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How Should We Define Clinically Significant Outcome Improvement on the iHOT-12?

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Abstract *Background:* There is increased emphasis on efficiently administering patient-reported outcome measures (PROMs). The International Hip Outcome Tool-12 (iHOT-12) is a short-form version of the iHOT-33, and relatively little is known about clinically significant outcomes using the iHOT-12. *Questions/Purposes:* The purpose of this study was to define minimal clinically important difference (MCID) and patient acceptable symptomatic state (PASS) for the iHOT-12 and to identify predictors for achieving these psychometric end points in patients undergoing arthroscopic treatment of femoroacetabular impingement (FAI). *Methods:* Data was prospectively collected and retrospectively analyzed as part of an institutional hip preservation repository. One hundred and twenty patients were included; mean age and body mass index (BMI) were 38.7 years and 25.9, respectively. A majority of patients were female (67.5%) and white (81.7%) and participated in recreational sports (79.2%). The iHOT-12 was administered pre-operatively and at 1-year follow-up to patients undergoing primary hip arthroscopy for FAI. The following anchor question was also asked at 1-year follow-up: "Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?" MCID was calculated using a distribution-based method. Receiver-operating characteristic analysis with area under the curve was used to confirm the significance of the PASS threshold. *Results:* Mean iHOT-12 scores improved from 35.6 at pre-operative assessment to 70.7 at 1-year follow-up. Patients indicating satisfaction with their outcome improved from 37.5 pre-operatively to 79.0 at 1-year follow-up. MCID value for the iHOT-12 was 13.0. The PASS threshold was 63.0, indicating an excellent predictive value that patients scoring above this threshold were likely to have met an acceptable symptom state. Worker's compensation patients and those with increased BMI were less likely to achieve PASS; lower pre-operative iHOT-12 score was predictive for achieving MCID, and achieving MCID was predictive for achieving PASS. *Conclusion:* This is the first study to define PASS and MCID for the iHOT-12, which measures clinically significant outcome improvement comparably to that of other commonly used hip PROMs. As its use becomes more widespread, the iHOT-12 data-points presented in this study can be used to determine clinically significant improvement of patient-reported outcomes.

Level of Evidence: Level IV: Case Series.

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Introduction

Femoroacetabular impingement (FAI) refers to an atypical anatomic relationship involving the acetabulum and/or the femoral head-neck junction within the hip [1]. It is caused by bony deformities or spatial incongruence that can lead to pathologic contact and shearing forces at the acetabular labrum during normal hip motion [8]. These forces can lead

to cartilage wear and progression to hip osteoarthritis. Arthroscopic surgery has become the mainstay of treatment for symptomatic FAI, with a significant increase in the number of elective hip arthroscopic procedures seen in the past decade [3, 10, 11, 14, 19]. Patient-reported outcome measures (PROMs) are the most common method for reporting outcomes after orthopedic procedures. In hip arthroscopic surgery, the Hip Outcome Score (HOS), the modified Harris Hip Score (mHHS), and the International Hip Outcome Tool-33 (iHOT-33) are the most commonly used, and the iHOT-33 has been validated as a reliable measure of functional and quality-of-life outcomes [13].

Although PROMs are increasingly reported in orthopedic surgery, there is still a need to improve the quality of outcome reporting. A prior review noted that few studies use clinically significant outcome parameters to quantify the degree of outcome improvement [20]. Previously reported measures of clinically significant outcome for arthroscopic hip surgery include minimal clinically important difference (MCID) [18], patient acceptable symptomatic state (PASS) [4], and substantial clinical benefit (SCB) [16]. MCID is defined as the "the smallest difference which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" [21]. Thus, MCID is the smallest change in a measurement that indicates an important improvement or worsening in a symptom [12]. SCB is defined as the upper threshold of outcome improvement that a patient must achieve in order to feel *substantially* better [16]. In addition to MCID and SCB, PASS has been adopted as a measure of clinical significance capable of discriminating between feeling acceptably well and unacceptably unwell [20]. PASS is thus considered the minimum score required for a patient to feel well and goes beyond what is minimally detectable (MCID).

With no clear consensus on preferred PROMs, a variety of hip PROMs are employed to grade outcomes of arthroscopic hip surgery. Each offers certain advantages, and some authors have suggested that the iHOT-33 is the most sensitive tool for measuring outcome improvement while also exhibiting minimal ceiling effect [16]. To reduce patient burden and administrative effort, a short version of the iHOT-33, known as the iHOT-12, was developed [6]. The iHOT-12 has shown excellent agreement with the longer iHOT-33 and comparable sensitivity to change [6]. While the iHOT-12 has been validated as a useful tool, most of the evidence has focused on statistically significant differences between groups rather than clinically significant differences. Specifically, the MCID and PASS have yet to be defined for the iHOT-12. The purpose of this study was to define MCID and PASS for the iHOT-12 and to identify predictors for achieving these psychometric end points. We hypothesized that MCID and PASS for the iHOT-12 would be comparable to those of other commonly used hip PROMs.

Methods

This study was approved by the institutional review board at Rush University. Data was prospectively collected and retrospectively analyzed as part of an institutional hip preservation repository. All patients undergoing primary hip arthroscopy for the treatment of FAI syndrome (FAIS) between January 1, 2012 (the initiation of the repository), and June 25, 2012, for the treatment of FAIS by a single, fellowship-trained surgeon were eligible for inclusion. Inclusion criteria consisted of clinical and radiographic diagnosis of symptomatic FAIS, failure of non-operative management (including physical therapy, activity modification, oral anti-inflammatories, and for some patients fluoroscopically guided intra-articular cortisone injection); and hip arthroscopy performed to address the FAIS, with completion of pre-operative and 1-year follow-up for iHOT-12 (Appendix Table 5). All arthroscopic procedures were performed by the senior author with the patient under general anesthesia in the supine position on a standard traction table using previously described surgical technique [5]. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist was used.

One hundred and twenty patients met the inclusion criteria. Mean age and body mass index (BMI) were 38.7 (SD ± 11.8) years and 25.9 (SD ± 5.1) kg/m^2, respectively. The majority of patients were female ($n = 81$, 67%) and white ($n = 98$, 81.7%) and participated in recreational sports ($n = 95$, 79.2%). Mean radiographic measurements for pre-operative alpha angle and lateral center-edge angle of Wiberg (LCEA) were 62.3° (SD ± 9.6) and 33.4° (SD ± 17.9), respectively (Table 1).

All patients received a series of pre-operative radiographs consisting of a standing anteroposterior (AP) pelvis radiograph, an AP hip radiograph, a false-profile hip radiograph, and a Dunn lateral hip radiograph. The joint-space

Table 1 Demographics of cohort

Demographic	N/mean
Total	120
Female (%)	81 (67.5%)
Age at surgery[a]	38.7 ± 11.7
Body mass index[a]	25.9 ± 5.1
Race and ethnicity	
White	98 (81.7%)
African American	8 (6.7%)
Hispanic	5 (4.2%)
Other	2 (1.7%)
Worker's compensation	
No	112 (93.3%)
Yes	6 (5%)
Sports/physical level of competition	
None	18 (15%)
Recreational	95 (79.2%)
High school	3 (3%)
College	2 (1.7%)
Professional	1 (0.8%)
Alpha angle[a]	62.3 ± 9.6
Lateral center-edge angle[a]	33.4 ± 6.8
Tönnis grade	
0	93 (77.5%)
1	6 (5.0%)

[a] Reported in mean ± standard deviation

width was measured in three positions on the AP hip radiograph, as was the LCEA. Alpha angle was measured on the Dunn lateral view of the hip. The Tönnis grade was determined.

Patients enrolled in the registry complete PROMs, which are delivered pre-operatively and at 1-year follow-up assessment. In addition to PROMs, patients respond to the following anchor question at 1-year follow-up: "Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?" Patients can answer "yes" or "no."

Numerous models exist to calculate MCID and PASS, two of which are distribution and anchor methods [9, 22]. Within distribution-based models, statistical analyses calculate changes in outcome that represent the minimal clinically significant change occurring beyond expected variance or error [17]. Prior investigations have demonstrated that half the standard deviation of outcome scores for a given instrument can reliably determine MCID [7, 15]. Within anchor-based models, patients answer an "anchor" question, based upon their global function, pain, or satisfaction. Anchor questions seek to ascertain patient-perceived improvement. Anchor responses are then compared to outcome scores to determine values for MCID or PASS, respectively.

In this study, MCID was calculated using a distribution-based method. PASS was calculated using a distribution-based method while a non-parametric receiver-operating characteristic (ROC) analysis with area under the curve was used to confirm the significance of the PASS threshold. Post-operative outcome score means between the "satisfactory" and "non-satisfactory" groups were compared with ROC analysis to identify a mean post-operative score that significantly differentiated the two groups; this score was defined as the absolute post-operative PASS value. In order to determine the validity of identified threshold values for predicting a patient's likelihood to achieve PASS (strength of association), an area under the curve (AUC) of ROC analysis was performed. Based on prior evidence, the strength of association was considered "acceptable" for AUC of more than 0.7 and "excellent" for AUC of more than 0.8 [2].

To determine factors associated with and predictive of MCID/PASS, separate analyses were conducted. Univariate analyses were performed, and multivariable logistic models were fitted to determine which patient factors and clinical characteristics are associated with achieving MCID and PASS. Variables used in univariate and regression analyses included age, sex, BMI, ethnicity, worker's compensation status, alpha angle, LCEA, Tönnis grade, labral treatment (repair vs. debridement), acetabular/femoral osteoplasty, and level of sports participation. Additionally, pre-operative outcome score was controlled for in regression analyses. Significance was set at a p value of less than 0.05. Analyses were performed using SAS software, version 9.3 (SAS Institute, Cary, NC, USA).

Results

Mean outcome score for the iHOT-12 showed statistically significant improvement from 35.6 (SD ± 17.9) at pre-operative baseline to 70.7 ± 5.1 at 1-year follow-up ($p < 0.001$) (Fig. 1). Seventy-six of the 120 (63.3%) patients provided responses to the anchor question at 1-year follow-up, and 74% reported that they were satisfied with their current state. Patients indicating that their current state was satisfactory improved from mean baseline iHOT-12 score of 37.5 (SD ± 17.4) to 79.0 (SD ± 16.4) at 1-year follow-up.

The MCID for the IHOT-12 was 13.0. A 1-year post-operative iHOT-12 absolute score of 63 (AUC 0.93) significantly corresponded to PASS. Based on the AUC score,
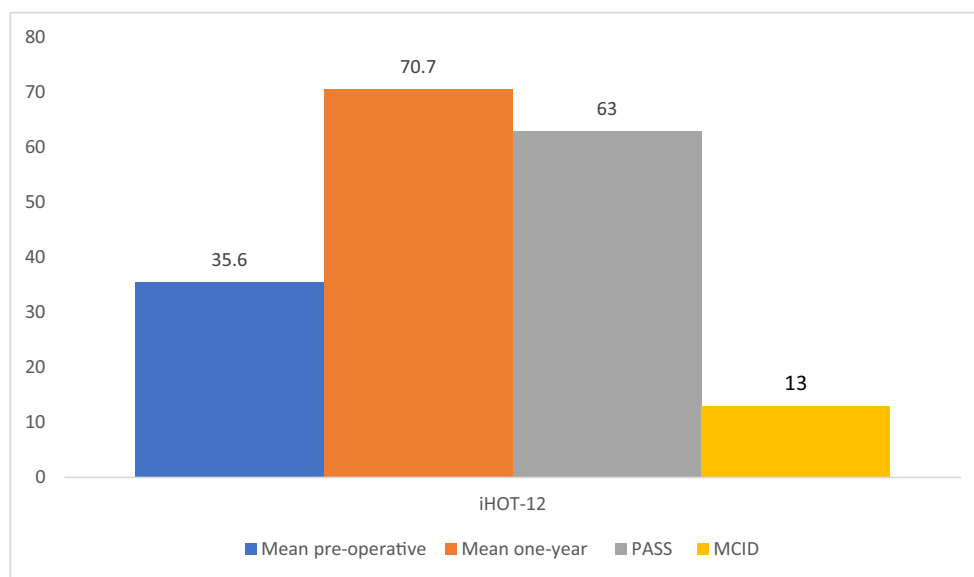

Fig. 1. Comparison of pre-operative, post-operative, patient acceptable symptomatic state (PASS), and minimal clinically important difference (MCID) values for the international Hip Outcome Tool-12 (iHOT-12).

Table 2 Univariate analysis for minimal clinically important difference (MCID)

Predictor	Odds ratio	Lower 95% CI	Upper 95% CI	*p* value
Age	1.00	0.96	1.04	0.894
Sex (female vs. male)	1.73	0.71	4.23	0.230
Body mass index	0.97	0.89	1.06	0.546
Race/ethnicity (white vs. non-white)	0.52	0.09	3.04	0.468
Worker's compensation (yes vs. no)	0.26	0.05	1.37	0.111
Alpha angle	0.99	0.94	1.04	0.619
Lateral center-edge angle	0.96	0.90	1.02	0.177
Tönnis grade (1 vs. 0)	> 999.99	< 0.001	> 999.99	0.973
Labral repair (yes vs. no)	0.26	0.04	1.97	0.194
Acetabular rim trimming (yes vs. no)	1.12	0.12	10.51	0.919
Cleared to return to sport (yes vs. no)	1.29	0.52	3.22	0.570
Sport level of competition (Ref: recreational)				
None	0.61	0.19	1.92	0.397
High school	0.12	0.01	1.36	0.087
College	> 999.99	< 0.001	> 999.99	0.978
Professional	< 0.001	< 0.001	> 999.99	0.985

the identified value has an excellent predictive value that patients scoring above this threshold are likely to have met a minimum acceptable symptom state.

In univariate analysis for MCID, no clinical or demographic factor was significantly predictive of achieving MCID (Table 2). However, in logistic regression analysis, patients with higher pre-operative iHOT-12 scores were significantly less likely to achieve MCID (OR 0.95; 0.93–0.98) (Table 3).

In univariate analysis for PASS, patients with worker's compensation status (OR 0.1; 0.01–0.84) and increased BMI (OR 0.92; 0.85–1.00) were less likely to achieve PASS (Table 4). In multivariable analysis, however, lower pre-operative iHOT-12 score was predictive of achieving MCID, and achieving MCID was predictive of achieving PASS ($p < 0.0001$ for both), after adjusting for age and sex (Table 3).

Discussion

In this study, we defined MCID and PASS for the iHOT-12 after arthroscopic FAI surgery. We found that a 13-point increase on the iHOT-12 is representative of MCID, while attaining an absolute post-operative score of 63 constitutes PASS. Although increased BMI and worker's compensation status were predictive of not achieving PASS, in

multivariable analysis, only pre-operative outcome score was predictive of achieving MCID, and achieving MCID was predictive of achieving PASS. Our study findings provide useful reference values as clinicians and researchers increasingly utilize the iHOT-12.

This study has several limitations. Our anchor question was administered at 1-year follow-up, and we are thus able to comment only on clinically significant outcome improvement by this point in time. It is possible that clinically significant outcome improvement continues to occur beyond the 1-year point, and this may change the magnitude of our MCID and PASS values. Additionally, we are limited in our methodology and reporting by the use of our anchor question, which was administered with a goal to elicit PASS. Different anchor questions are required in order to calculate SCB and an anchor-based MCID (we used a distribution-based MCID). Furthermore, our study is limited by the predominantly female population, the low response rate for the PASS anchor question (63.3%), and the use of a single fellowship-trained hip surgeon at a high-volume institution; therefore, our findings have limited generalizability.

Interest has increased in understanding clinically significant outcome improvement after arthroscopic treatment of FAI [4, 16–18]. Chahal et al. [4] derived PASS on the mHHS and the HOS after arthroscopic FAI treatment. Based on analysis of 130 patients, the authors found that

Table 3 Logistic regression analysis for minimal clinically important difference (MCID) and patient acceptable symptomatic state (PASS)

Predictor	Odds ratio	Lower 95% CI	Upper 95% CI	*p* value	Model AUC
MCID					
Age	0.97	0.93	1.01	0.195	0.71
Sex (male vs. female)	1.54	0.58	3.98	0.376	
Pre-op. iHOT-12 score	0.95	0.93	0.98	0.001	
PASS					
Age	0.99	0.95	1.03	0.502	0.76
Sex (male vs. female)	0.64	0.22	1.68	0.383	
MCID achieved vs. not achieved	17.09	5.94	59.02	< 0.0001	

AUC area under the curve, *iHOT-12* International Hip Outcome Tool-12

Table 4 Univariate analysis for patient acceptable symptomatic state (PASS)

Predictor	Odds ratio	Lower 95% CI	Upper 95% CI	p value
Age	0.99	0.96	1.02	0.511
Sex (female vs. male)	0.95	0.42	2.12	0.894
Body mass index	0.92	0.85	1.00	0.047
Race/ethnicity (white vs. non-white)	0.41	0.08	2.13	0.287
Worker's compensation (yes vs. no)	0.10	0.01	0.84	0.034
Alpha angle	0.98	0.94	1.02	0.365
Lateral center-edge angle	1.00	0.94	1.06	0.953
Tönnis grade (1 vs. 0)	>999.99	<0.001	>999.99	0.968
Labral repair (yes vs. no)	0.17	0.02	1.64	0.124
Acetabular rim trimming (yes vs. no)	0.78	0.13	4.87	0.790
Cleared to return to sport (yes vs. no)	1.50	0.68	3.32	0.318
Sport level of competition (Ref: recreational)				
None	0.35	0.13	0.98	0.046
High school	0.88	0.08	10.08	0.917
College	>999.99	<0.001	>999.99	0.982
Professional	<0.001	<0.001	>999.99	0.986

at 1 year after surgery, PASS values were 74 (mHHS), 87 (HOS-activities of daily living subscale), and 75 (HOS-sports subscale). To our knowledge, PASS has yet to be described for the iHOT. The present study builds on the work by Chahal et al. by also describing PASS values for the iHOT-12. Notably, we found that the PASS value for the iHOT-12 (63) was lower than previously reported values for the mHHS and the HOS. This finding is consistent with prior psychometric analyses that have demonstrated lower threshold values and limited ceiling effects for the iHOT-33 [16, 17]. MCID has also been previously derived for arthroscopic FAI surgery. Nwachukwu et al. [18] derived MCID values for the mHHS, iHOT-33, and HOS based on 364 patients who underwent arthroscopic FAI surgery. In their study, the MCID for the mHHS, HOS-Activities of Daily Living (HOS-ADL), HOS-Sports, and iHOT-33 was 8.2, 8.3, 14.5, and 12.1, respectively. In the present study, the derived MCID on the iHOT-12 was 13.0 and is comparable to the values previously reported by Nwachukwu et al. [18]. Given the similarities to previously reported values for MCID and PASS, our study supports the use of the iHOT-12 for assessing clinically significant outcome change.

As part of our secondary analyses, we found that achieving MCID was predictive of achieving PASS, suggesting that patients able to achieve a detectable change are also likely to achieve a well state. We also found that pre-operative outcome score was predictive of achieving MCID. This relationship between baseline patient-reported outcome and the degree of outcome improvement has been previously demonstrated [16–18] and is likely explained by the increased capability of patients with low baseline outcome scores to achieve a clinically significant delta in outcome score. Interestingly, Chahal et al. [4] noted a contrasting relationship, wherein patients with higher baseline scores were more likely to achieve PASS. We propose that for patients with higher baseline scores with limited capacity for MCID delta, PASS may represent a more appropriate measure of clinically significant outcome. As part of our univariate analysis, we also found

that patients with worker's compensation status and increased BMI were less likely to achieve PASS. These variables lost significance in our logistic regression analyses when we tested for clinical/demographic variables, as well as pre-operative baseline outcome scores. It is possible that we were underpowered to detect a difference once multiple variables were controlled or that the demonstrated association for worker's compensation status and BMI was confounded by baseline outcome score.

In conclusion, the iHOT-12 measures clinically significant outcome improvement that is comparable to that of other commonly used hip PROMs. Achieving MCID is predictive for achieving PASS, and patients with lower pre-operative outcome scores are most likely to achieve MCID. As use of the iHOT-12 spreads, the data presented in this study can be used to determine clinically significant patient reported improvement.

Appendix

Table 5 The International Hip Outcome Tool-12 (iHOT-12) Survey

Question	Scale	
Overall, how much pain do you have in your hip/groin?	Extreme pain	No pain at all
How difficult is it for you to get up and down off the floor/ground?	Extremely difficult	Not difficult at all
How difficult is it for you to walk long distances?	Extremely difficult	Not difficult at all
How much trouble do you have with grinding, catching, or clicking in your hip?	Severe trouble	No trouble at all
How much trouble do you have pushing, pulling, lifting, or carrying heavy objects?	Severe trouble	No trouble at all
How concerned are you about cutting/changing directions during your sport or recreational activities?	Extremely concerned	Not concerned at all
How much pain do you experience in your hip after activity?	Extreme pain	No pain at all
How concerned are you about picking up or carrying children because of your hip?	Extremely concerned	Not concerned at all
How much trouble do you have with sexual activity because of your hip?	Severe trouble	No trouble at all
How much of the time are you aware of the disability in your hip?	Constantly aware	Not aware at all
How concerned are you about your ability to maintain your desired fitness level?	Extremely concerned	Not concerned at all
How much of a distraction is your hip problem?	Extreme distraction	No distraction at all

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