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Computerized Adaptive Testing in Ankle Fracture Surgery

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Purpose: The goal of this study was to compare the legacy patient-reported measures used in foot and ankle surgery to the Patient Reported Outcomes Measurement Information System (PROMIS) scores in terms of ability to detect clinically significant differences.

Methods: Patients who underwent osteosynthesis for an unstable ankle fracture completed legacy outcome scores as well as the PROMIS Physical Function (PROMIS PF) and PROMIS Lower Extremity (PROMIS LE). Patients also completed the Olerud and Molander (O&M), the Weber score, and the Foot and Ankle Outcome Score (FAOS). Patients also electronically completed the PROMIS PF and PROMIS LE. Clinically significant outcome improvement was determined using the minimal clinically important difference (MCID).

Results: A total of 169 patients were analyzed at 310 total follow-up visits. Correlations between PROMIS and legacy measures are listed in Table 1. Smaller changes in outcome score were required to achieve clinically significant change on the PROMIS. Clinically significant changes in the PROMIS LE score were detected in patients between their 6-month and 12-month postoperative visit (P = 0.0019), whereas the reported O&M and Weber scores did not significantly differ between the 6-month and 12-month visit (P = 0.11) (Table 2).

Conclusion: PROMIS LE has enhanced ability to distinguish clinically significant changes in patients between time points following surgery. The PROMIS LE requires relatively smaller changes in order to detect meaningful outcome improvement and continues to detect clinical improvements out to 12 months.

| Measures | Correlation (rho) | p. value | R ² | |
|---------------------------------------|----------------------|-------------|----------------|-------|
| PROMIS LE – O&M | 0.22 | 0.0026 | 0.0096 | N=187 |
| PROMIS LE- Weber | 0.72 | <0.001 | 0.53 | N=187 |
| PROMIS LE- FAOS Symptoms | 0.56 | <0.001 | 0.32 | N=277 |
| PROMIS LE- FAOS ADLs | 0.73 | <0.001 | 0.42 | N=277 |
| PROMIS LE- FAOS Quality of Life | 0.71 | <.001 | 0.52 | N=274 |
| PROMIS LE- FAOS Pain | 0.69 | <0.001 | 0.45 | N=276 |
| PROMIS LE- FAOS Sports | 0.72 | <.001 | 0.50 | N=218 |

| Table 2: MCID and Difference in Ankle Outcome Scores from 6-months to 12-months post-surgery | | | | | | |
|---|-------|------------|----------|--|--|--|
| | | | | | | |
| | | 6-12 month | | | | |
| PROMIS PF | 4.67 | 1.69 | P=0.33 | | | |
| PROMIS LE | 3.97 | 4.04 | P=0.0019 | | | |
| Weber | 9.38 | 3.88 | P=0.124 | | | |
| Olerud & Molander | 11.46 | 3.33 | P=0.11 | | | |
| (O&M) | | | | | | |

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