scale was translated and adapted, if necessary, from French to English. Only item 1 was adapted. "Wash yourself with a flannel" was completed with "keeping your hand flat" because the object used in France for washing involves the

Table 3. Construct validity study of the URAM scale by Spearman's correlation coefficients in 53 patients*

	URAM scale
Tubiana scale	0.61
Disability VAS†	0.67
CHFS	0.63
DASH	0.55
Pain VAS‡	0.26
HADS anxiety subscale	0.26
HADS depression subscale	0.05

- * The Tubiana scale, self-assessed disability on a VAS, CHFS, and DASH were used for the convergent validity. Self-assessed pain on a VAS, HADS anxiety subscale, and HADS depression subscale were used for divergent validity. URAM = Unité Rhumatologique des Affections de la Main; VAS = visual analog scale; CHFS = Cochin Hand Function Scale; DASH = Disabilities of the Arm, Shoulder, and Hand questionnaire; HADS = Hospital Anxiety and Depression Scale.
- † The disability VAS question was, "Can you indicate how much Dupuytren's disease prevented you from doing daily activities with the hand if 0 means no difficulty and 100 means impossible?"
- ‡ The pain VAS question was, "Can you indicate how much you are in pain due to Dupuytren's disease if 0 means no pain and 100 means the maximum?"

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Table 4. Responsiveness of the URAM scale by means and effect sizes at 1 month after needle aponeurotomy in 53 patients*						
	Baseline, mean ± SD	1 month, mean ± SD	Effect size	P†		
Tubiana score (range 0–20)	4.8 ± 2.8	2.5 ± 2.3	0.82	< 0.0001		
URAM score (range 0-45)	13.2 ± 10.0	7.6 ± 8.6	0.56	< 0.0001		
Disability VAS score (range 0-100)	29.9 ± 23.5	16.7 ± 18.1	0.56	< 0.0001		
DASH score (range 0-100)	13.3 ± 13.7	9.0 ± 15.1	0.31	0.0464		
CHFS score (range 0-90)	13.0 ± 12.8	9.7 ± 14.9	0.26	0.0119		

^{*} URAM = Unité Rhumatologique des Affections de la Main; VAS = visual analog scale; DASH = Disabilities of the Arm, Shoulder, and Hand questionnaire; CHFS = Cochin Hand Function Scale.

hand opened, which is not the case in the UK. The English version of the URAM scale is provided in Table 5.

DISCUSSION

Our study provides the first validated functional outcome measure specific to Dupuytren's disease. The resulting URAM scale is a 9-item patient-reported questionnaire with total scores for Dupuytren's disease—associated disability ranging from 0 (best) to 45 (worst). High scores suggest high levels of disability and disturbance. A patient's subjective perception of their own difficulties in daily living is pertinent in current practice (20) and is also

recognized as an important part of the assessment in clinical studies (20,30). The URAM scale has been developed and validated in synchronization with previous reports and recommendations (21–24). Furthermore, the URAM scale is short for easy application.

Several functional outcome measures have been developed or validated in hand rheumatic disorders such as rheumatoid arthritis and osteoarthritis, but not Dupuytren's disease (4,31,32). Functional outcome measures previously used in Dupuytren's disease studies are the DASH, the MHQ, the Patient Evaluation Measure (PEM) (6,9–14), and the CHFS (33). The use of these functional outcome measures raises the question of their content

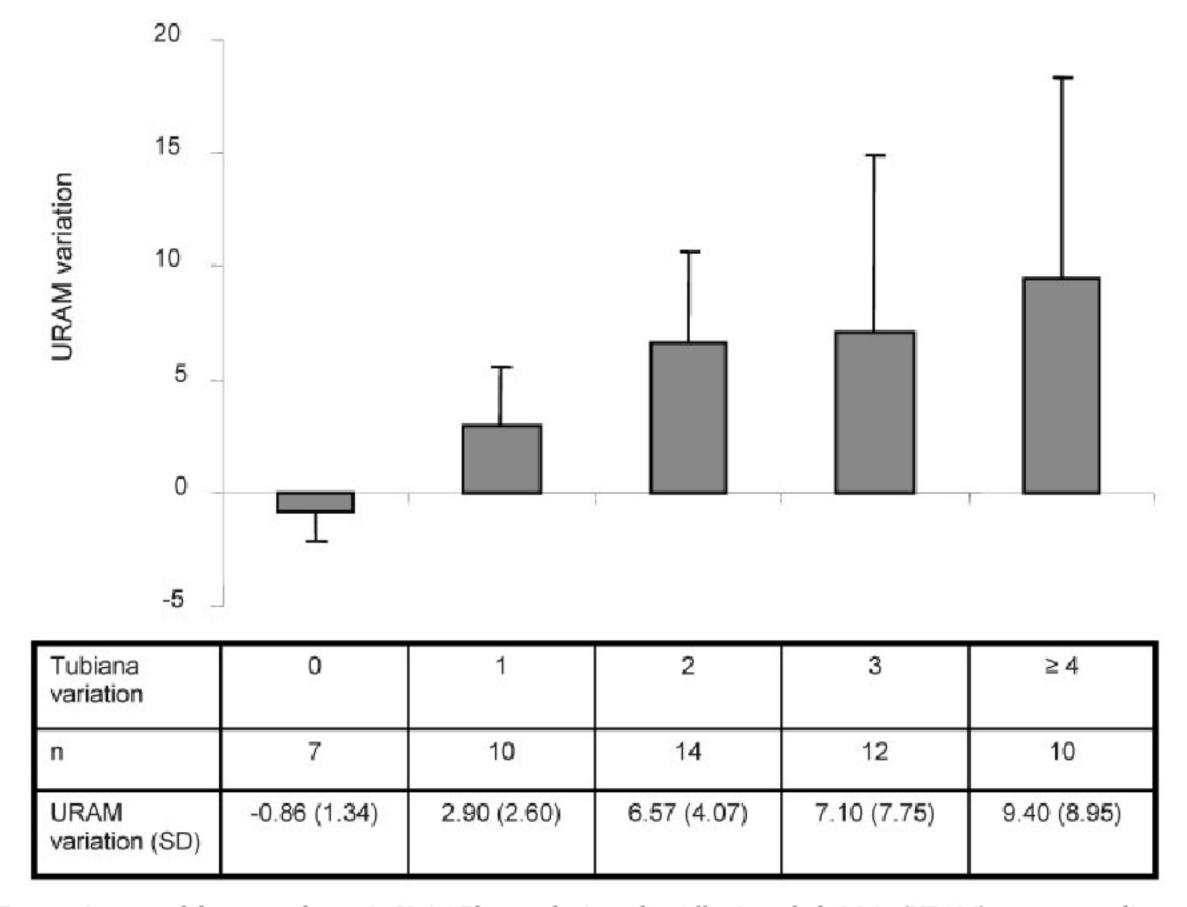


Figure 2. Responsiveness of the mean change in Unité Rhumatologique des Affections de la Main (URAM) scores according to responder status. Increasing numbers for Tubiana variation categories reflected increasing structural response. Positive values for URAM variation represented decreased disability. Kruskal-Wallis test indicated significant intergroup differences (P = 0.0027).

[†] Wilcoxon's signed rank test.

Can you	Without difficulty (0)	With very little difficulty (1)	With some difficulty (2)	With much difficulty (3)	Almost impossible (4)	Impossible (5)
1. Wash yourself with a flannel,						
keeping your hand flat?						
2. Wash your face?						
3. Hold a bottle in one hand?						
4. Shake someone's hand?						
5. Stroke something or caress someone?						
6. Clap your hands?						
7. Spread out your fingers?						
3. Lean on your hand?						
9. Pick up small objects with your thumb and index finger?						

validity for Dupuytren's disease (24). Our own clinical experience and our results support that, as compared with most rheumatic hand diseases, in Dupuytren's disease pain is not common or markedly linked with the disability. The DASH, MHQ, and PEM consist of items related to pain, so they are probably not suitable for Dupuytren's disease (15,25,34). Furthermore, the loss of finger extension, and not finger flexion, is specific to the disease (4). This feature is not found in arthropathies of the fingers and may be a concern when using the CHFS for Dupuytren's disease. Indeed, the CHFS is adapted to rheumatoid arthritis and osteoarthritis (21,35). The content validity of the URAM scale was ascertained by an item-generation process (23,36). Experts and patients were asked about daily activities difficult to perform because of Dupuytren's disease to generate a provisional scale. The final scale is composed of 3 items provided by patients, 2 by experts, and 4 by both. It reflects a shared point of view in which the patient's opinion remains of key importance, as it should.

The URAM scale is a 1-domain outcome measure postulated to be related to disability associated with Dupuytren's disease. Measuring one concept of interest, one dimension was achieved by item selection after factor analysis and reinforced by the Cronbach's alpha coefficient, thus indicating good internal consistency. The testretest reliability was excellent and supported the reliability of the scale. Because flexion contracture induces Dupuytren's disease-associated disability, we included a structural criterion for convergent validity study of the URAM scale. We chose the Tubiana scale, which is currently used in clinical studies of Dupuytren's disease (37). A single-item measure can be useful to help interpret multi-item measures to determine whether they relate to each other and to ascertain conceptual agreement (23). Therefore, we also used the self-assessed disability on a VAS for convergent validity with the URAM scale. The DASH and the CHFS were also considered because they were previously used for patients with Dupuytren's disease. The URAM scale seems representative of disability associated with Dupuytren's disease.

As expected, with its content validity, the URAM scale provided higher correlations with the Tubiana scale and self-assessed disability on a VAS than it did with the DASH and the CHFS. This result underlines the appropriate value of our functional outcome measure compared with other measures previously used in Dupuytren's disease. Furthermore, the divergent validity of the URAM scale reflects its specificity. Pain, but also anxiety and depression, were not expected to be associated with, and were effectively not linked to, functional consequences of the physical impairment assessed by the URAM scale.

The responsiveness of the URAM scale showed its ability to detect clinical meaningful changes after needle aponeurotomy, a known successful and beneficial intervention. Needle aponeurotomy is a noninvasive treatment of interest previously demonstrated to have structural effectiveness in Dupuytren's disease (37). The ES was largest for the Tubiana scale, which reflected the results of the intervention. However, the Tubiana scale assesses the grade of the condition, which requires assessment by a clinician. The URAM scale is a measure of self-reported functional limitations and thus assesses a different dimension of Dupuytren's disease. The clinical relevance of the URAM score change was attested by the size of its significant correlation with that of the Tubiana score after treatment. The estimated clinically important change of the URAM score was 2.9, which was commensurate with a 1-point categorical change in the Tubiana score. It corresponded to an approximately 6% change in the 45-point range of the total score. Interestingly, a continuously increasing difference across Tubiana scale response categories indicated the absence of a ceiling effect and the ability of the URAM scale to proportionally reflect functional improvement associated with small as well as higher levels of structural variations.

Our study has some limitations. All of the patients were recruited in our unit and most required needle aponeurotomy. Our results may therefore not be generalizable to a primary care setting or a surgical care setting. The sample sizes for testing the provisional and the final scales were not large (38). However, they were in the range, i.e., 50 patients at least, of previously reported guidelines to analyze most relevant clinimetric properties (39). They were also not inconsistent with sample sizes used in other validation studies (21,35). The ability of the URAM scale to

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detect deterioration could not be determined because none of the participants reported deterioration. Using the scale to monitor gradual progression of the disease over time and decide on treatment requires a new validation study in an observational cohort of patients with Dupuytren's disease.

In conclusion, our study provides the first patient-reported outcome measure for Dupuytren's disease: the URAM scale. This measure is a 9-item scale that showed suitable content validity, reliability, construct validity, and responsiveness. Furthermore, it is short and convenient enough for easy use in daily practice and in clinical trials.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Beaudreuil had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Beaudreuil.

Acquisition of data. Beaudreuil, Allard, Quintero, Bernabé. Analysis and interpretation of data. Beaudreuil, Allard, Zerkak, Gerber, Cappelleri, Lasbleiz, Orcel, Bardin.

ROLE OF THE STUDY SPONSOR

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APPENDIX A: MEMBERS OF THE URAM STUDY GROUP

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