

## The LIMB-Q: A Novel Patient-Reported Outcomes Instrument Specific to Lower Extremity Trauma Patients

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**Purpose:** Complex lower-extremity traumatic injuries can be devastating events with a multifaceted impact on patients. Capturing patient-reported outcomes (PROs) is essential. There are currently no PRO instruments developed specific for this patient population applicable to both limb salvage and amputation patients. The objective of this multidisciplinary, international collaboration was to develop the LIMB-Q, a PRO instrument for lower-extremity trauma patients.

**Methods:** The LIMB-Q was developed using international standards for PRO instrument development. A conceptual framework and preliminary set of scales were developed from 33 semi-structured qualitative interviews in patients after limb-threatening lower-extremity injuries at a single Level I trauma center. The conceptual framework included 10 domains: physical, psychological, social, appearance, prostheses, sexual, financial, process of care, treatment, and environment. The preliminary LIMB-Q scales (n = 20 scales, n = 364 total items) were revised (n = 20 scales, n = 382 total items) and content validity was confirmed through cognitive debriefing interviews (n = 12 patients, same inclusion criteria) and collection of expert opinion (n = 43 multidisciplinary international experts). An international multi-institutional field test was conducted at 6 sites in English, Dutch, German, and Danish in 402 patients with lower-extremity injuries distal to the mid-femur (54% fracture only, 29% soft-tissue reconstruction, 10% amputation, 7% both amputation and reconstruction); mean age was 49 years (standard deviation 17), 64% male, and mean time from injury 5 year.

**Results:** 14 independently functioning scales as well as process of care scales were developed and validated specifically for lower-extremity trauma patients. Core scales included Physical Function (person separation index [PSI] = 0.97, Cronbach's  $\alpha$  = 0.98, 95.6% targeting [percentile in field test that fit Rasch ruler]), Symptoms (PSI = 0.89,  $\alpha$  = 0.91, 97.8%), Psychological (PSI = 0.91,  $\alpha$  = 0.96, 83.5%), Social (PSI = 0.84,  $\alpha$  = 0.92, 84.7%), Sexual Well-Being (PSI = 0.86,  $\alpha$  = 0.87, 97.0%), Work (PSI = 0.87,  $\alpha$  = 0.96, 80.8%), Financial Burden (PSI = 0.84,  $\alpha$  = 0.91, 91.9%), Injury Acceptance (PSI = 0.81,  $\alpha$  = 0.86, 77.4%), and Impact of Injury (PSI = 0.93,  $\alpha$  = 0.96, 92.4%). Additional scales developed included scales for Appearance, Decision-Regret, Expectations, Prostheses, and Process of Care.

**Conclusion:** The LIMB-Q is a novel PRO instrument developed specifically for lower-extremity trauma patients. With independently functioning scales, the LIMB-Q will allow researchers and clinicians to collect a wide range of PRO data, selecting scales tailored to the specific research question and/or clinical goal. As a disease-specific PRO instrument, outcomes captured by the LIMB-Q will be both relevant and comprehensive of issues experienced by lower-extremity trauma patients. The LIMB-Q additionally will have the sensitivity and specificity to capture clinical change over time.