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Original Article

Safe and effective is not always acceptable: The case for PASS scores in foot and ankle orthopedic surgery

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Abstract

Objective: To determine whether additional perspectives would be added to surgical reports in the foot and ankle literature by including outcomes for patient acceptable symptomatic state (PASS) (value beyond which the residual symptoms are felt to be acceptable) to minimum clinically important difference (MCID) outcomes (minimal amount of change that is felt to be clinically significant).

Methods: Visual analog scale (VAS) pain was chosen as a common, intuitively understandable patient-reported outcome for which PASS thresholds have been established in a variety of orthopedic conditions. A total of 21 consecutive studies in Foot and Ankle International from December 2020 to August 2022 that reported VAS scores before and after an intervention were included. Improvement beyond an MCID of 2/10 VAS pain was noted, and a 2/10 VAS PASS threshold was used. Subjective ratings of success were also extracted.

Results: All 21 studies reported improvement in VAS pain beyond the MCID, and 15 (71%) reported subjectively successful results. Based on a VAS PASS threshold of 2/10, successful results were observed in only 13 studies (62%).

Conclusion: Residual pain above the threshold that is acceptable to patients is frequently present in foot and ankle surgery, despite the common reporting of subjectively positive results. This demonstration illustrates that using PASS thresholds, in addition to improvement beyond an MCID, provides further context for determining successful surgical outcomes.

Level of evidence III; Retrospective Comparative Study.

Keywords: Patient Reported Outcome Measures; Ankle Joint; Pain.

Introduction

Clinical papers assessing patient-reported outcomes (PROs) typically determine success or failure based on the minimum clinically important difference (MCID) of the scale, the smallest change in an outcome's score that is of clinical value to patients[1]. This approach can demonstrate that an intervention has a measurable effect, but does not provide insight as to whether the patient is satisfied with their outcome. Recently, the patient acceptable symptomatic state (PASS) has been proposed as a threshold value of any PRO beyond which patients with a specific condition consider their outcome "acceptable"[2]. Philosophically, the approach can be summarized as "it is more important to feel good than to feel better." PASS data may represent an essential dimension of patient outcomes and supplement the use of the MCID for determining surgical success.

Study performed at the Department of Orthopedic Surgery, MedStar Union Memorial Hospital, Baltimore, Maryland, USA.

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In theory, a valid PASS threshold must be established for a specific PRO and pathology. This is accomplished by asking patients with that condition a global anchor question to determine whether their symptoms are acceptable and correlating the answer with their PRO outcome. One possible exception to this standard may be the visual analog scale (VAS) for pain, the simplest PRO. All papers that have formally calculated PASS thresholds for VAS pain in orthopedic conditions have reported values ranging from 14/100 to 30/100 (Table 1)[3-25]. This correlates with the intuitive point that patients seek final pain outcomes of less than 2 or 3/10[26]. Precedent exists to use a PASS threshold in the foot and ankle literature. Baumhauer et al.[27] used a pain value of 2/10 as the threshold of "significant" pain after autograft harvest for foot and ankle fusions.

As a demonstration of how the use of PASS thresholds may alter the interpretation of surgical results, we reexamined a sequential set of studies in Foot and Ankle International (FAI) that reported pre- and post-intervention VAS pain results and sought to answer the following questions:

1. Did the patients' VAS pain scores improve beyond the MCID?
2. Did the investigators subjectively rate the outcome as successful?
3. Did the patients' final VAS pain scores exceed a PASS threshold of 2?

Methods

Articles published in FAI from December 2020 to August 2022 were reviewed to identify studies reporting pre- and post-intervention VAS pain results after a therapeutic procedure. Four of the 25 papers identified were excluded because of inconsistent data reporting, leaving 21 studies for analysis (Table 2)[28-48]. If a study compared multiple interventions, the intervention interpreted as most favorable was used in the analysis.

The pre- and post-intervention VAS scores and the investigators' subjective descriptions of the intervention's efficacy were extracted. Surgical success was determined in three ways:

1. An intervention was considered successful by MCID criteria if the VAS pain score improved by more than 2/10 (or 20/100). This value is conservatively high in the range of MCIDs used for the scale in the orthopedic literature[26].
2. An intervention was considered successful by subjective criteria if the text included the descriptors of "reliable," "good," "effective," or "satisfactory."

Table 1. Orthopedic literature reporting MCID and PASS scores for VAS pain

Study	Subject	MCID value	PASS value	MCID reached	PASS reached
Abufoul et al.[3]	Rotator cuff	15	17	71%	48%
Allahabadi et al.[4]	Femoroacetabular syndrome	14.6	27.5	88.6%	70.9%
Ardebol et al.[5]	Glenohumeral arthritis	16	15	97%	78%
Beck et al.[6]	Femoroacetabular syndrome	14.8	21.6	97.6%	66.4%
Bilsel et al.[7]	Rotator cuff	14	30	100%	66.7%
Daniel et al.[8]	Anterior cruciate ligament	12	10	57.9%	79%
Fenn et al.[9]	Femoroacetabular syndrome	14.6	27.5	88.9%	60%
Ju et al.[10]	Femoroacetabular syndrome	15	19	76.9%	26.9%
Kunze et al.[11]	Femoroacetabular syndrome	21.6	21.6	89.7%	58.7%
Levins et al.[12]	Glenohumeral arthritis	21	15	89.7%	93.1%
Li et al.[13]	Cervical dizziness	25	30	82.5%	75%
Lu et al.[14]	Biceps tenodesis	12.9	27.4	73.3%	52.8%
Maldonado et al.[15]	Femoroacetabular syndrome	11	21.6	66%	71.7%
Menendez et al.[16]	Shoulder instability	17	25	61.1%	84%
Nakajima[17]	Achilles tendinopathy	10.6	14	100%	77.3%
Pasqualini et al.[18]	Adhesive capsulitis	11	20	98%	84%
Rice et al.[19]	Femoroacetabular syndrome	15.8	15.5	66.7%	56.8%
Rupp et al.[20]	Patellofemoral arthroplasty	24.6	25.5	54.4%	53.6%
Saks et al.[21]	Femoroacetabular syndrome	16.5	21.6	70.5%	58.3%
Scanaliato et al.[22]	Glenohumeral instability	11	30	97.3%	67.1%
Shao et al.[23]	Femoroacetabular syndrome	15	19	93.9%	48.5%
Yang et al.[24]	Femoroacetabular syndrome	15	19	83.8%	66.7%
Yokota et al.[25]	Knee osteoarthritis	14	30	55%	38%

MCID: Minimum clinically important difference; PASS: Patient acceptable symptomatic state; VAS: Visual analog scale

3. An intervention was considered successful based upon PASS criteria if the post-intervention VAS pain score was below 2/10 (or 20/100). This threshold was based upon the range of PASS scores found for VAS pain in previous orthopedic conditions (Table 1) and its previous use in the foot and ankle literature[27].

Results

The mean preoperative and postoperative VAS scores for the 21 included studies are shown in Figure 1. All 21 studies (100%) demonstrated improvement of VAS pain well beyond the MCID, 15 studies (71%) reported subjectively successful

Table 2. Studies in Foot and Ankle International 2020-2022 reporting VAS pain

No.	Article	No. patients	Follow-up	VAS		p-value
				Preoperative	Postoperative	
1	Del Vecchio et al.[32]	135	42.4 (30-66) months	7.9 ± 0.9	0.7 ± 0.9	< 0.001
2	Wang et al.[46]	32	56.9 ± 18.0 months	6.7 ± 0.9 (4-8)	2.3 ± 1.9 (0-8)	< 0.001
3	Amann et al.[29]	17 (20 feet)	15.87 (12-33) months	7.6 (4-9)	1.4 (0-4)	< 0.05
4	Yontar et al.[48]	77	35.5 (6-92, median 32) months	7.21 ± 1.08	2.21 ± 2.65	< 0.001
5	Fram et al.[34]	58	24 (12-33) months	64.5 (26.0)	26.8 (30.3)	0.001
6	Qin et al.[43]	43	28.23 ± 3.64 months (23-34)	4.38 ± 1.95	0.79 ± 1.06	< 0.1
7	Bahar et al.[30]	52	24 months	7.1 ± 1.1	0.4 ± 0.8	< 0.001
8	Kim et al.[38]	13	31 (24-60) months	7.3 ± 1 (95% CI, 6.7-7.9)	2.5 ± 1.5 (95% CI, 1.6-3.5;	< 0.05
9	Ferranti et al.[33]	27	26.5 (6-68) months	8.1 ± 0.9	2.4 ± 2.3	< 0.001
10	Greiner et al.[36]	42	32.8 (18-52) months	8.91 ± 1.0	1.47 ± 2.5	< 0.01
11	Piat et al.[42]	36	56 ± 36 (12-207) months	6.7 ± 2.4	2.3 ± 1.9	< 0.0001
12	Choi et al.[31]	42	31.8 (24-62) months	6.2 ± 2.1	1.1 ± 0.8	< 0.001
13	Neufeld et al.[41]	94	11.2 ± 4.4 (6-28) months	5.2 ± 2.4	1.6 ± 2.1	< 0.001
14	Scott et al.[45]	70	Minimum 1 year	7.5 ± 1.8	1.7 ± 2.2	< 0.0001
15	Garcia-Ortiz et al.[35]	29	3.4 (2-5) years	7.9 (2.5)	2.5 (2.7)	0.001
16	Hau et al.[37]	16	4.8 ± 0.91 years	60 (27)	16 (23)	< 0.001
17	Akoh et al.[28]	33	3.7 (1.0-9.8) years	4.8 (4.0-5.6)	0.2 (0.1-0.4)	< 0.001
18	Martin et al.[40]	93	19 (3-48) months	4.8 ± 1.5	1.3 ± 1.5	< 0.001
19	Yang et al.[47]	30 (43 joints)	28.2 (24-96) months	5.0 (4.2-5.9)	1.8 (1.2-2.5)	< 0.001
20	Li et al.[39]	7	17.4 (9-27) months	4.0 (2.0-5.0)	0 (0-1.0)	0.016
21	Rogero et al.[44]	81	58.9 (24-104) months	8.6 ± 1.2	3.7 ± 3.0	< 0.0001

VAS: Visual analog scale

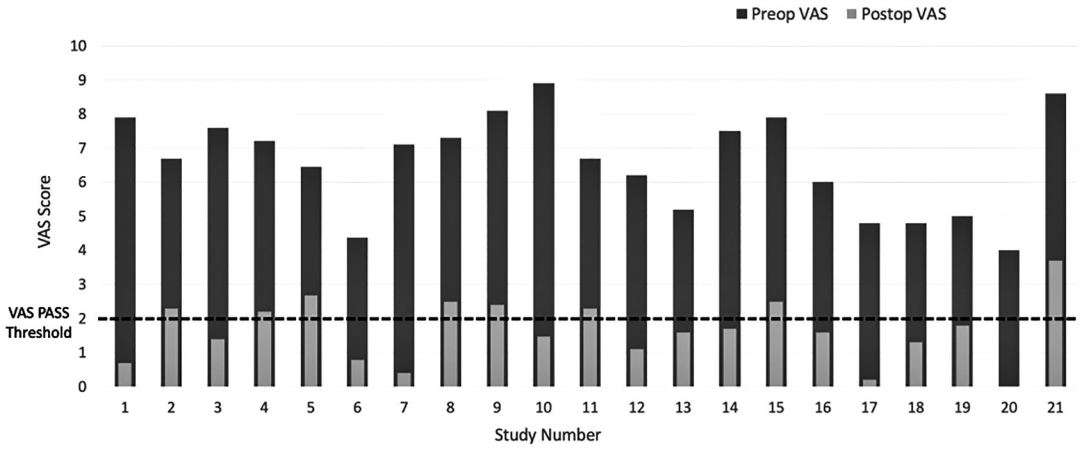

Figure 1. Preoperative and postoperative VAS pain in Foot and Ankle International studies. Preop: Preoperative; Postop: Postoperative; VAS: Visual analog pain scale. Broken line, VAS PASS threshold 2/10. See Table 2 for references.

results, and 13 studies (62%) reported final mean VAS pain scores below the chosen PASS threshold of 2 (Figure 2).

Discussion

Reaching a defined threshold in a PRO is a higher standard than simply demonstrating improvement. As in this analysis, it commonly results in a less satisfactory view of orthopedic interventions. Although many procedures result in improvement, patients commonly have residual pain and limitations.

PASS thresholds have gradually been established across a variety of orthopedic conditions for different PROs, including VAS pain. Nakajima[17] studied endoscopic debridement for Achilles insertional tendinopathy using the VAS MCID and a PASS threshold of 1.4. Although 100% of his sample reached MCID, only 77% achieved PASS. The 1.4 VAS value was obtained from a receiver operating curve (ROC) for "very satisfied" and "satisfied" states (area under curve [AUC]: 0.94). Similarly, using an ROC to determine the PASS threshold in patients who underwent an inlay patellofemoral arthroplasty, Rupp et al.[20] established a 2.55 threshold (AUC: 0.81) for VAS. In their sample, 53% reached this value, a rate similar to the rate who achieved the MCID for VAS (54%). After arthroscopic capsular release for adhesive capsulitis, Pasqualini et al.[18] obtained an MCID of 1.1 for VAS and a PASS threshold of 2 using distribution-based methods and ROC (AUC: 0.78), respectively. A total of 97% of patients achieved MCID, and 84% reached PASS. Using a distribution-based method for MCID and ROC method for PASS in VAS scores after hip arthroscopy for femoroacetabular impingement, Beck et al.[49] found that 98% achieved an MCID of 1.4 and only 66% achieved a PASS of 2.1.

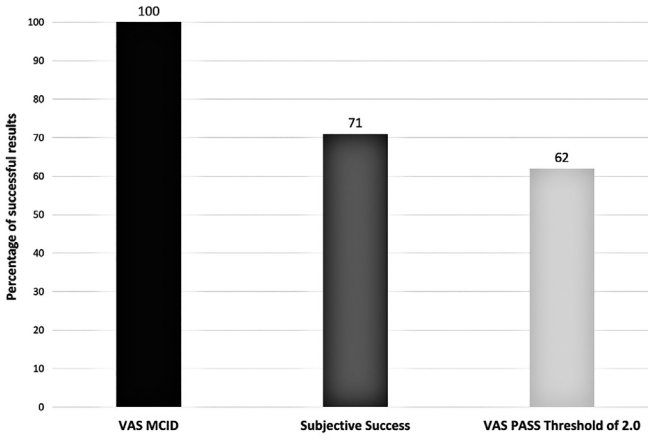

Figure 2. Percentage of successful results in the studied groups based on three different criteria. MCID: Minimum clinically important difference; PASS: Patient acceptable symptomatic state.

This study is best viewed as a demonstration of how surgical outcomes can vary depending on the standards used to define success. It is not a rigorous quantitative analysis. VAS pain was chosen for this demonstration because it is both intuitively understandable and backed by a body of literature across a variety of orthopedic conditions. It is far from a complete description of a patient's condition. Many other PROs can be used to assess function, strength, motion, and interference with activities. Nevertheless, the concepts of assessing outcomes using the MCID versus the PASS threshold are universal regardless of the rating scale used.

Surgical outcomes are complex, and the final level of satisfaction and relative improvement represent different facets of success. In more challenging conditions, such as a Charcot hindfoot, a limited outcome may be a reasonable expectation, even if the patient does not consider the final result acceptable. Patients may be less likely to find a limited outcome acceptable for simpler problems.

Conclusion

In this demonstration, PASS threshold analysis applied to VAS pain data from studies in the foot and ankle literature yielded a substantially more negative interpretation of pain outcomes compared with improvement beyond the MCID or subjective assessment. A more comprehensive picture of the outcomes of foot and ankle procedures and overall patient satisfaction can be gained by analyzing PROs in terms of both clinically relevant improvement (MCID) and the patient's acceptability of the final outcome (PASS).

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