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ORIGINAL RESEARCH

# Functional Ability Level Development and Validation: Providing Clinical Meaning for Spinal Cord Injury Functional Index Scores

Richa Sinha, MPH, PhD,[a] Mary D. Slavin, PT, PhD,[a] Pamela A. Kisala, MA,[b] Pengsheng Ni, MPH, MD,[a] David S. Tulsky, PhD,[b,c] Alan M. Jette, PT, PhD[a]

*From the [a]Health and Disability Research Institute, Boston University School of Public Health, Boston, MA; [b]Center on Assessment Research and Translation, Department of Physical Therapy, College of Health Sciences, University of Delaware, Newark, DE; and [c]Kessler Foundation Research Center, West Orange, NJ.*

**Abstract**

**Objectives:** To develop functional ability levels for the Spinal Cord Injury Functional Index (SCI-FI) and to validate them using calibration and reliability samples.

**Design:** Three-phase strategy involved (1) performing quantitative synthesis of SCI-FI data to create item maps; (2) using a panel of experts to identify functional ability levels after the bookmarking and Delphi consensus-building process; and (3) performing quantitative analyses to examine demographic characteristics across 2 samples, assessing the distribution pattern across functional ability levels, and examining concurrent validity using the self-reported functional measure and the observer-rated FIM.

**Setting:** Inpatient and community settings.

**Participants:** People 18 years or older with traumatic spinal cord injury (N = 1124) were recruited from the Spinal Cord Injury Model Systems programs and stratified by diagnosis, severity, and time since injury (n = 855 and n = 269 for calibration and reliability samples, respectively).

**Interventions:** Not applicable.

**Main Outcome Measure:** SCI-FI.

**Results:** Five functional ability levels were identified for all SCI-FI domains, except fine motor having 4 functional ability levels. Statistical test results indicated no significant differences in the distribution pattern across the 2 samples across functional ability levels for all domains except for ambulation. Known-group comparisons were able to discern the spinal cord injury population as expected. Basic mobility, self-care, and wheelchair mobility domains had a cluster of persons with paraplegia and incomplete lesions at higher functional ability levels and persons with tetraplegia and complete lesions at lower functional ability levels. For the ambulation domain, the distribution was skewed to the lower end, with a relatively small percentage of persons with incomplete lesions (paraplegia and tetraplegia) at higher functional ability levels. For the fine motor domain, the distribution was skewed to higher functional ability levels, with a high percentage of persons with paraplegia at the highest level (complete and incomplete lesions). Concurrent validity analyses revealed SCI-FI functional levels to be significantly ($P<.001$) positively correlated with both the self-reported functional measure and the observer-rated FIM.

**Conclusions:** Clinicians can use functional ability levels to discuss patients' functional capabilities with them and their family.

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The need for accurate and sensitive functional measures for spinal cord injury (SCI), emphasized by the International Campaign for Cures of Spinal Cord Injury Paralysis Clinical Guidelines Panel,[1] an international panel established to review the methodology for clinical trials in SCI, and by the 2006 National Institute on Disability and Rehabilitation Research SCI Measures Meeting,[2] led to the development of the Spinal Cord Injury Functional Index (SCI-FI).[1,3] Existing measures are limited in the range of activities being assessed, such as the Spinal Cord Independence Measure,[4,5] which is composed of 19 items that assess 3 domains of functioning (self-care, respiration and sphincter management, mobility), and the FIM,[6] composed of 13 items that assess motor function. The FIM was developed as a generic measure for use in individuals with chronic health conditions and has been shown to have high floor and ceiling effects,[2,7,8] whereas other currently available SCI measures can be used for 1 diagnosis or domain of function. For example, the Quadriplegic Index of Function[9] provides a more detailed assessment of upper extremity functioning but is used only for persons with tetraplegia. Similarly, the Walking Index for Spinal Cord Injury[10] is used only for persons with SCI who ambulate. In summary, current measures used to assess the functioning of persons with SCI have inherent limitations, including an inadequate range of items and limited applicability to all persons with SCI.[11]

The SCI-FI can be administered as a Computerized Adaptive Test (CAT) and uses item banks calibrated with an item response theory approach to hierarchically organize items along a continuum of difficulty in a given domain. CATs use a computer algorithm to select items from the calibrated item bank on the basis of an individual's response to previous items. CAT results provide an estimate of an individual's functional ability on the basis of responses to items appropriate for that individual. Because items are selected from the same calibrated item bank, scores can be compared across individuals even though different sets of items are administered. Initial examination of the SCI-FI demonstrated the measure's validity.[1]

The SCI-FI measures activity limitations in 5 domains: basic mobility (54 items), ambulation (39 items), wheelchair mobility (56 items), self-care (90 items), and fine motor function (36 items). SCI-FI scores provide interval-level data that are useful for research purposes; however, without a functional context, it is difficult to interpret the clinical significance of these numeric scores. Clinicians may not be able to judge the level of functioning implied by SCI-FI numeric scores, which would hinder their ability to use SCI-FI scores to guide clinical practice.[12] Providing meaning to SCI-FI scores in a context that summarizes relevant functional information would enable clinicians to interpret these scores to better understand, communicate, and use the assessment results.

Our approach to interpreting SCI-FI scores identifies hierarchical functional stages, or levels, that characterize a range of scores related to meaningful and distinct functional abilities.[13] This approach has roots in the bookmarking procedure, traditionally used in educational testing to distinguish students of different abilities according to their level of performance.[14] The bookmarking procedure involves ordering items by difficulty, from the easiest to the most difficult, followed by the placement of bookmarks by content experts along the continuum of difficulty to identify the location of the cutoff scores that distinguish different functional levels.[8] Functional levels are simple to understand and provide a clinical context for numeric scores. In this study, we applied the bookmarking procedure to develop item response theory-based functional ability levels for each of the 5 SCI-FI domains. We further examined the known-groups and concurrent validity of SCI-FI functional levels on the basis of the following objectives: (1) to test whether the distribution of persons with SCI across SCI-FI functional levels differs by level of lesion (persons with paraplegia at higher functional levels and persons with tetraplegia at lower functional levels, specifically for fine motor a higher percentage of persons with paraplegia at the highest functioning level) and completeness (persons with incomplete lesions at higher functional levels and persons with complete lesions at lower functional levels, specifically for ambulation a higher percentage of persons with incomplete lesions at the highest functioning level) and (2) to examine whether there are positive correlations between SCI-FI levels and legacy measures (ie, observer-rated FIM and self-reported functional measure).

***List of abbreviations:***

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|---|---|
| **AIS** | **American Spinal Injury Association Impairment Scale** |
| **CAT** | **Computerized Adaptive Test** |
| **SCI** | **spinal cord injury** |
| **SCI-FI** | **Spinal Cord Injury Functional Index** |

# Methods

## Study samples

### SCI-FI study participants

Two samples of SCI-FI study participants were used in the study: one from the SCI-FI calibration study (from here on referred to as the calibration sample) and the other from the SCI-FI reliability study (from here on referred to as the reliability sample). The calibration sample was used to develop functional ability levels, and both the calibration and reliability samples were used for the purpose of establishing validity of the functional levels. The SCI-FI calibration study consisted of 855 adults with traumatic SCI.[1] The reliability study consisted of 269 participants. Participants for both studies were recruited by the Spinal Cord Injury Model Systems programs.

Both studies were cross-sectional, and the following inclusion criteria were used for both samples: (1) participants with a traumatic SCI, (2) 18 years or older, and (3) able to read and understand English. Both samples were stratified by level (paraplegia vs tetraplegia) and completeness of injury (complete vs incomplete) and time since injury (<1, 1−3, >3y) to ensure a heterogeneous sample with an adequate representation of functional abilities. The study was approved by the institutional review board of each of the participating Spinal Cord Injury Model Systems programs.

### Expert panel participants

The qualitative methodology of the study involved the recruitment of a content expert panel consisting of researchers and/or consumers (people with SCI) involved in disability and SCI research. The expert panel comprised 6 individuals (5 women and 1 man) with professional training in rehabilitation: physical therapy (n=2), occupational therapy (n=1), and public health (n=3). Panel members had experience in SCI research and/or clinical practice. One panel member was an individual with SCI.

## Data collection and measures

### Calibration sample

For the calibration sample, all SCI-FI items were administered and SCI-FI domain scores were derived. SCI-FI items were administered by trained interviewers either by phone or in person.