Pelvic and Acetabulum Fractures – Which Functional Outcome Measure Should We Use? An Analysis of Responsiveness Over the First Year of Recovery Sebastian Ko, MD; Kelly A. Lefaivre, MD<sup>1</sup>; Peter J. O'Brien, MD<sup>1</sup>; Pierre Guy, MD; Abdullah Mamun; Henry Broekhuyse, MD <sup>1</sup>University of British Columbia, Vancouver, British Columbia, CANADA

**Purpose:** Pelvic and acetabulum fractures are complex injuries. The best clinical outcome tools to use in research related to these injuries remain largely unstudied. A recent systematic review found a lack of validity and responsiveness testing with pelvic-specific instruments. For generic health scores, the Short Form-36 (SF-36) and Short Musculoskeletal Function Assessment (SMFA) have been used in pelvic and acetabular fracture research, but no comparison of the responsiveness of the 2 in this population has been done. The purpose of this study is to compare the responsiveness of SF-36 PCS to SMFA DI in pelvic/acetabular fracture patients over the first year of recovery.

**Methods:** 465 patients with pelvic or acetabulum fractures were recruited at a Level I trauma center between 2005 and 2015. SF-36 PCS and SMFA DI were collected prospectively at baseline, 6 months, and 12 months. Responsiveness was evaluated with the standard response mean (SRM), proportion of patients that achieved MCID, and ceiling and floor effects. Paired t tests were used to compare SRMs, and McNemar's test was used to compare the proportion of patients experiencing MCID in SF-36 versus SMFA. Statistical significance was set at a P <0.01.

**Results:** The mean ISS was 14.3. Mean age was 44.2 years. SF-36 PCS and SMFA DI showed strong correlation for all time intervals. The SRM of SF-36 PCS was significantly greater than the SRM of SMFA DI between baseline and 6 months (P < 0.0001) and nearly so between 6 and 12 months (P = 0.06). The proportion of patients achieving MCID in SF-36 PCS was greater than in SMFA DI between baseline and 6 months (82.24% vs 69.74%, P < 0.0001). Between 6 and 12 months, more patients met MCID with SF-36 PCS (60.53% vs 55.59%), but did not reach significance. There were no ceiling or floor effects found for SF-36 PCS at any time point. The SMFA was found to have a floor effect at baseline (17.82%), and consistently had higher floor estimates at each time point than the SF-36 PCS, but not greater than 10%.

**Conclusion:** This study demonstrates that the SF-36 PCS is a more responsive measure of functional outcome than the SFMA DI in patients with pelvic and acetabulum fractures, despite the theoretical advantage of a musculoskeletal-specific measure. This superiority was found in using the SRM, proportion of patients meeting MCID, and floor effects. These findings support the isolated use of the SF-36 PCS as the best general functional outcome measure in patients with pelvic and acetabulum fractures, while limiting the burden for both the patient and clinician.

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.