Achieving Minimal Clinically Important Difference after Osseointegration in Transfemoral Amputees

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Limited literature exists regarding the definition or achievement of minimal clinically important difference (MCID) in pain or function after osseointegration in the setting of transfemoral amputation.

We prospectively administered PROMIS Pain Interference, Pain Behavior, and Physical Function tests to patients with transfemoral amputation presenting for osseointegration. Testing was administered preoperatively and one year postoperatively. Patients who did not complete all PROMIS questionnaires were excluded. Minimal clinically important differences were derived from baseline scores by the distribution-based method. We compared baseline characteristics, including age, sex, BMI, and etiology of amputation, of patients who did and did not improve by the MCID at one year postoperatively. Continuous variables were assessed by independent sample t-test. Categorical variables were assessed by chi-square, unless expected cell counts were <5, in which case Fisher's exact test was used. Statistical significance was defined at p <0.05. Analyses were conducted by same software.

Our cohort comprised 36 patients, the majority of whom were male (33 of 36, 91.7%). Mean age at presentation was 37.9 years (SD 10.4) and mean BMI was 26.8 (SD 5.2). A preponderance of patients (24 of 36, 66.7%) had sustained transferoral amputation in the setting of combat-related blast injury.

We calculated MCIDs for PROMIS Pain Interference, Pain Behavior, and Physical function as 4.2, 3.5, and 2.0, respectively. At one year postoperatively, 52.8% (19 of 36) of patients achieved improvement of MCID or greater in Pain Interference; 33.3% (12 of 36) of patients achieved improvement of MCID or greater in Pain Behavior; 41.7% (15 of 36) of patients achieved improvement of MCID or greater in Physical Function.

There was no significant difference in patient age, sex, and history of blast injury between those who did and did not achieve MCID in Pain Interference, Pain Behavior, or Physical Function domains. Patients who failed to achieve MCID in Physical Function did have increased BMI at presentation (28.3, SD 5.3) compared to those who did achieve clinically significant improvement at one year postoperatively (24.7, SD 4.4; p = 0.037). There was no significant difference in BMI between patients who did and did not achieve MCID in Pain Interference or Pain Behavior.

DISCUSSION AND CONCLUSION:

A considerable number of patients undergoing osseointegration after transfemoral amputation achieve clinically significant improvement at one year postoperatively. A patient's age at presentation, sex, and history of blast injury are not associated with failure to achieve MCID at one year postoperatively. However, failure to achieve MCID in Physical Function was associated with increased BMI at presentation. These results may help counsel patients preoperatively. Longer term follow up will allow for further assessment of improvement after osseointegration in transfemoral amputees.