

Minimal Clinically Important Difference for the Short Musculoskeletal Functional Assessment: Pooled Data From 9 Multicenter, Prospective Clinical Trials

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Purpose: The Short Musculoskeletal Functional Assessment (SMFA) is a widely used outcome measure for orthopaedic patients, yet has no defined minimal clinically important difference (MCID). In this analysis, we leverage a large data collection effort by an orthopaedic trauma consortium to calculate distributional MCIDs using various statistical approaches by sex, age, and timing. The study benefits from broad inclusion criteria, which captures a wide range of orthopaedic fractures, unlike prior studies that focused on homogeneous populations.

Methods: SMFA assessments were collected at 3, 6, 12, 18, and 24 months post-injury from 4537 surgical lower extremity trauma patients at 70 Level I trauma centers across 9 multicenter, prospective clinical studies. Three distributional approaches were used to calculate MCIDs: half a standard deviation (0.5 SD), twice the standard error of the mean (2 SEM), and minimal detectable change (MDC). Alpha coefficients are reported for all subgroups.

Results: The table summarizes the results for the SMFA Dysfunction Index. Alpha ranged between 0.95 and 0.96 for all subgroups, suggesting strong internal consistency. The 3 statistical approaches yielded fairly different MCIDs, but there were no consistent differences across time, sex, or age.

Conclusion: A defensible MCID for the Dysfunction Index can be found between 7 and 10 points for the Dysfunction Index. The precise choice of MCID may depend on the preferred statistical approach.

Group	n	Mean	SD	0.5SD	2SEM	MDC	alpha
Total	4537	29.1	18.5	9.3	7.7	10.7	0.956
Female	1329	30.6	18.9	9.4	7.8	10.9	0.957
Male	3208	28.5	18.4	9.2	7.7	10.6	0.956
18-29	1085	25.7	18.1	9.1	7.7	10.6	0.955
30-44	1386	29.6	18.3	9.2	7.5	10.4	0.958
45-59	1597	31.9	18.7	9.3	7.9	10.9	0.956
60+	469	26.2	17.9	8.9	7.8	10.8	0.952
3 Months	169	38.4	17.4	8.7	8.8	12.2	0.936
6 Months	2686	29.8	18.2	9.1	7.8	10.7	0.955
12 Months	715	26.0	19.1	9.6	7.6	10.6	0.960
18 Months	790	27.9	18.2	9.1	7.4	10.2	0.959
24 Months	177	26.9	19.8	9.9	7.5	10.3	0.964

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.