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Original article

Determining the minimal clinically important difference of the hand function sort questionnaire in vocational rehabilitation

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ABSTRACT

Objective: To estimate the Minimal Clinically Important Difference (MCID) of the French version of the Hand Function Sort questionnaire (HFS-F). As a comparison, the MCID of the Disabilities of the Arm, Shoulder, and Hand (DASH) was also estimated.

Materials and methods: We included French-speaking patients hospitalized in a multidisciplinary rehabilitation program for chronic pain of the upper limb after an accident. HFS-F and DASH scores were collected at admission and discharge; the Patient Global Impression of Change measure (PGIC; 7 levels) was collected at discharge. The MCID was estimated by 2 methods: the anchor-based method (receiver operating characteristic [ROC], delta (Δ) mean of scores) and the objective method based on the distribution of scores (standard error of measurement, SEM).

Result: We included 225 patients. By the anchor-based method, the MCID for the HFS-F and DASH was +26 (SD 35) ($P < 10^{-4}$) and −13 (SD 13) ($P < 10^{-4}$), respectively, and by the ROC curve, it was +10 to +12 for the Δ-HFS-F and −7.5 to −5 for the Δ-DASH. The area under the ROC curve (AUC) was 0.726 [0.638–0.781] for Δ-HFS-F and 0.768 [0.701–0.83] for Δ-DASH. The correlations between the anchor and delta scores were > 0.38 ($P < 10^{-4}$). The SEM was 16.2 for the HFS-F and −4.3 for the DASH.

Conclusions: Values below the SEM must be rejected. Our anchor was significantly correlated with the outcome. Therefore, we propose an MCID for the HFS-F of 26, corresponding to approximately 10% progression of the score.

1. Introduction

Musculoskeletal complaints involving upper extremities are frequently responsible for limited activity and participation [1]. Several tools assessing activity and participation have been developed according to the International Classification of Functioning, Disability and Health domains [2,3]. Among self-reported evaluations of the upper limb, the Hand Function Sort (HFS) and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaires are commonly used [4]. The HFS measures functional ability level, which represents the person's beliefs in their ability to perform tasks successfully [5]. The DASH measures difficulties (disabilities) in performing 21 tasks and other dimensions, such as social participation and pain [4].

The HFS was originally based on the review of the Dictionary of Occupational Titles and the Handbook of Analyzing Jobs [4]. It is a pictorial questionnaire that can be easily used and so reduces missing data for patients with a low literacy level or migrant manual workers with foreign languages [6]. It was developed and validated in a population with upper-extremity musculoskeletal conditions [4] and is frequently used with a functional capacity evaluation [7] to determine the ability to resume work. Effectively, when the functional capacity evaluation is an objective measure, the HFS addresses patient's perspectives to implement coping behavior when necessary. The coherence between the 2 measures is used to predict the ability to resume work and guides the therapeutic project: to undergo training or a reintegration of manual activity. The HFS-F is a cross-cultural adaptation of the HFS

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that has been validated for French-speaking patients with upper-limb complaints. The internal consistency of the HFS-F and its test–retest reliability are excellent, with a Cronbach α of 0.98, and an intraclass correlation (ICC) of 0.92 [8].

Widely used and considered a gold standard, the DASH is a 30–item questionnaire that assesses upper-limb disability and pain. It is the most studied tool, with positive clinimetric properties [9]. The French version was validated by Fayad et al., with a Cronbach α of 0.96 and an ICC of 0.95 [10].

Evaluating whether therapeutic interventions are useful and effective, especially for chronic conditions when complete recovery is not possible, requires interpreting a change in questionnaire scores [11]. The Minimal Clinically Important Difference (MCID) is a patient-derived score that reflects changes that are meaningful to the patient after a clinical intervention and which would require, in the absence of troublesome side effects and excessive cost, a change in management. The MCID was developed by Jaeschke et al., in 1989 [12,13]. For research purposes, the MCID is often used in sample size calculations [14]. However, how to determine the MCID lacks consensus. Over the last decades, 2 main methods have been used: anchor-based and distribution-based calculations. As a result, the MCID is a variable concept and is defined by a range of values. None of the previous methods have provided an indisputable result; each has strengths and weaknesses [14–16]. For the anchor-based method, the score's progression is compared with an external criterion (termed "anchor") to determine an MCID. The Patient Global Impression of Change (PGIC) score is commonly used as an anchor [17]. For the distribution-based method, statistically significant effects occur beyond some level of chance, reflecting changes that occur beyond the measurement error of the questionnaire. To that end, the standard error of measurement (SEM) is the most popular index used. The SEM reflects the unreliability of the instrument rather than the clinical relevance of the treatment effect [11,14]. Many authors agree that the MCID equals at least one SEM [11,14,18].

To the best of our knowledge, no MCID has been calculated for the HFS or HFS-F. The aim of this study was to estimate the MCID of the HFS-F for patients hospitalized for musculoskeletal rehabilitation for chronic pain of the upper limb, to better manage their follow-up, adapt the multidisciplinary therapeutic intervention and improve communication between patients, therapists, and care providers. As indicated below, the DASH is considered the gold-standard instrument to evaluate upper-limb disability. The MCID of the DASH was also calculated for benchmarking purposes.

2. Methods

2.1. Study design, settings, and participants

The study took place in a rehabilitation hospital. Data were prospectively collected for French-speaking patients aged 18 to 65 years and hospitalized for musculoskeletal rehabilitation from January 1, 2012 to June 30, 2015 with various upper-limb pathologies after an accident. In our centre, rehabilitation care is multidisciplinary, and its actors are physiatrists, physiotherapists, psychologists, occupational therapists, etc. Length of stay for this type of care is approximately 4 weeks. At admission, patients provided informed consent for the use of their anonymized clinical data. The current study was approved by the local ethical committee (CCVEM 001/10). Patients meeting one of the following 4 conditions were excluded from the study:

- severe psychiatric pathologies (personality disorder, severe mood or psychotic disorder, somatoform disorder or post-traumatic stress disorder);
- central neurological disease or severe impairment of brachial plexus;
- diseases of the musculoskeletal system outside of the upper limb (trunk, pelvis and lower extremities);
- unable to read or to understand the questionnaire.

2.2. Variables and measurement

We collected both HFS-F and DASH scores at hospital admission and discharge and the PGIC score at discharge. The outcomes of interest were the difference between discharge and admission scores: delta (Δ)-HFS-F and Δ-DASH.

The HFS contains 62 pictorial questions of tasks involving the upper limb. These tasks represent a wide range of daily living or vocational activities and cover a broad range of physical demands. Questions 1 to 16 correspond to sedentary activities, 17 to 34 light activities, 35 to 52 medium activities and 53 to 62 heavy activities. Each question allows for a 5-point rating from "able", "slightly restricted", "restricted", "very restricted" to "unable." There is also a sixth rating, depicted as "?", indicating "I don't know". There are some similar items represented by different drawings (questions #1 and #14, #18 and #33, #55 and #60) used to check the "internal validity" of the answers. The total score ranges from 0 to 248. The HFS contains a "reliability check box," represented by 3 levels of score interpretation based on a combination of the value of the discrepancy between the reliability check-item pairs and the number of "?" items: when the check indicates level 3, the result of the questionnaire is considered "unreliable". Different levels of perceived physical work are categorized: sedentary (scores 100 to 136), light (scores 154 to 190), medium (scores 200 to 228) and heavy (scores 238 to 248). Scores < 100 correspond to a level less than sedentary [4].

The DASH contains 30 questions: 21 are about various activities of daily living including 5 heavy activities, and 9 are about pain and interference of the pathology with functioning. Each question allows for a 5-point rating from "no difficulty", "mild difficulty", "moderate difficulty", "severe difficulty" to "unable". The scores range from 0 (no disability) to 100 (most severe disability) [10].

The PGIC (Likert scale of 7 levels) asks patients how their health status has improved after hospitalization (1, worse than ever; 2, much worsened; 3, slightly worsened, 4, unchanged, 5, slightly improved; 6, much improved; 7, completely improved) [19].

Other data collected were age;

- sex;
- educational level (≤ 9 vs. > 9 years' compulsory schooling);
- number of surgical procedures;
- localization of the lesion;
- length of stay;
- diagnostics retained according to the International Classification of Diseases, 10th revision [2,3] for the principal lesion and any secondary upper-limb lesions;
- the Abbreviated Injury Scale (AIS) score, which describes the severity of initial traumatic injuries [20];
- work incapacity at hospital admission;
- number of days since the accident;
- and pain severity at admission and discharge measured by the Brief Pain Inventory (BPI) questionnaire [21], with each item rated from 0, no pain, to 10, pain as bad as you can imagine.

2.3. Statistical analysis

2.3.1. Anchor-based approach

The anchor used was the level of improvement based on patients' subjective feelings reported on the PGIC. The score was treated as a binary outcome (scores of 6 or 7, "improved," vs. 1–5,

"not improved"). The MCID was estimated by the receiver operating characteristic (ROC) method by comparing patients with and without improvement. The optimal cutoff on the ROC curve was determined by the optimal Youden's Index [22] and equal specificity/sensitivity of at least 0.65. We also calculated the mean change in score according to each patient's response level on the PGIC.

2.3.2. Distribution-based approach

We calculated the SEM, the variation in scores due to the unreliability of the scale used. An SEM value is based on the standard deviation (SD) of the sample and the reliability of the measurement instrument, expressed as [11] SEM = SD from the 1st test x ($\sqrt{}$ (1-ICC)). The ICC for test–retest reliability of the HFS-F was 0.921 [8].

As a comparison, the MCID of the DASH was estimated by the anchor-based approach and distribution-based method. The ICC for the test-retest reliability of the DASH was 0.95 [10].

To reinforce the validity of our anchor, we calculated the Pearson correlation coefficient between the PGIC and delta scores. Revicki [23] recommended that MCID must be based primarily on appropriate patient-based anchors that are correlated at ≥ 0.30 with the patient-reported outcome.

Regarding the DASH score, the SEM is reported as negative because of a decline, representing improvement in function on that instrument.

Data collection and analysis were performed with the Number Cruncher Statistical System (NCSS) v9 [24].

2.3.3. Floor and ceiling effects

Floor and ceiling effects for both questionnaires were defined as present if at least 15% of results reached the maximum or the minimum value [9].

3. Results

In total, 325 eligible patients with an upper-limb problem were hospitalized from January 2012 to June 2015. We excluded 100 patients because of incomplete ($n = 28$) or unreliable ($n = 72$) HFS-F scores. Therefore, 225 patients were included in the study. The mean HFS-F score was 138 (SD 58) at admission and 146 (SD 63) at discharge. The mean DASH score was 48 (SD 19) at admission and 42 (SD 22) at discharge. We found no floor or ceiling effects for the 2 questionnaires (Fig. 1). The mean pain severity on the BPI was 4 (SD 2.25) at admission and 4 (SD 2.55) at discharge. Most patients were male (82%), manual workers (84%) and about 43 (SD 12) years old. The mean hospitalization period was 29 (SD 9) days. The median duration since the accident was 397 (interquartile range [IQR] 251–581) days. Patients' demographic and descriptive characteristics are in Table 1.

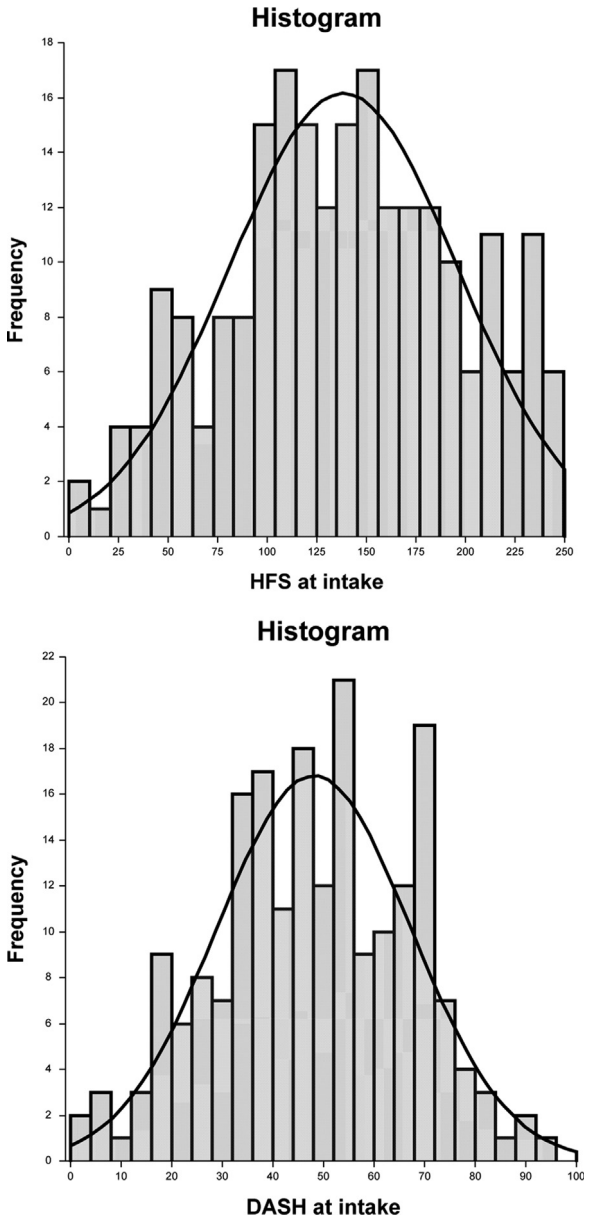

Fig. 1. Distribution of the HFS and DASH scores at hospital admission. Absence of floor and ceiling effects. For the HFS-F, the mean score was 138: 10% of the patients had a score < 53 and 10% had a score > 220. For the DASH, the mean score was 48: 10% of the patients had a score < 21 and 10% had a score > 72.

3.1. Anchor-based approach

Patients were classified into 2 groups according to their answers to the anchor question; 42% reported improvement, and 58% reported no improvement.

ROC curves for the progression of scores (Δ-HFS-F and Δ-DASH): the AUC was 0.726 [0.638–0.781] for the Δ-HFS-F and 0.768 [0.701–0.83] for the Δ-DASH (Fig. 2).

The MCID was estimated by the optimal ROC cut-off value. A threshold between +10 and +12 for the Δ-HFS-F and between −7.5 and −5 for the Δ-DASH gave both sensitivity and specificity values > 65% and an optimal Youden Index of 0.30 (Table 2).

In the "improved" group, Δ-HFS-F and Δ-DASH values were +26 (SD 35) ($P < 10^{-4}$) and -13 (SD 13) ($P < 10^{-4}$), respectively. In the "non-improved" group, Δ-HFS-F and Δ-DASH values were −5 (SD 39) ($P = 0.14$) and −0.4 (SD 11.5) ($P = 0.72$). The difference in HFS-F and DASH scores when considering answer 6 on the PGIC as an improvement were 18 and −8, respectively. The differences in HFS-F and DASH scores when considering answer 7 on the PGIC as an improvement were 34 and −16, respectively.

The PGIC score was significantly correlated with the Δ-HFS-F ($r = 0.40$, $P < 10^{-4}$) and Δ-DASH ($r = 0.51$, $P < 10^{-4}$).

With the exception of educational level and BPI score, associations between all the other variables and the anchor were not significant. In the improved group, 74% of patients had an education level > 9 years, whereas 52% of patients reporting no improvement had an education level < 9 years ($P < 10^{-4}$). The PGIC score was significantly correlated with BPI scores at discharge ($r = 0.56$, $P < 10^{-6}$) and admission ($r = 0.24$, $P < 10^{-3}$).

Table 1
Patient characteristics ($n = 225$).

Characteristics	
Injury localization	
Proximal (shoulder/elbow)	147 (65%)
Distal (wrist/hand)	78 (35%)
Diagnosis retained for principal lesion	
Fracture/dislocation	91 (40%)
Rotator cuff	74 (33%)
Other	23 (10%)
Complex	18 (8%)
Tendon/ligament/sprain	17 (8%)
Peripheral nerve	2 (1%)
Upper-limb secondary lesion	
Shoulder	15 (6%)
Peripheral nerve	15 (6%)
Wrist/hand	8 (3%)
Elbow	4 (1%)
Others	4 (1%)
Cervical column	1 (0.4%)
Abbreviated Injury Scale ($n = 214$)	
Minor	104 (49%)
Moderate	86 (40%)
Severe	24 (11%)
Number of surgical interventions	
0	59 (26%)
1	91 (41%)
2	46 (21%)
>2	27 (12%)
Working capacity at hospital admission	
None	187 (83%)
Partial	27 (12%)
Total	11 (5%)
Profession ($n = 224$)	
Manual worker	189 (84%)
Employee	23 (10%)
Company manager	6 (3%)
Student	4 (2%)
Other	2 (1%)
Educational level ($n = 220$)	
>9 years	129 (59%)
≤ 9 years	91 (41%)

3.2. Distribution-based approach

Calculation of the SEM yielded values of 16.2 for the HFS-F and −4.3 for the DASH. Calculation results are summarized in Table 3.

4. Discussion

The aim of this study was to estimate the MCID of the HFS-F for patients undergoing treatment for musculoskeletal complaints of the upper limb. At the same time, to obtain comparison values, we estimated the MCID of the DASH for the same cohort. According to the anchor-based method with the ROC curve, the MCID for the HFS-F and DASH was +10 to +12 and −7.5 to −5. In the improved group, changes in HFS-F and DASH scores were +26 and −13, respectively. In looking at the different delta scores according to responses on the PGIC, the HFS-F MCID at +18 and DASH MCID at −8 represent patients at least "much improved". Using the distribution-based method, values of +16 and −4 were calculated as the SEM for the HFS-F and DASH, respectively. Because values below the SEM must be rejected [18], we suggest the HFS-F MCID at +26 and DASH MCID at −13 as cutoffs. This choice corresponds to results obtained with the anchor-based method and based on the choice of our anchor being validated a posteriori by finding an acceptable correlation between our anchor and a patient-reported outcome change score. Therefore, our anchor seems useful to estimate the MCID [23]. In addition, the optimal Youden Index was intermediate, and results using an ROC curve are not contributory.

For our population of manual workers, the HFS-F MCID value of +26 can be easily used to measure a subjective improvement. In clinical practice, this value can be used as a common language on reports after multidisciplinary care in vocational rehabilitation or during an outpatient evaluation, between therapists, patients and care providers. In rehabilitation research, it can be useful to study the effect of a treatment. Finally, this estimation can better orient the therapeutic project by intensifying or not the treatment and to answer the question of a return to the same work or not in association with multiple other data, particularly functional capacity evaluation.

The MCID value for the HFS-F obtained by using the ROC curve was smaller than the SEM. Crosby et al. observed that with lower baseline values, the MCID became much smaller than one SEM [25]. In the current study, the mean baseline HFS-F (138 [SD 58]) was smaller than the average reported for male unemployed patients (147/248 to 198/248) [26]. Furthermore, the MCID was smaller because the change reported on the PGIC with open questions will also depend on many factors and dimensions other than the improvements reported on the questionnaire, such as improvement in mood, appetite, and pain. For example, in our sample, the BPI score was significantly correlated with the anchor.

The PGIC focusing on the questionnaire's dimensions was used as an anchor by Jaeschke et al. [13] and other authors to define the MCID of upper-extremity rating scales such as the DASH, Quick-DASH, Patient-Rated Wrist Evaluation, and Michigan Hand Questionnaire [27,28], whereas other authors used the PGIC with open questions as an anchor [11,14].

Some authors do not support the validity of the PGIC for determining true changes over time in routine clinical practice, and other authors suggest that the PGIC may lack temporal stability [29,30]. Despite these criticisms, our PGIC score was significantly correlated with the delta scores, which validates the choice of our anchor and guides our choice of results [23].

Many authors conclude that the MCID depends on the definition of what is an "important change" on the anchor. In our study, we required "much and completely improved" on the PGIC, corresponding to the definition of MCID as the "important change". Indeed, other authors tend to focus on the amount of change rather than the importance of the change [11,14] and thus, tend to require "slightly improved". The difference in HFS-F and DASH scores when considering separately answer 5 (slightly improved) on the PGIC as an improvement were +1 and −5, respectively, which is a very small score derivation for the HFS-F and the lower end of the optimal range estimated for the DASH with the ROC curve method. Therefore, our choice of "much and completely improved" on the PGIC seems adequate.

The MCID value of −10 is commonly accepted for DASH MCID [31–33]. Some authors have found a value of −10 for various upper-limb pathologies using a specific anchor asking about pain, function, and treatment response [27,34]. A systematic review showed a value of −10 [32]. For shoulder complaints, Kampen et al. suggested a DASH MCID of −12 by using a specific anchor asking about function [33]. Malay et al. estimated the DASH MCID at −7 after decompression of the ulnar nerve by using a change in scores in the satisfaction domain of the Michigan Hand Questionnaire as an anchor [35]. Our DASH MCID estimation at −13 is comparable to previous estimations. The variations in these different DASH MCID estimations could be explained by the factors that influence the MCID calculation, such as patient demographic characteristics, symptom duration, therapeutic context, and the nature of the anchor used [14].

With an AUC > 0.70, both the DASH and the HFS-F seem relevant to discriminate patients with subjective improvement [36]. This AUC is congruent with a systematic review of the clinimetric properties of the DASH among individuals with

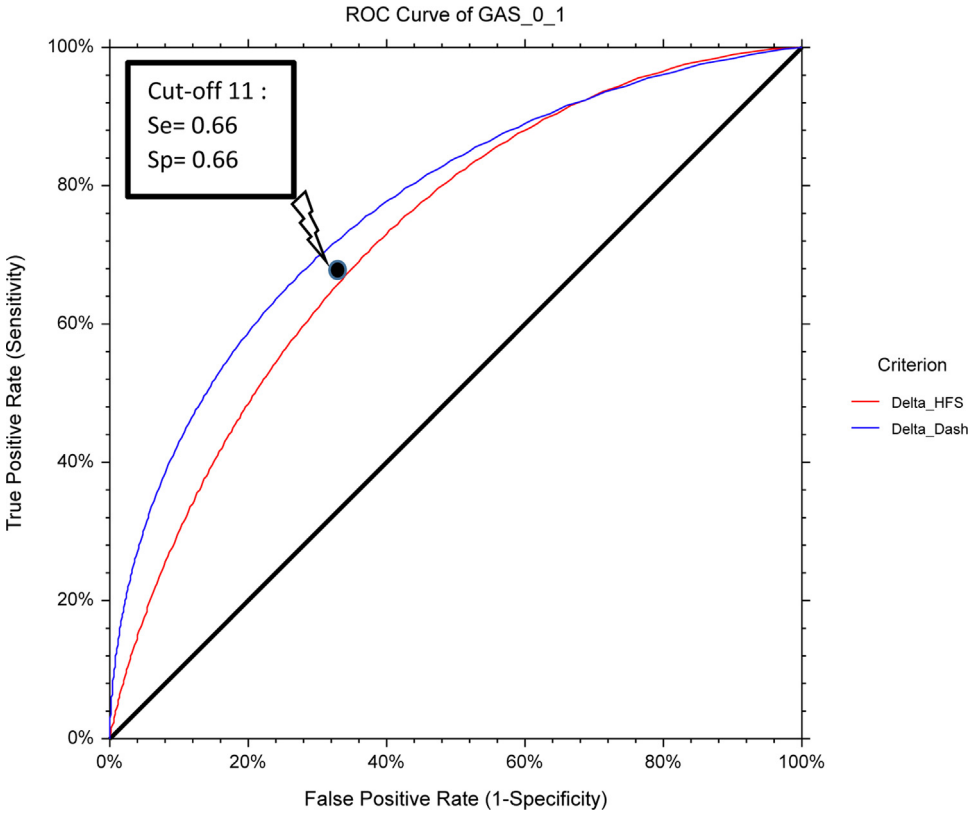

Fig. 2. Receiver operating characteristic (ROC) curves for the progression of Δ-HFS-F and Δ-DASH scores. se, sensitivity; sp, specificity.

Table 2
Points on the ROC curve with equal sensitivity and specificity of about 60% for the French version of the Hand Function Sort questionnaire.

Cut-off value	Sensitivity	Specificity
8.00	0.69368	0.63733
9.00	0.68348	0.64705
10.00	0.67312	0.65667
11.00	0.66264	0.66619
12.00	0.65202	0.67561
13.00	0.64129	0.68491
14.00	0.63044	0.69410

ROC: receiver operating characteristic.

Table 3
Summary of results: estimation of Minimal Clinically Important Difference values by different methods.

Calculation methods	HFS-F	DASH
Anchor-based method		
ROC curve	+10 to +12 points	−7.5 to −5 points
Mean Δ score	+26 points	−13 points
Distribution-based method		
SEM	+16 points	−4 points

HFS-F: Hand Function Sort questionnaire French version; DASH: Disabilities Arm Shoulder and Hand questionnaire; ROC: receiver operating characteristic; SEM: standard error of measurement.

shoulder disorders in which AUC values ranged from 0.60 to 0.86 [37].

In our patients, educational level was correlated with PGIC score; the estimation of an "important change" on the anchor may depend on patients' interpretation and with lower educational level, lower compliance and outcome. The influence of educational level and therapeutic education on outcomes is still debated [38–40].

4.1. Study limitations

The limitations of the current study arise from the type of the population studied. Most of the individuals studied were young manual workers, and their recovery expectations were relatively high, which led to inflated MCIDs. We did not consider Rasch analysis for this study because we believe it was not essential. Some articles have been published over the last 8 years regarding the DASH and QuickDASH Rasch analysis [41,42]. All concluded that the questionnaire is good but not strictly unidimensional. For the HFS, to our knowledge, no Rasch analysis has been performed. Matheson, in a first article [4], undertook a principal component analysis and found 6 factors explaining 75% of the variance, suggesting a 3-factor solution (1 global and 2 minor). The global factor (tasks that require strength and involve the whole upper extremity) includes 55 of the 62 items and accounts for 52.4% of the variance.

5. Conclusion

By combining different approaches to assess the MCID of the French version of the HFS, we can suggest an MCID value of +26. However, because of the variety of factors that influence the MCID calculation, further studies are needed to estimate HFS-F MCID scores in other patient populations, especially in patients with aging pathologies and a less challenging functional request. The building of a consensus on calculation methodology is also needed, to generalize an estimation of the MCID score across patient populations and to reinforce the application of the MCID score in clinical and research practice [12,14].

Ethical standards

All patients provided informed consent for the use of their anonymized clinical data for the current study. The current study

was approved by the local ethics committee, and the study was performed in accordance with the ethical standards listed in the 1964 Declaration of Helsinki.

Disclosure of interest

The authors declare that they have no competing interest.

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