

### **Evaluation of a Custom Energy-Storing Lower Limb Carbon Fiber Orthosis**

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**Purpose:** The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a custom, energy-storing carbon fiber orthosis developed for lower limb salvage patients. Early studies conducted at one military treatment facility (MTF) where the IDEO was developed demonstrate benefits of the IDEO when used with a sports medicine approach to physical therapy (PT). This study was designed to see if we could replicate results at other MTFs, and examine if early gains in performance translate into longer-term improvements in patient-reported outcomes.

**Methods:** The study is a pre-post design where participants served as their own controls. Eligible were service members who were at least 1 year out from an injury at or below the knee with functional deficits. Participants were evaluated before receiving the IDEO (T0), immediately following completion of PT (T2), and 6 months (T3) following PT. Functional performance was assessed using several well-established tests. Self-reported function was measured using the Short Musculoskeletal Function Assessment (SMFA). The Orthotics and Prosthetics Users' Survey (OPUS) was administered at T2 and T3 to assess satisfaction with the IDEO.

**Results:** Of 87 participants with complete baseline data, 6 did not complete any PT and were excluded from analysis. The mean number of sessions attended by participants was 9.2; 83% attended 7 or more sessions. 88% of participants completed the T2 assessment and 74% completed the T3 SMFA. Compared to baseline, statistically significant improvement at T2 was observed in all but 1 performance test. SMFA scores were significantly lower at 6 months compared to baseline in Mobility (30.1 vs 37.6; 95% confidence interval [CI] of difference: -11.9, -2.9) and Daily Activity (25.1 vs 32.1; 95% CI: -11.3, -2.7). There was no impact on high baseline emotional subscores of the SMFA. Satisfaction with the IDEO was high at T2 (91% had OPUS scores >65) with some attenuation at T3 (68%).

**Conclusion:** This study adds to the evidence in support of the efficacy of the IDEO and PT in improving function, regardless of where it was fabricated and fitted. But despite improvement in both performance and self-reported functioning at 6 months, deficits persist compared to population norms. Results support the need for further refinement of the IDEO and continued efforts at addressing psychosocial consequences.