PROMIS Computer Adaptive Tests Compared with Time to Brake in Patients with Complex Lower Extremity Trauma

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Background/Purpose: A current standard in the literature for measuring a driver's ability to brake after a lower extremity trauma is total time to brake (TTB), which shows significant improvement at 6 weeks after weight bearing. The TTB is the sum of the time required to react, move the foot to the brake pedal, and apply enough brake pressure to stop the vehicle. However, using just one objective measurement may not produce a full assessment of driving ability. The PROMIS Initiative (Patient Reported Outcomes Measurement Information System) may be a useful adjunct to TTB in evaluating driving ability. The system uses item response theory and computer adaptive testing to obtain precise outcome measurements in the least amount of time. Recent studies have validated the PROMIS physical function (PF) and pain interference (PI) computer adaptive tests (CATs) to evaluate recovery after lower extremity traumas. The purpose of this study was to compare the PROMIS PF CAT and PI CAT to TTB in assessing a patient's readiness to drive after a lower extremity orthopedic trauma.

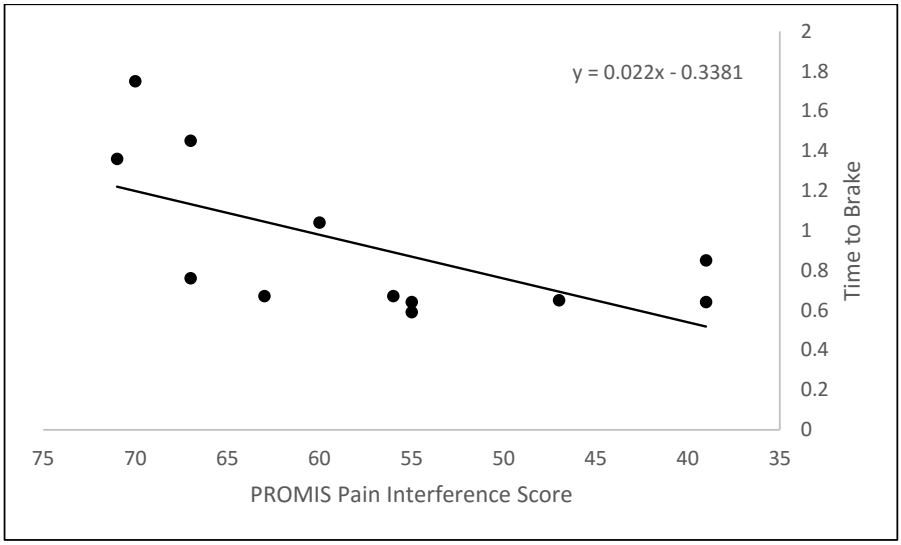
Methods: The study involved 70 patients with lower extremity injuries, located in the pelvis, acetabulum, hip, femur, knee, tibia/fibula, ankle, and foot. These patients were tested on a driving simulator constructed using the Vericom Stationary Reaction Timer. A control group of six healthy volunteers with no history of prior lower extremity fracture or surgery was tested to establish a normal mean value for TTB. The simulator consisted of a digital driving scene displayed on a computer, a speedometer, and a timer that recorded the patient's ability to depress the brake in response to an on-screen stimulus. After completing the driving simulation test, patients completed the PI and PF instruments through the PROMIS online Assessment Center. The PROMIS instrument employs an algorithm that selects questions based on answers to previous questions, eliminating the need for the patient to answer all questions in the bank. All statistical testing was done using IBM SPSS version 21.

Results: 63 patients were enrolled, after excluding 7 patients who did not meet inclusion criteria. The patient group was 75% male, with an average age at injury of 45 years. Injury laterality consisted of 26 left-sided, 33 right-sided, and 5 bilateral injuries. The most frequent sites of lower extremity injury were the acetabulum (18.8%) and ankle (29.7%). 11 patients (17.2%) received nonoperative management and 53 patients (82.8%) received surgical fixation. The mean TTB for the healthy control group was 0.61 seconds (min = 0.56, max = 0.64, SD = 0.03, 95% CI = 0.58-0.64). When the injuries were stratified as above knee (pelvis, acetabulum, hip, femur) or below knee (tibia/fibula, ankle, foot), TTB significantly improved with time for right below-knee injuries (B = -0.008 sec/day, P = 0.041). For right-sided injuries that were below the knee, there was a statistically significant correlation between TTB and PROMIS PI score (B = 0.022, P = 0.029). There was no significant correlation between TTB and PROMIS PF (B = -0.009, P = 0.32). Figure 1 graphs the TTB for right-sided injuries that

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.

were below the knee as a function of the PROMIS PI score. In our linear regression model, the TTB range for healthy controls (0.61 seconds or less) is associated with a PROMIS PI score of T=43 or less.

Figure 1. Time to Brake vs. PROMIS Pain Interference Score.



Conclusion: The correlation between the PROMIS PI score and TTB suggests that the PROMIS PI score can add to TTB when assessing driving ability. We found that the patients who regained normal TTB had a PROMIS PI score below T = 43, compared to the average pain interference score of T = 50 for the US general population. Our study demonstrates that the PROMIS Pain Interference CAT correlates to TTB, and can be used as an additional measure to determine when patients may return to driving.

See pages 49 - 106 for financial disclosure information.