Safe and Effective is Not Always Acceptable: The Case for PASS Scores in Foot and Ankle Orthopaedic Surgery

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Determining the success of a clinical intervention can be challenging even with modern patient-reported outcomes. Traditionally studies have used the Minimum Clinically Important Difference (MCID), the smallest difference in an outcome that is felt to have clinical significance. More recently some authors have emphasized the alternative model of the Patient Acceptable Symptomatic State (PASS), the threshold of a PRO defining where patients consider their overall status to be acceptable. PASS scores have not yet seen wide use in the foot and ankle literature but may add insight to surgical outcomes beyond simply measuring the minimal changes implied by the MCID.

The most universal patient-reported outcome in the foot and ankle literature is the simple Visual Analog Pain Scale (VAS), in which a patient rates their pain along an analog scale between 0 to 10 cm. Articles in Foot and Ankle International from December 2020 to August 2022 that reported VAS pain scores and variance following an intervention were included. Although specific PASS thresholds for VAS scores in many conditions in the foot and ankle have not been determined analytically, values ranging from 2.0 to 3.0 are typical for orthopaedic conditions, corresponding to the intuitive statement "I would like my pain to be less than 2 or 3 out of 10." A PASS threshold of 2.0 has been used previously in the foot and ankle literature. The studies were therefore analyzed against PASS thresholds for the VAS of 2.0, 2.5, and 3.0. RESULTS:

Twenty-one studies were included. Five had multiple internal groups, yielding a total of 27 total sets of VAS scores. All 27 (100%) showed improvements well beyond the MCID and were considered successful. Seventeen (81%) of the 21 studies subjectively described their intervention as "reliable," "good," "effective," or "satisfactory." Despite this, 8 (38%) of the 21 studies reported final mean VAS scores for all internal groups above a PASS threshold of 2.0. An analytically calculated weighted average final VAS pain score for all studies was 1.78 +/- 1.89. Based upon this, the expected percentages of patients included in FAI studies whose results failed to meet VAS PASS thresholds were 45% for a threshold of 2.0, 35% for a threshold of 2.5, and 26% for a threshold of 3.0.

DISCUSSION AND CONCLUSION:

Studies in the foot and ankle literature almost universally report positive results, both subjectively in their discussions and by statistically demonstrating improvement of patient-reported outcomes beyond the MCID. PASS threshold analysis yields a much less positive interpretation and emphasizes the number of negative outliers in the population who do not find their outcome acceptable. A fuller picture of the outcome of foot and ankle procedures and overall patient satisfaction can be gained from reporting both changes in the mean and comparing final outcomes to PASS thresholds.