

# Minimal Clinically Important Difference and Substantial Clinical Benefit Values for a Pain Visual Analog Scale After Hip Arthroscopy



RobRoy L. Martin, Ph.D., P.T., Benjamin R. Kivlan, Ph.D., P.T., John J. Christoforetti, M.D., Andrew B. Wolff, M.D., Shane J. Nho, M.D., M.S., John P. Salvo Jr., M.D., Thomas J. Ellis, M.D., Geoff Van Thiel, M.D., M.B.A., Dean Matsuda, M.D., and Dominic S. Carreira, M.D.

**Purpose:** To define minimal clinically important difference (MCID) and substantial clinical benefit (SCB) values for a pain visual analog scale (VAS) in patients undergoing hip arthroscopy for femoroacetabular impingement or chondrolabral pathology. **Methods:** This was a retrospective review of prospective collected data on patients having hip arthroscopy for femoroacetabular impingement and/or chondrolabral pathology. On initial assessment and follow-up between 335 and 395 days postsurgery, subjects completed a pain VAS and categorical self-rating of function. MCID was calculated using one-half the standard deviation (SD) of the change in 1-year pain VAS values. Receiver operator characteristic analysis was performed to determine SCB values. A change in SCB value was determined based on change in categorical self-rating of function to create “improved” and “not improved” groups. Absolute postoperative SCB scores were calculated to determine scores that would be associated with “normal” or “abnormal” function ratings. **Results:** Of 1,034 eligible patients, 733 (71%) met the inclusion criteria, with 537 (73%) women and 196 (27%) men having a mean age of 35.3 years (SD 13). At a mean of 352 (SD 21) days postsurgery, 536 (73%) were in the improved group and 197 (27%) in the not improved group. MCID was  $-15.0$  mm. A change of  $-22.7$  mm on the pain VAS was able to identify those that improved with high sensitivity (0.74) and specificity (0.63). Values of  $\leq 10.4$  mm and  $\geq 29.0$  mm were cutoffs identifying subjects that rated their function as normal or abnormal, respectively, with high sensitivity (0.79 and 0.76) and specificity (0.88 and 0.76). **Conclusions:** This study provides surgeons with information to help interpret pain VAS values at a follow-up period ranging from 335 to 395 days with MCID and SCB values of  $-15.0$  mm and  $-22.7$  mm, respectively.

*From the Department of Physical Therapy, Rangos School of Health Sciences (R.L.M., B.R.K.), Duquesne University, Pittsburgh, Pennsylvania; the Center for Sports Medicine, University of Pittsburgh Medical Center (R.L.M.), Pittsburgh, Pennsylvania; the Center for Athletic Hip Injury, Allegheny Health Network (J.J.C.), Pittsburgh, Pennsylvania; the Department of Orthopaedic Surgery, Drexel University School of Medicine, Faculty-at-Large, American Hip Institute (J.J.C.), Pittsburgh, Pennsylvania; Hip Preservation and Sports Medicine, Washington Orthopaedics and Sports Medicine (A.B.W.), Washington, D.C.; the Division of Sports Medicine, Department of Orthopedic Surgery, Hip Preservation Center, Rush University Medical Center (S.J.N.), Chicago, Illinois; Orthopaedic Surgery, The Sydney Kimmel Medical College at Thomas Jefferson University Hospital (J.P.S.), Philadelphia, Pennsylvania; the Hip Arthroscopy Program, Rothman Institute (J.P.S.), Philadelphia, Pennsylvania; Orthopedic One, Ohio Orthopedic Surgery Institute, Dublin Methodist Hospital (T.J.E.), Columbus, Ohio; OrthoIllinois (G.V.T.), Chicago, Illinois; Rush University Medical Center (G.V.T.), Chicago, Illinois; US National Soccer Teams (G.V.T.), Chicago, Illinois; Chicago Blackhawks Medical Network (G.V.T.), Chicago, Illinois; DISC Sports and Spine Center (D.M.), Marina del Rey, California; and Peachtree Orthopedics (D.S.C.), Atlanta, Georgia, U.S.A.*

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*Address correspondence to RobRoy L. Martin, Ph.D., P.T., Department of Physical Therapy, Rangos School of Health Sciences, Duquesne University, 600 Forbes Avenue, Pittsburgh, PA 15282, U.S.A. E-mail: [martinr280@duq.edu](mailto:martinr280@duq.edu)*

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Additionally, a patient who assesses a pain level at  $\leq 10.4$  mm is likely to have a normal rating of function, whereas a patient who assesses a pain level at  $\geq 29.0$  mm is likely to have an abnormal rating of function. **Level of Evidence:** III, retrospective comparative study.

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**M**easuring pain intensity as part of a comprehensive assessment of health-related quality of life is an essential component of clinical practice and research.<sup>1-3</sup> A visual analog scale (VAS) is commonly used to measure pain and can be found in the literature dating back to the 1950s.<sup>4-6</sup> Evidence is available to support the use of the VAS in pain assessment for those with acute and chronic pain conditions.<sup>4,6-11</sup> However, there is an absence of information to meaningfully interpret changes on the pain VAS for hip arthroscopy outcome assessment.

Nonarthritic intra-articular pathologies, which commonly include acetabular labral tears, chondral lesions, and femoroacetabular impingement (FAI), are well-recognized causes of hip pain, with pain being the most common symptom and indication for arthroscopic surgery.<sup>12-16</sup> Philippon et al.<sup>17</sup> specifically noted that 85% of patients with FAI reported moderate or marked pain.

Pain intensity is commonly assessed with a single-item instrument such as VAS, numerical rating scale, or verbal rating scale.<sup>8,18</sup> The benefit of a VAS is that it represents a continuous measure and is appropriate for parametric tests, which include responsiveness analysis.<sup>18</sup> Responsiveness is the ability to detect change when a change in status has occurred and can be defined with values for minimal clinically important difference (MCID), patient acceptable symptom state (PASS), and substantial clinical benefit (SCB).<sup>19-23</sup> MCID, PASS, and SCB values represent the lower, intermediate, and upper thresholds for clinically significant improvement, respectively, and can be used to interpret score changes on the pain VAS when given periodically over time.<sup>21</sup> MCID is defined as the smallest change the patient is able to appreciate, with SCB being an improvement in outcome or absolute postoperative health state that the patient considers to be substantial.<sup>19,20</sup> PASS represents a clinical outcome between MCID and SCB and is defined as a satisfactory outcome status.<sup>21,22</sup>

The purpose of this study was to define MCID and SCB values for a pain VAS in patients undergoing hip arthroscopy for FAI or chondrolabral pathology. It was hypothesized that the pain VAS would be responsive to change in status over a 1-year follow-up period for subjects who underwent hip arthroscopy.

## Methods

This was a retrospective review of prospective collected data maintained in a secure electronic registry.

The registry consisted of patients who were assessed by their surgeon and consented to undergo hip arthroscopy at 1 of 7 centers between January 2014 and April 2017. Inclusion criteria specific to this study included subjects who underwent surgery for FAI or chondrolabral pathology with preoperative and follow-up pain VAS scores available. The follow-up data were required to be collected between 335 and 395 days postsurgery. Exclusion criteria for the registry included those with primary lumbopelvic pathology, advanced hip arthrosis ( $>$ Tönnis 1), or other conditions contraindicated for arthroscopic hip surgery. An inability to read or understand English was also an exclusion criterion for the registry. An investigator (B.R.K.) assessed data and applied the inclusion and exclusion criteria for this study. The pre-hoc collection and storage of agreed-on clinical data points was granted according to individual institutional requirements and Institutional Review Board approval granted to review the deidentified registry of patient data.

On initial assessment, subjects were given patient-reported outcome questionnaires to complete, including the pain VAS, Hip Outcome Score (HOS) activities of daily living (ADL) and Sports subscales, and a categorical self-rating of function. For 1-year follow-up data collection ( $\pm 1$  month), subjects were emailed the pain VAS, HOS subscales, and a self-rating of current function to complete between 335 and 395 days after surgery. The pain VAS considered the question "How much pain do you have in your hip?" and was scored using a 100-mm horizontal line with the anchors defined as "no pain" (0 mm) and "worst imaginable pain" (100 mm). The self-rating of function consisted of the following question: "How would you rate your current level of function?" The subject chose from the following categorical responses: "severely abnormal," "abnormal," "nearly normal," or "normal." Demographic information was recorded from the electronic registry.

Analysis was completed to assess the relation between the pain VAS and function status at 1-year follow-up. The Pearson correlation coefficient ( $r$ ) was calculated between pain VAS and HOS ADL and Sports subscales, with 0.00-0.25 indicating little or no relation; 0.25-0.50, fair relation; 0.50-0.75, moderate to good relation; and 0.75 or greater, good to excellent relation.<sup>24</sup> It was hypothesized that a significant moderate to good inverse correlation (less than  $-0.50$ ) would be identified. This would indicate that as pain decreased, subjects'

**Table 1.** Subject Demographics

Age (years)	35.3 (13)
Sex	
Female	537 (73)
Male	196 (27)
Diagnosis	
Femoroacetabular impingement	677 (92)
Labral pathology	659 (90)
Procedures performed	
Femoroplasty	608 (83)
Synovectomy	586 (80)
Labral repair	557 (76)
Acetabuloplasty	425 (58)
Acetabular chondroplasty	410 (56)
Femoral chondroplasty	169 (23)
Labral reconstruction	139 (19)

NOTE. Data are mean (standard deviation) or n (%).

function improved and would therefore support the use of self-reported functional status as an appropriate anchor in determining SCB values for the pain VAS.

### Psychometric Analysis

MCID and SCB were calculated using distribution-based and anchor-based methods, respectively, similarly to previous descriptions.<sup>21,25,26</sup> One-half of the standard deviation of the change in 1-year pain VAS scores was used to calculate the distribution-based MCID.<sup>27</sup> An anchor-based method using a patient-centered criterion to define meaningful changes in pain VAS score was used to calculate SCB values. An SCB change score and absolute postoperative SCB values were calculated with receiver operator characteristic (ROC) analysis calculating the area under the curve (AUC) at a 95% confidence interval (CI).<sup>28,29</sup> For the SCB change score, an improvement in the categorical rating of function was used to group patients into those who improved from those who did not improve. Absolute postoperative SCB scores were calculated to determine a score that would be associated with a patient response of being normal and a score that would be associated with being abnormal or severely abnormal. The AUC of the ROC analysis defines the strength of association and the accuracy of the instrument in distinguishing between groups.<sup>29</sup> An AUC >0.7 and a 95% CI that does not contain 0.5 are considered acceptable levels of responsiveness.<sup>29-31</sup> Youden's Index was used to optimize sensitivity and specificity values and identify the best cutoff pain VAS values for SCB that represent the following: (1) a score change that is most likely to be associated with being in the improved group, (2) an absolute score that is likely to represent a patient who reports a normal function rating, and (3) an absolute score that is likely to represent a patient who reports a function rating of abnormal or severely abnormal.<sup>32</sup> Statistical analysis was performed using the SPSS software package version 24 (IBM Corp., Armonk, NY).

## Results

### Participants

Of 1,034 eligible patients, 733 (71%) met the inclusion criteria for this study and had follow-up outcome data available for analysis; 301 (29%) subjects were excluded because of missing pain VAS information. The average follow-up time was 352 days (standard deviation 21). Demographic information, including age, sex, diagnosis, and procedures performed, is presented in Table 1. It should be noted that 577 subjects (79%) had multiple procedures performed, and 12 (2%) were revisions.

The correlation of the HOS ADL and Sports subscales with the pain VAS were  $r = -0.70$  ( $P < .0005$ ) and  $r = -0.66$  ( $P < .0005$ ), indicating a strong and significant inverse relation between pain level and function status. This supports the use of self-reported functional status as an appropriate anchor in determining SCB values for the pain VAS.

### Psychometric Results

Mean preoperative, 1-year postoperative, and average change scores for the pain VAS and HOS ADL and Sports subscales are presented in Table 2. Pre- and postoperative ratings of function are provided in Table 3. At ~1 year postoperatively, 536 patients (73%) were in the improved group and 197 (27%) in the not improved group. MCID was -15.0 mm. The results of the ROC analysis for the change in SCB score and absolute scores associated with normal and abnormal ratings of function for the pain VAS are presented in Table 4. A change of -22.7 mm on the pain VAS was able to identify those who improved from those not improved with high sensitivity and specificity. Values  $\leq 10.4$  and  $\geq 29.0$  mm were cutoffs to identify subjects who rated their function as normal or abnormal, respectively, with high sensitivity and specificity.

## Discussion

This study found pain VAS MCID and change SCB scores to be -15.0 and -22.7 mm, respectively, with  $\leq 10.4$  mm being associated with a normal self-rating of function, and  $\geq 29.0$  mm, an abnormal self-rating of function. These results offer evidence of responsiveness

**Table 2.** Change Scores for Pain VAS and HOS ADL and Sports Subscales

	Preoperative	1 Year Postoperative	Average Change
Pain VAS (mm)	52.4 (21.0)	20.5 (20.4)	-31.9 (27.0)
HOS ADL	62.7 (17.6)	85.8 (15.2)	22.9 (19.3)
HOS Sport	38.7 (22.0)	70.0 (27.1)	30.6 (27.2)

NOTE. Data are mean (standard deviation).

ADL, activities of daily living; HOS, Hip Outcome Score; VAS, visual analog scale.

**Table 3.** Pre- and Postoperative Rating of Function

Rating	Preoperative	1 Year Postoperative
Normal	8 (1)	224 (30)
Nearly normal	138 (19)	350 (48)
Abnormal	461 (63)	137 (19)
Severely abnormal	126 (17)	22 (3)

NOTE. Data are n (%).

for the pain VAS at a follow-up time period ranging from 335 to 395 days postsurgery for patients who underwent hip arthroscopy for an intra-articular hip pathology. The pain VAS was found to have acceptable properties of responsiveness to change, as the AUC was  $>0.70$  with a 95% CI not containing 0.5. The results of this study can be used in clinical practice and research to help surgeons interpret changes in pain levels after hip arthroscopy.

The application of the MCID and SCB values may best be provided in a clinical scenario. Consider a patient who presents with a preoperative pain VAS score of 70.0 mm. A pain score of 55.0 mm would represent a decrease in pain that the patient could appreciate, whereas a pain score of 47.3 mm would be associated with an improvement in function at 335 to 395 days of follow-up. Additionally, if a patient had a pain VAS score of  $\leq 10.4$  mm, the surgeon could be confident the patient's pain level allowed a normal level of function, whereas if a patient had a pain score of  $\geq 29.0$  mm, the patient would likely have an abnormal level of function. In the current study, 30% of subjects reported a normal level of function at 335 to 395 days of follow-up. This was consistent with an average postoperative pain VAS score of 20.5 mm. Therefore, the average subject did not have a pain level associated with a perceived normal level of function. The systematic review performed by Kierkegaard et al.<sup>33</sup> found similar results in hip arthroscopy outcome studies that reported pain VAS values in 6-month to  $<1$ -year follow-up periods. In that review, the average pain levels were above the absolute SCB pain value for a perceived normal level of function identified in the current study (10.4 mm). This is consistent with clinical experience, as most patients have good outcomes and are satisfied but continue to have some mild pain that limits their achieving a complete return to a normal level of function at 1-year follow-up.

A decrease in pain of 30% to 40% from baseline is generally used as a guideline for minimally important difference for a wide range of conditions.<sup>5,34,35</sup> Values to interpret change in pain VAS scores have been reported to range between  $-9$  and  $-31.1$  mm in short-term follow up of individuals with acute or postsurgical pain.<sup>10,36,37</sup> Clinically important change scores on a pain VAS over a 4-week period for those with knee and hip osteoarthritis were  $-19.9$  and  $-15.3$  mm, respectively.<sup>38</sup> A meaningful improvement of  $-14.0$  mm over a 6-week period was defined for individuals with rotator cuff disease undergoing nonoperative treatment.<sup>39</sup> The MCID and SCB values of  $-15.0$  and  $-22.7$  mm, respectively, identified in the current study seem comparable to these previously reported values. However, a meaningful comparison may be difficult given the wide range of follow-up times and variety of subjects involved in the previous studies.

Pain and limited functional status are primary concerns for patients.<sup>7,40,41</sup> Nonarthritic intra-articular pathologies are known to lead to pain, which negatively affects a patient's general state of health and health-related quality of life.<sup>15,42</sup> Also, the most common indication for hip arthroscopic surgery is pain.<sup>12-16</sup> The results of the current study help to confirm that pain level and functional status are related, as there was a moderate to good inverse correlation between pain VAS and HOS subscale scores. Brunner et al.<sup>43</sup> found similar findings, with a significant correlation between level of postoperative sports activities and pain level in subjects undergoing arthroscopic surgery for FAI.

### Limitations

There are a number of limitations of this study that need to be acknowledged. The MCID and SCB found in this study only relate to a follow-up time period ranging between 335 and 395 days postsurgery. MCID and SCB values for VAS may be different depending on the methods used to define these values, including follow-up period and patient characteristics. A review by Olsen et al.<sup>44</sup> found MCID to be strongly associated with baseline pain levels in those with chronic conditions. It has been recommended that pain-related outcome studies incorporate multiple items that measure more than one domain and use different methods of assessment.<sup>7</sup> The current study used a single item of pain assessment that asked, "What is your current level of

**Table 4.** Receiver Operator Characteristic Analysis for Substantial Clinical Benefit

Rating in Pain VAS	Score Change (mm)	Sensitivity	Specificity	AUC (95% CI)
To identify a change in function rating	$-22.7$	0.74	0.63	0.75 (0.71-0.79)
To identify normal rating of function	$\leq 10.4$	0.79	0.76	0.84 (0.81-0.87)
To identify abnormal rating of function	$\geq 29.0$	0.88	0.76	0.87 (0.83-0.90)

AUC, area under the curve; CI, confidence interval; VAS, visual analog scale.

pain?" Further studies are needed to evaluate pain with multiple items that look at pain during rest and activity as well as pain at its best and worst over varying time frames. True assessment of pain changes may be difficult because of short-term fluctuations resulting from many factors, including expectations and emotional state.<sup>3</sup> There is controversy with regard to the linear responsive behavior of the VAS for all levels of pain.<sup>45</sup> However, studies have found the pain VAS to show properties of linearity for acute mild, moderate, and severe pain levels.<sup>4,9</sup> Although this study defined MCID and SCB values for the pain VAS, a PASS value also needs to be defined. It should be noted that the findings of this current study are applicable only to patients at a follow-up time period ranging between 335 and 395 days. Further studies are needed to provide specific information to help interpret scores at other evaluation time periods that clinicians may typically encounter. This study included subjects with intra-articular hip pathology, and therefore the results cannot be used for other hip conditions. This data set contained >700 patients from 7 different centers across the United States, but it should be noted that there was <80% follow-up, and most subjects were women. This large proportion of women introduces potential sex bias in these results.

### Conclusions

This study provides surgeons with information to help interpret pain VAS values at a follow-up period ranging between 335 and 395 days with MCID and SCB values of -15.0 and -22.7 mm, respectively. Additionally, a patient who assesses a pain level at  $\leq 10.4$  mm is likely to have a normal rating of function, whereas a patient who assesses a pain level at  $\geq 29.0$  mm is likely to have an abnormal rating of function.

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