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.

The QuickDASH and Patient-Rated Wrist Evaluation Scores Are Not Optimal Measures to Assess the Outcome of Distal Radial Fractures: Potential Implications for Future Research

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**Purpose:** The abbreviated version of the Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH) and Patient-Rated Wrist Evaluation (PRWE) are frequently employed patient-reported outcome measures to assess outcomes following distal radial fractures. When ceiling or floor effects are present this suggests an inability to potentially discriminate clinically significant differences between available interventions. However, there are limited data reporting the ceiling/floor effects of QuickDASH or PRWE following distal radial fractures and they are for defined patient populations with small cohorts and/or following a specific treatment modality. The primary aim was to assess whether QuickDASH or PRWE demonstrates a ceiling or floor effect following a distal radius fracture. Secondary aims were to identify how ‘normal’ a patient felt their wrist was when achieving a ceiling effect and if there were any independent patient factors associated with a ceiling effect.

**Methods:** A retrospective cohort study was undertaken of patients sustaining distal radius fractures at the study centre during a single year. Outcome measures included the QuickDASH, PRWE, EQ-5D-3L (EuroQol 5 Dimensions 3 Levels), and normal wrist score. A floor or ceiling effect was defined as (1) when >15% of respondents reach the highest or lowest possible score as defined by McHorney and Tarlov, or (2) a score within the minimal clinical important difference (MCID) of the minimal or maximal score.

**Results:** There were 526 patients with a mean age of 65 years (range, 20-95) and 421 (77%) were female. Most patients were managed nonoperatively (73%, n = 385). The mean follow-up was 4.8 years (4.3-5.5). A ceiling effect was observed for both the QuickDASH (22.3%) and PRWE (28.5%). When defined to be within the MCID of the best score, the ceiling effect increased to 62.8% for QuickDASH and 60% for PRWE. Patients who achieved the best available functional outcome (ceiling score) according to QuickDASH and PRWE subjectively felt their wrist was only 91% and 92% normal, respectively. Male sex (P = 0.004), younger age (P<0.001), and better health-related quality of life (HRQoL) as measured by EQ-5D-3L (P<0.001) were associated with achieving a QuickDASH ceiling score, whereas only a better EQ-5D-3L (P<0.001) was associated with a PRWE ceiling score.

**Conclusion:** The QuickDASH and PRWE demonstrated ceiling effects when used to measure the outcome of distal radius fractures. Patients achieving ceiling scores did not consider their wrist to be ‘normal’ suggesting their outcome may not be optimal. Future patient-reported outcome assessment tools should aim to abolish the observed ceiling effects.