ORIGINAL ARTICLE

Ambulation and Balance Outcomes Measure Different Aspects of Recovery in Individuals With Chronic, Incomplete Spinal Cord Injury

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ABSTRACT. Forrest GF, Lorenz DJ, Hutchinson K, VanHiel LR, Basso DM, Datta S, Sisto SA, Harkema SJ. Ambulation and balance outcomes measure different aspects of recovery in individuals with chronic, incomplete spinal cord injury. Arch Phys Med Rehabil 2012;93:1553-64.

Objective: To evaluate relationships among ambulation and balance outcome measures over time for incomplete spinal cord injury (SCI) after locomotor training, in order to facilitate the selection of effective and sensitive rehabilitation outcomes.

Design: Prospective observational cohort.

Setting: Outpatient rehabilitation centers (N=7) from the Christopher and Dana Reeve Foundation NeuroRecovery Network.

Participants: Patients with incomplete SCI (N=182) American Spinal Injury Association Impairment Scale level C (n=61) and D (n=121).

Interventions: Intensive locomotor training, including step training using body weight support and manual facilitation on a treadmill followed by overground assessment and community integration.

Main Outcome Measures: Six-minute and 10-meter walk tests, Berg Balance Scale, Modified Functional Reach, and Neuromuscular Recovery Scale collected at enrollment, approximately every 20 sessions, and on discharge.

Results: Walking and standing balance measures for all participants were strongly correlated ($r \geq .83$ for all pairwise outcome correlations), standing and sitting balance measures were not highly correlated ($r \leq .48$ for all pairwise outcome correlations), and walking measures were weakly related to sitting balance. The strength of relationships among outcome measures varied with functional status. Correlations among evaluation-to-evaluation changes were markedly reduced from performance correlations. Walk tests, when conducted with different assistive devices, were strongly correlated but had substantial variability in performance.

Conclusions: These results cumulatively suggest that changes in walking and balance measures reflect different aspects of recovery and are highly influenced by functional status and the utilization of assistive devices. These factors should be carefully considered when assessing clinical progress and designing clinical trials for rehabilitation.

Key Words: Berg Balance Scale; Locomotor training; Modified functional reach; Rehabilitation; 6-minute walk; 10-meter walk.

FUNCTIONAL OUTCOME MEASURES play 2 important roles in rehabilitation after spinal cord injury (SCI). First, they guide clinical decisions by measuring changes in functional performance over the course of a therapeutic intervention. Clinical measures used in outpatient settings often need to establish responsiveness over short time frames to ensure reimbursement from third-party payers. Moreover, tests that delineate responders from nonresponders over a short period allow careful treatment selection and will support studies of treatment mechanisms for SCI. Second, they are the foundation by which to determine efficacy of interventions in clinical trials. Phase 3 clinical trials require the use of a primary outcome measure that reaches an acceptable threshold of statistical and clinical relevance as well as capturing the range of recovery expected from the intervention across the studied population. The efficacy of functional outcome measures, therefore, depends on good reliability (the instrument reproduces similar scores over time and across raters), validity (the ability of the test to measure what it is intended to measure), and responsiveness (the capacity for detecting clinically important changes).[1-3]

In SCI, reliance on a battery of performance-based outcome measures increases the likelihood of detecting functional improvement; however, only a few of these outcome measures have established psychometric properties for use in individuals with chronic SCI. Reliability and validity have been estab-

List of Abbreviations

AIS	American Spinal Injury Association Impairment Scale
CI	confidence interval
NRN	NeuroRecovery Network
NRS	Neuromuscular Recovery Scale
SCI	spinal cord injury

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lished for timed measures of walking, including the 10-meter walk and the 6-minute walk tests, in SCI up to 1 year postinjury.[4,5] For balance measures, the validity and reliability of the Berg Balance Scale have been established,[6,7] while reliability, but not validity, for the Functional Reach/Modified Functional Reach has been shown for SCI.[8,9] In addition, a principal component analysis revealed limitations in Berg Balance Scale scoring sensitivity as a function of performance capacity and that seated performance contributed little to the overall Berg Balance Scale score.[10] While Berg Balance Scale scores correlate with walking performance after SCI, the relationship between longitudinal changes among balance and walking performance remains unexamined. The Modified Functional Reach, a solely seated test, was specifically developed for SCI, but does not capture aspects of balance related to standing or locomotion.

Efficiently using sensitive outcome measures in the clinic is important to avoid creating an unnecessary time burden for patients and clinicians. The 6-minute walk and 10-meter walk tests were found to be highly redundant within the first 6 months after incomplete SCI, indicating redundant constructs; however, performance differences emerged between these 2 tests at later time points (12mo) and for individuals who could walk at higher speeds.[11,12] Responsiveness of the measures is critical for assessing the effects of interventions. Recently, a large multicenter European study[13] found that responsiveness of the 10-meter walk and Spinal Cord Independence Measure II decreased as functional capacity and time after injury increased. Thus, changes in functional capacity of individuals with SCI appear to be a factor in the responsiveness of outcome measures.

Scientific evidence has facilitated a dramatic shift in neurorehabilitation toward activity-based therapy with the development of new treatments that reduce disability and improve quality of life after SCI.[14-18] A group of 7 rehabilitation centers in the United States form the NeuroRecovery Network (NRN), whose goals include improving health, quality of life, and functional outcomes for people with incomplete SCI by using activity-based therapy. Standardized locomotor training is used for individuals with SCI undergoing outpatient rehabilitation.[17-21] It is one of the first therapies for SCI to be implemented across multiple clinical rehabilitation sites in a systematic and standardized manner in the United States. Standardization includes treatment and progression techniques, common discharge considerations, and extensive program evaluation based on motor, sensory, and quality-of-life indicators.[17] Outcome measures including the 6-minute walk, 10-meter walk, Berg Balance Scale, and Modified Functional Reach are collected at baseline and approximately every 20 sessions throughout the standardized locomotor training. The resultant NRN database contains outcomes for locomotor training, applied at a unique time postinjury within a multicenter format.

The purpose of this study was to examine the relationships among the 6-minute walk, 10-meter walk, Berg Balance Scale, and Modified Functional Reach in response to standardized locomotor training in individuals with clinically incomplete SCI. We correlated the longitudinally collected outcome measures themselves (performance correlations), as well as the evaluation-to-evaluation changes in each of the measures (change correlations). High performance correlations and high change correlations would suggest that the compared tests are redundant, as performance and the change in performance on one test would closely estimate these same results on another test. We also assessed whether the relationships among the outcome measures were dependent on the patient's level of functional ability by using a new functional classification (Neuromuscular Recovery Scale [NRS]).[21] To estimate relationships among these 4 outcome measures in the presence of repeated measurements per participant, we used the statistical methodology within-cluster resampling.[22]

METHODS

Participants

We evaluated data from 182 patients enrolled in the standardized locomotor training therapy from February 2008 through June 2009 at 7 outpatient clinical sites in the Christopher and Dana Reeve Foundation NRN that includes Boston Medical Center, Boston, MA; Frazier Rehab Institute, Louisville, KY; Kessler Institute for Rehabilitation, West Orange, NJ; Magee Rehabilitation Hospital, Philadelphia, PA; The Ohio State University Medical Center, Columbus, OH; Shepherd Center, Atlanta, GA; and The Institute for Rehabilitation and Research, Houston, TX. We obtained institutional review board–approved statement of consent before obtaining the clinical information and evaluating the outcome measures. All patients provided informed consent to provide their deidentified data to the national database. As in most clinical rehabilitation programs, outcome measures were collected by the treating physical therapist. Each therapist underwent standardization training to administer locomotor training and all outcome measures in a standardized manner. To facilitate standardization, written descriptions of techniques for locomotor training and all outcomes were provided to all clinical sites in a manual.[17,18] Patients were selected for participation in the NRN locomotor training program based on (1) the presence of a nonprogressive spinal cord lesion above T11; (2) no current participation in an inpatient rehabilitation program; (3) no use of onabotulinumtoxinA or other medications for chemodenervation for spasticity for the 3 months prior; (4) some lower limb movement or visible voluntary contraction; (5) the capacity to generate a lower limb reciprocal alternating flexion/extension stepping pattern in the step training environment; and (6) medical referral by a physician for physical therapy. Patients receiving antispasticity medications were weaned from its use during participation in the NRN program as directed by the NRN physician.

The NRN locomotor training therapeutic program has been described in detail elsewhere.[17,23,24] In brief, individuals with clinically incomplete SCI received manual-facilitated locomotor training 3 to 5 days a week for 1 hour, followed by approximately 30 minutes of overground assessment and community integration (table 1). Progression of locomotor training sessions was based on a standardized functional approach across all sites. All sessions were provided by physical therapists, physical therapist assistants, and activity-based technicians who underwent yearly hands-on training and education to deliver standardized treatment across centers.

Outcome Measures

The 4 outcome measures (6-minute walk,[5,25,26] 10-meter walk, Berg Balance Scale,[6,7,23,27-34] and the Modified Functional Reach) were acquired at enrollment, sequentially after every 20 sessions, and at discharge from the locomotor training program. The standardized procedures for the balance and gait assessments performed within the NRN standardized outcome measurement protocol have been outlined in a previous article.[17] In brief, for the 6-minute walk, the placement of turns, precise verbal feedback, and the location of the observer conformed to standardized methods.[35] The need to sit or use physical assistance ended the test. For the 10-meter walk, a

Table 1: Demographic and Clinical Characteristics at Enrollment of NRN Sample

Characteristics	Values (N=182)
Sex	
Male	134 (74)
Female	48 (26)
Age (y)	41±17
AIS level	
C	60 (33)
D	122 (67)
Initial phase	
1	73 (40)
2	71 (39)
3/4	38 (21)
Injury level	
Cervical	136 (75)
Thoracic	46 (25)
Mechanism of injury	
MVC	70 (38)
Fall	38 (21)
Sporting accident	29 (16)
Nontrauma	20 (11)
Medical/surgical	15 (8)
Violence	10 (5)
Assistive walking device	
Nonambulatory	61 (34)
Walker	59 (32)
Cane(s)/crutch(es)	43 (24)
None	19 (10)
Time since SCI (y)	0.9 (0.1, 25.8)
<1	97 (53)
1–3	41 (23)
3+	44 (24)
Treatment and enrollment characteristics	
Time of NRN enrollment (d)	96 (14, 649)
Cumulative treatment sessions received	40 (2, 385)
Cumulative no. of evaluations	4 (2, 14)
Treatment intensity (Tx/evaluation)	19±5

NOTE. Values are n (%) for categorical variables, and mean ± SD or median (minimum, maximum) for continuous variables.
Abbreviations: MVC, motor vehicle collision; Tx, number of treatment sessions.

14-m path was used to avoid acceleration/deceleration effects associated with starting and stopping during this assessment. Both tests included use of assistive devices when required; however, no lower limb bracing or physical assistance was allowed. When patients changed assistive devices during the course of treatment, each gait outcome measure was conducted twice—once with the device used at enrollment, termed the "initial device," and once with the device currently being used, termed the "current device." A minimum of 5 minutes of seated rest preceded each of the gait tests. The Modified Functional Reach test was performed according to Lynch[8] and Adegoke[9] and colleagues, where participants are seated with their feet supported and their trunk rested on the back of the chair (reclined 10° from vertical). Participants raise their preferred arm to 90° of shoulder flexion parallel to, but not touching, a wall-mounted yardstick. The location of the ulnar styloid is noted before and after their maximal reach. On return to an independent and upright position, without use of upper limb weight-bearing, the difference between the "start" and "stop" locations is used to determine reach distance in centimeters. Two practice trials are followed by 3 scored trials, the mean of which constitutes the Modified Functional Reach score.

The NRS[21,36] includes 7 tasks in the overground environment including sit, sit up, reverse sit up, trunk extension, sit to stand, stand, and walk. Four tasks occur in the body weight–supported treadmill environment and include stand retraining, stand adaptability, step retraining, and step adaptability. Retraining (stand or step) uses therapist/trainer manual facilitation, while adaptability (stand or step) does not use physical assistance. For the overground tasks, physical assistance is only given when helping a patient achieve a position, but not during the scoring of the task. The NRS is composed of 4 phases of recovery, from phase 1 representing the lowest degree of functional recovery to phase 4 designating full recovery of function. Overall, the progression of recovery from phase 1 to phase 4 in the body weight–supported treadmill environment is characterized by (1) decreases in the amount of body weight support required for standing or stepping; (2) decreases in manual facilitation required sequentially at the trunk, pelvis, and legs; (3) increases in independence for standing or stepping (at preinjury speeds) while maintaining proper body kinematics; and (4) increases in treadmill speed during step adaptability. In the overground environment, progression of recovery is delineated by an increasing ability to independently perform the functional tasks without compensation.

Data Analysis

The purpose of our analysis was to examine relationships among 4 functional outcome measures: 2 walking measures (6-minute walk and 10-meter walk) and 2 balance measures (Berg Balance Scale and Modified Functional Reach). We estimated nonparametric Spearman rank correlation coefficients for each pairing of the 4 outcome measures. Since our data set was longitudinal, in that outcome measures were repeatedly measured for each patient as treatment progressed over time, regular methods for estimating the Spearman correlation were invalid. Therefore, we applied the within-cluster resampling algorithm[22] to estimate the marginal correlations between pairs of outcome measures, where we use the term "marginal" to indicate that the correlations were estimated irrespective of patient and treatment characteristics. The within-cluster resampling algorithm efficiently estimates marginal quantities in the clustered data framework, such as in repeated-measures settings, under which observations within a cluster may be correlated, and the number of observations per cluster may be informative for the marginal quantity being estimated. A detailed description of within-cluster resampling is provided in the appendix 1.

We applied the within-cluster resampling algorithm to estimate correlations among the outcome measures, referred to as performance correlations because they estimate relationships among measures relative to patient performance. Evaluation-to-evaluation changes in the outcome measures were analyzed to assess relationships among the measures with respect to functional recovery over time, defined as change correlations. In this analysis, for example, a set of 5 observations of the outcome measures on a single patient became a set of 4 evaluation-to-evaluation changes in the measures by calculating the difference between successive evaluations. We also conducted these analyses in 3 groups of patients defined by the phase of recovery[21] at a given evaluation—phase 1, 2, and 3/4. Finally, we estimated correlations for the initial and current devices used during the walking tests for the full sample and for each of the 3 phase groups.

Demographic and clinical characteristics were summarized with means and SDs for continuous variables; medians, minima, and maxima for ordinal and continuous data; and counts with percentages for categorical data. Comparison of enrollment and final evaluation measurements of the Modified Functional Reach were conducted with the Wilcoxon signed-rank test. Linear mixed-effects models were fit to predict 6-minute walk speeds with 10-meter walk speeds and to predict current-use device assessments of the walk tests with enrollment device assessments. All analyses were conducted using the open-source R software package.[37] Ninety-five percent confidence intervals (CIs) were calculated, and significance tests were conducted at the .05 level. In calculating the correlations, we adopted a pairwise complete convention, in that the correlation for each pairing of outcome measures was calculated on the available data. Therefore, the sample sizes used to calculate each correlation varied, as data for some outcome measures were unavailable. The sample size used to estimate each correlation is presented.

RESULTS

Demographic and Clinical Characteristics

The patients (N=182) considered in our analysis were generally representative of the SCI population in the United States, relative to demographics such as sex, age, time since injury, and device at enrollment (see table 1).[38] The time since injury ranged from months to years; however, the median was less than 1 year. Time of enrollment, cumulative treatment sessions received, and number of evaluations varied; however, treatment intensity per evaluation was a controlled variable. A median of 4 evaluations was contributed by each patient, which corresponds to the number of observations contributed to the within-cluster resampling estimation of the correlation coefficients. There were significant improvements in the Modified Functional Reach from enrollment to the final evaluation for the overall sample and phase 1 and 2 groups, but not for phase 3 patients (table 2). Significant improvements in 6-minute walk distance, 10-meter walk speeds, and Berg Balance Scale scores among NRN patients have been illustrated previously.[17]

Full-sample change correlations for these measures were considerably lower than the corresponding performance correlations (figs 1 and 2; tables 3 and 4). Gait speed and endurance (see fig 1A; see table 3) were highly correlated, as was the Berg Balance Scale with endurance (see fig 1B) and gait speed (see fig 1C), although to a lesser degree and with a noticeable ceiling effect. The changes in outcomes were correlated, but to a much lower magnitude than the performance correlations (see fig 1D–F). Although the correlation between the Berg Balance Scale and Modified Functional Reach was statistically significant, the value was much lower than that for the Berg Balance Scale and the walking tests (see fig 1G; see table 4). The Modified Functional Reach was poorly correlated with the walking measures (see fig 1H, 1I), and changes in the Modified Functional Reach were only weakly related to changes in the Berg Balance Scale, gait speed, or gait endurance (see fig 1J–L).

Table 2: Summary Statistics for Enrollment and Final Evaluations of the Modified Functional Reach for the Full Sample and by Phase at Enrollment

Modified Functional Reach	Overall	Phase 1	Phase 2	Phase 3
Enrollment	43.9±18.0	34.0±19.3	48.3±13.7	55.6±13.2
Final	49.0±16.8	41.4±18.0	53.1±14.5	56.1±12.7
P	.00002	.0007	.003	.59

NOTE. Values are mean (cm) ± SD. *P* values were calculated from the Wilcoxon signed-rank test.

Performance and change correlations for the 6-minute and 10-meter walk tests for phase 1 patients, although significant and highly correlated, were representative of the inability of phase 1 patients to walk and the low sample size used to estimate the correlations (see figs 1A–F and 2; see table 3). Performance and change correlations in the phase 2 and 3 groups for the walk tests generally paralleled the full sample, although were reduced for phase 2 patients and increased for phase 3 patients. The Modified Functional Reach scores of phase 3 patients only were significantly correlated with the walk tests, but these correlation coefficients were of low magnitude.

Variability Patterns for Walking Measures

Although 10-meter walk and 6-minute walk speeds were strongly correlated (ρ=.94, P<.001), there was considerable variability in predicting 6-minute walk speeds from 10-meter walk speeds. Speeds for the 10-meter walk were generally higher than the 6-minute walk, and the difference increased at higher speeds (figs 3A and 3B) since the estimated slope of the linear mixed-effects model line was significantly less than 1.0 (β=.87; 95% CI, .84–.91). Further, the error associated with predicting 6-minute walk speeds from 10-meter walk speeds also increased with the speed of the walk (fig 3C). The residual SE from the mixed-effects model was .06 for speeds less than 0.5m/s, .14 for speeds of 0.5 to 1.0m/s, .16 for speeds of 1.0 to 1.5m/s, and .26 for speeds greater than 1.5m/s.

Additional variability was introduced to the walk tests when different assistive devices were considered. Walking measures conducted with different assistive devices were strongly correlated for the 6-minute (ρ=.90; 95% CI, .65–1.00; P<.001, n=58) and 10-meter walk (ρ=.88; 95% CI, .62–1.00; P<.001, n=59) tests (figs 4A, 4B). Despite these strong correlations, the prediction of walk performance from using 1 device to the other had substantial variability. Neither the initial nor current device exhibited uniformly better performance (see figs 4C, 4D, 4E, 4F). For the 6-minute walk speeds, the linear mixed-effects model predicting current with initial device performance had an intercept of −32m (95% CI, −49 to −16), significantly different from 0, and a slope of 1.10 (95% CI, 1.04–1.17), significantly different from 1. Predictions of current device distance came with a notable degree of error. The mixed-effect model residuals ranged from −85m (initial > current) to 103m (current > initial), and the residual SD, an average measure of prediction error, was 37m. There were no apparent patterns in the prediction errors (see figs 4C, 4D). In contrast, the average difference between initial and current device speed for the 10-meter walk was stable in magnitude over all speeds, since the estimated slope (−.03m/s; 95% CI, −.09 to .04) and intercept (1.00m/s; 95% CI, .91–1.08) were not significantly different from 0 and 1, respectively. Model residuals for the 10-meter walk ranged from −.64m/s (initial > current) to .51m/s (current > initial), and the residual SD was .16m/s. The error associated with predicting current device speeds with initial device speeds increased with speed, as indicated by the sideways funnel shape of the model residuals (see figs 4C, 4D).

DISCUSSION

The speed of walking, ability to walk for a distance for up to 6 minutes, and standing balance were related for individuals with incomplete SCI. However, changes in these functional measures from evaluation to evaluation were not as strongly related in the same population. These results indicate that

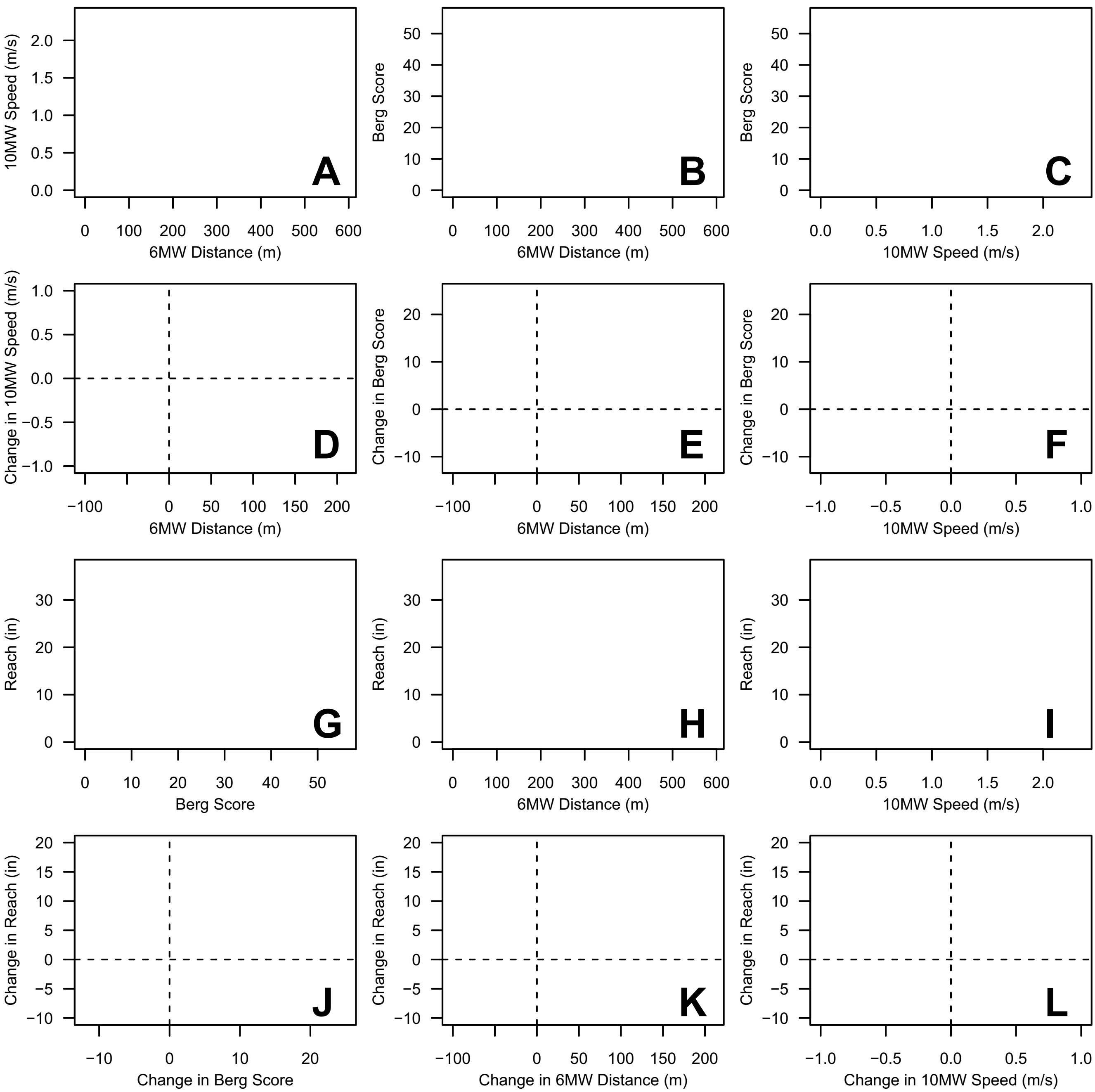

Fig 1. Scatterplots depicting relationships among assessments of 6MW, 10MW, BBS, and MFR. Plots in the first and third rows show relationships in performance on the measures, and plots in the second and fourth rows show relationships among evaluation-to-evaluation changes in the measures. (A) 10MW vs 6MW. (B) BBS vs 6MW. (C) BBS vs 10MW. (D) Change in 10MW vs change in 6MW. (E) Change in BBS vs change in 6MW. (F) Change in BBS vs change in 10MW. (G) MFR vs BBS. (H) MFR vs 6MW. (I) MFR vs 10MW. (J) Change in MFR vs change in BBS. (K) Change in MFR vs change in 6MW. (L) Change in MFR vs change in 10MW. Measurements of phase 1 patients are in red, phase 2 in green, and phase 3 in blue. Abbreviations: 6MW, 6-minute walk; 10MW, 10-meter walk; BBS, Berg Balance Scale; MFR, Modified Functional Reach.

the level of performance of 1 measure can predict the performance of another with some precision; yet, this apparent redundancy is diminished when improvements in these measures over time are considered. The strength of correlation between measures was affected by the level of functional ability as measured by the NRS. In addition, there was significant prediction error when speeds from the walk tests were directly compared. The use of assistive devices also introduced additional variability in these measures. These results cumulatively suggest that changes in these measures reflect different aspects of recovery and are highly influenced by the utilization of assistive devices.

Several studies[11,39-41] suggest that the use of both a 6-minute walk and a 10-meter (or 15.2-m) walk should be discouraged

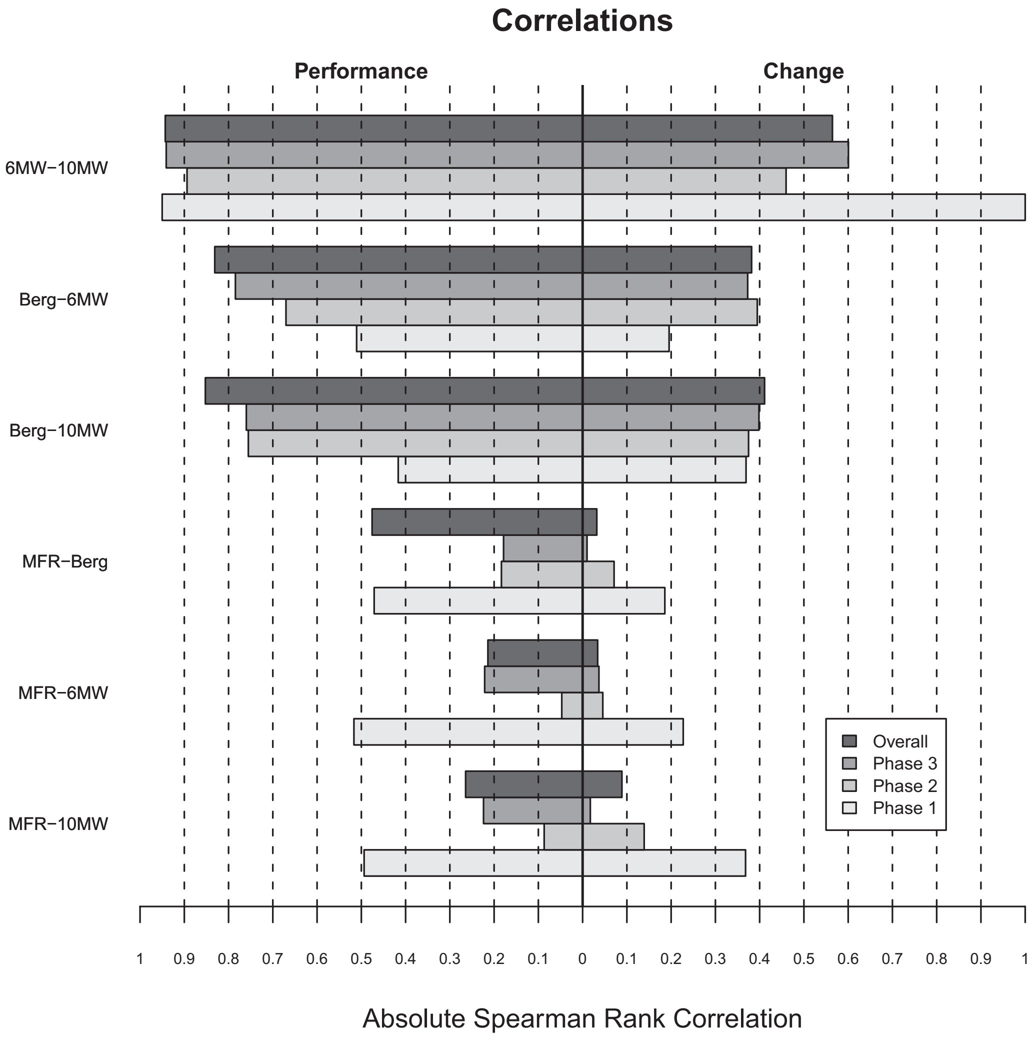

Fig 2. Barplot of the absolute value of Spearman rank correlation coefficients for each pairing of measurements of the Berg Balance Scale, MFR, 6MW, and 10MW for the full sample and within groups defined by patient phase. Performance correlations are plotted to the left from the axis, change correlations to the right. Abbreviations: 6MW, 6-minute walk; 10MW, 10-meter walk; MFR, Modified Functional Reach.

based on high correlations of performance of these measures and clinically irrelevant differences. Other investigators found similar results for performance correlations using the 10-meter walk and the 6-minute walk[4,5,12] and balance after incomplete SCI. Kim et al[42] suggested a redundancy of measures based on an estimated .98 correlation between the 8-meter walk and a 6-minute walk among patients with incomplete SCI. Barbeau et al[11] reported a close relationship between gait speeds from the 6-minute walk test and the 15.2-meter walk test at 3, 6, and 12 months after injury, although a slight divergence between measures was observed after 12 months as recovery progressed. These strong correlations among walking measures for performance might be expected because the tests were performed with many common elements (eg, time, assistive device, functional task) representing similar domains of mobility. However, this does not necessarily indicate that the tests are redundant when evaluating recovery.

The level of recovery is reflected by the change in performance on the outcome variable(s) over successive evaluations, a value representing the rate of recovery over time.[5,43] The correlations between changes in performance across successive evaluations for the 6-minute walk and 10-meter walk were substantially reduced relative to performance itself (see table 3; see figs 1 and 2). Berg Balance Scale and Modified Functional Reach change correlations were not significant. This indicates that the rates of recovery of walking capacity specific to speed and endurance and for balance are not strongly related. Recovery of these functions occurred in a nonuniform manner for patients in the NRN locomotor training program. These data identify the uniqueness of these measures and support the conclusion that they may represent separable domains of mobility for recovery. These results should be considered in selecting outcome measures for clinical practice and research trials in that if only 1 walking or balance measure is selected, it is highly likely that aspects of recovery may not be measured.

Examination of the classification of patients by the NRS illustrated that the relationships between changes in pairs of outcome variables across successive evaluations were moderate at best and phase dependent (see table 3: phase 2 and phase 3, 10-meter walk vs 6-minute walk). The change correlation for the Berg Balance Scale and the 6-minute walk in phase 2 was greater than in phase 3, whereas the opposite occurred for the Berg Balance Scale and 10-meter walk. No substantial interpretation should be attached to the perfect correlation of 1.0 between the changes in walking measures noted for participants in phase 1; rather, this was reflective only of the general inability of phase 1 patients to walk. Hence, at different stages of recovery or levels of functional ability, the connection

Table 3: Performance and Change Correlations for the 6-Minute Walk and 10-Meter Walk, and Berg Balance Scale

Pairing	Group	Performance	Change
6-minute walk, 10-m walk	All patients	.94 (.76 to 1.00) n=110*	.56 (.39 to .74) n=107*
	Phase 3	.94 (.69 to 1.00) n=61*	.60 (.35 to .85) n=55*
	Phase 2	.89 (.65 to 1.00) n=63*	.46 (.16 to .76) n=37†
	Phase 1	.95 (.26 to 1.00) n=9†	1.00 (.52 to 1.00) n=18*
Berg, 6-minute walk	All patients	.83 (.65 to 1.00) n=111*	.38 (.22 to .54) n=110*
	Phase 3	.78 (.54 to 1.00) n=61*	.37 (.15 to .60) n=55†
	Phase 2	.67 (.43 to .91) n=64*	.39 (.11 to .68) n=38†
	Phase 1	.51 (−.14 to 1.00) n=10	.20 (−.23 to .62) n=22
Berg, 10-m walk	All patients	.85 (.67 to 1.00) n=109*	.41 (.25 to .57) n=105*
	Phase 3	.76 (.51 to 1.00) n=61*	.40 (.16 to .64) n=55†
	Phase 2	.76 (.51 to 1.00) n=62*	.37 (.09 to .66) n=37†
	Phase 1	.42 (−.28 to 1.00) n=9	.37 (−.10 to .84) n=18

NOTE. Values are Spearman coefficient (95% CI) and the sample size (n) used to estimate the correlation.
*P<.001; †P<.01.

between the rates of recovery of speed, endurance, and balance changed. These variations were also evident in our estimated performance correlations. Van Hedel et al[5] reported a strong relationship between the 10-meter walk and 6-minute walk tests when evaluating individuals with American Spinal Injury Association Impairment Scale (AIS) A, B, C, and D; however, 81% of the individuals were AIS D. They suggested that the results from the poor walkers should be interpreted cautiously, indicating that the level of functional ability impacts the reliability and validity of the walking measures. Likewise, our data suggest that walking capacity may show trends for greater correlations between walking tests with increased recovery (ie, phase 3 vs phase 2). This variability should be considered when selecting outcome measures for clinical practice and research.

The different aspects of mobility that may be measured by the 6-minute and 10-meter walk tests were highlighted by our analysis of the differences in speed between the 2 outcome measures (see fig 3). Predicting speed performance on one walk test with the other came with a substantial amount of error, and this error increased with the level of functional ability, indicating that the 2 walk tests were sensitive to different domains of mobility recovery. On average, 10-meter walk speeds were significantly faster than 6-minute walk speeds, and the disparity between the 2 increased with walk speed. These disparities of speed for a large sample population are greater than what has previously been reported[4,5,11] and may be considered clinically relevant.

A source of significant variability in the walking measures is the use of assistive devices. Although we noted a significant correlation between initial and current device assessments of the 6-minute and 10-meter walk tests, we also noted significant residual error in attempting to predict current device performance with initial device performance (see fig 4). The magnitude of these errors was as large as 100m and .64m/s for the 6-minute and 10-meter walk tests, respectively, and neither the initial device nor the current device was uniformly significantly superior in walk test performance. In other words, one could not predict whether changing the assistive device would have a positive or negative effect on the measurement. For example, slower walking speeds resulting from a progression to a less restrictive ambulatory device may be erroneously interpreted as a lapse in recovery. Conversely, an improvement in the measure may not indicate recovery, but rather use of a more facilitative compensatory device.

The Modified Functional Reach showed significant improvement with locomotor training, with poor correlations with the other measures. The overall sample and phase 1 and 2 groups (see table 2) showed significant increases from enrollment to final assessments, indicating that those with less functional ability did benefit from locomotor training in seated balance. Phase 3 had high scores at enrollment. Our results for the performance correlation illustrated a positive, but fair to poor relationship between the Modified Functional Reach and the Berg Balance Scale, 6-minute walk, and 10-meter walk. We thus conclude that seated balance as measured by the Modified Functional Reach is unrelated to standing postural balance or walking capacity for patients enrolled in the NRN. A similar

Table 4: Performance and Change Correlations for the Modified Functional Reach and Berg Balance Scale, Modified Functional Reach and 6-Minute Walk, and Modified Functional Reach and 10-Meter Walk

Pairing	Group	Performance	n	Change	n
Modified Functional Reach, Berg	All patients	.48 (.33 to .62)	154*	−.03 (−.17 to .10)	131
	Phase 3	.18 (−.03 to .38)	61	−.01 (−.23 to .21)	54
	Phase 2	.18 (−.01 to .38)	84	.07 (−.14 to .28)	58
	Phase 1	.47 (.21 to .73)	5	−.19 (−.50 to .13)	30
Modified Functional Reach, 6-minute walk	All patients	.21 (.06 to .37)	109†	−.03 (−.20 to .13)	103
	Phase 3	.22 (.01 to .43)	60‡	.04 (−.22 to .29)	51
	Phase 2	.05 (−.18 to .28)	63	.05 (−.22 to .31)	37
	Phase 1	−.52 (−1.00 to .14)	10	−.23 (−.67 to .22)	20
Modified Functional Reach, 10-m walk	All patients	.26 (.10 to .43)	107†	−.09 (−.26 to .08)	97
	Phase 3	.22 (.01 to .44)	60‡	−.02 (−.27 to .23)	51
	Phase 2	.09 (−.15 to .32)	61	.14 (−.14 to .42)	36
	Phase 1	−.49 (−1.00 to .20)	9	−.37 (−.89 to .15)	15

NOTE. Values are Spearman coefficient (95% CI) and the sample size (N) used to estimate the correlation.
*P<.001; †P<.01; ‡P<.05.

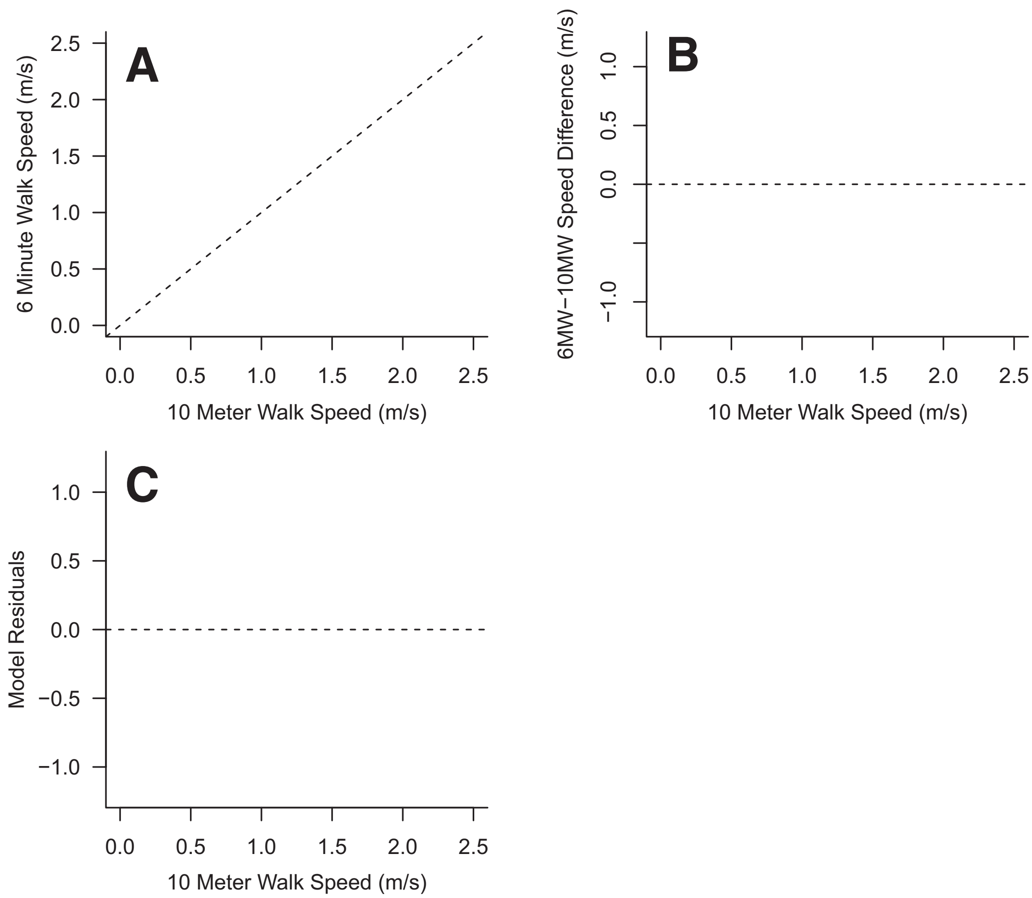

Fig 3. Scatterplots of 6MW test speed and 10MW test speed. (A) 6MW speeds against 10MW speeds. (B) Difference between 6MW and 10MW speeds against 10MW speeds. (C) Prediction error (residuals) from a linear mixed-effects model predicting 6MW speeds with 10MW speeds. Abbreviations: 6MW, 6-minute walk; 10MW, 10-meter walk.

finding was established by Hornby et al,[44] who determined that the Modified Functional Reach was poorly correlated with all outcome measures except the Berg Balance Scale, for which correlations were fair. Lynch et al[8] have shown repeatability and reliability of the Modified Functional Reach for both paraplegia and tetrapelgia, and our results demonstrate the uniqueness and independence of the Modified Functional Reach as a measure of balance recovery from the Berg Balance Scale and walk tests for ambulatory patients in the NRN locomotor training program. The only caveat to this result is for individuals classified as phase 1 who, at the very early stages of recovery or low level of function, showed a moderate relationship between the Modified Functional Reach and Berg Balance Scale.

This has not been shown to be the case for other pathologies. Field-Foté and Ray[45] have alluded to a number of stroke studies where, although not predictive, a relationship has been shown to exist between seated posture or trunk stability as measured by the Seated Functional Reach and other measures of recovery of function.[46,47] By comparison, the SCI research is more sparse and inconclusive, and there has been no established relationship between unilateral seated reach or standing reach, and functional tasks such as defined activities of daily living. Chen et al[48] determined that measurements of trunk or postural stability in patients with incomplete SCI may be more reflective of injury level or trunk lever length rather than an increase in trunk flexor or extensor muscle strength. While determining that the standing and seated Modified Functional Reach is a valid and reliable measure of postural control in individuals with incomplete SCI, Field-Foté and Ray[45] postulated that postural control may be more correlated to trunk excursion during the reach rather than the change in distance of the endpoint of the wrist. However, these previous studies are limited by small sample sizes. In summary, whether sitting balance is associated with locomotor capacity appears questionable given the poor relationship between Modified Functional Reach and walking measures within and across evaluations.

Study Limitations

There are limitations to the responsiveness of the 4 measures for performance evaluation. A number of authors have alluded to the ceiling effect of the Berg Balance Scale, the plateau effect of the 10-meter walk,[13] and the impact of any nonambulatory participants included in the assessment of the 10-meter walk and 6-minute walk. The ceiling effect of the Berg Balance Scale may bias the evaluation of the relationship between balance and walking since the Berg Balance Scale does not measure aspects of balance required for walking. This would be especially relevant for higher functioning patients and may influence both performance and change correlations, and perhaps underestimate the performance and rate of recovery of balance.

The within-cluster resampling methodology we used produces estimates of marginal correlations, in that the effects of patient and treatment factors are marginalized. We have, in essence, "averaged out" these factors. A particular implication of this is that the correlations we have estimated marginalize the 3 important factors: (1) duration of participation in a rehabilitative program, (2) functional capacity of the patient,

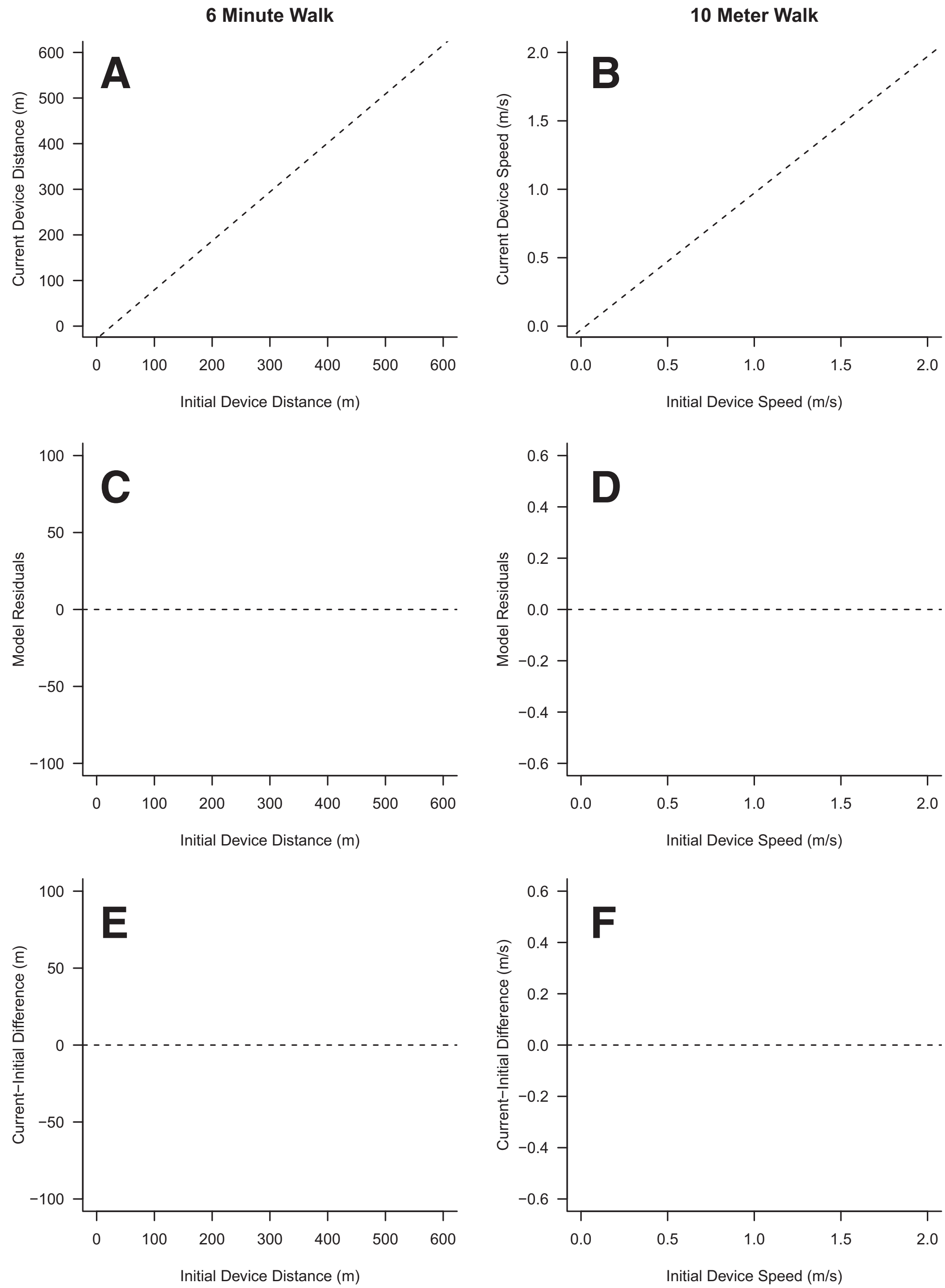

Fig 4. Scatterplots of the enrollment and current-use device assessments of the 6MW and 10MW. Top row shows initial device vs current device for the 6MW (A) and 10MW (B). Middle row shows residuals from the line of best fit for the 6MW (C) and 10MW (D). Bottom row shows the current device-initial device difference against the initial distance for the 6MW (E) and speed for the 10MW (F). Abbreviations: 6MW, 6-minute walk; 10MW, 10-meter walk.

and (3) time removed from SCI. A drawback to this approach is that by marginalizing over these factors, we may dilute potentially important information about how relationships among outcome measures may vary as functions of these factors. Past research has shown that relationships between outcome measures may be decidedly nonuniform across 1 or more of these factors.[13,25]

The interpretation and utility of the correlations we have estimated here may then be called into question, given that we have marginalized over a very diverse set of patients as well as over long periods of rehabilitation. However, these outcome measures have been used extensively in the past in very diverse sets of patients such as those in the NRN data set. Consequently, questions concerning redundancy of testing measures would ideally be addressed in diverse sets of patients, rather than within patient groups homogeneous with respect to injury and/or progression characteristics such as functional capacity, time since SCI, and duration of rehabilitation. The correlations we have estimated through the within-cluster resampling method serve this purpose and supplement rather than contradict the analyses of relationships among measures that have been longitudinal or cross-sectional in scope.

CONCLUSIONS

This article has introduced the "performance correlation" and "change correlation" as determinants of functional recovery for individuals who have participated in the NRN locomotor training program. The functional performance measurements for speed, endurance, and balance determined indices of performance, while the functional recovery measured by change in measurable outcomes for successive evaluations determined rates of recovery. When measuring functional balance, walking speed, and walking endurance clinically, it is important to carefully consider the outcome measurements and timing of their administration because, based on our data, outcome measures respond differently during different stages of recovery. For clinicians, evaluating outcome measure utility relative to stage of recovery is critically important for capturing change in our patients and determining the effectiveness of interventions. This may also facilitate the work of clinical trials researchers when deciding on the most optimal measure(s) to show efficacy of treatment, since they may need to consider responsiveness of these measures relative to the rate of recovery. Typical clinical outcome measures may not be sufficient for the earliest phase of recovery, where most clinical trials focus on regeneration and repair. Walking outcomes as determined by a single evaluation may only be relevant for the subset of the population of SCI with a higher phase of recovery. More importantly, changes in the walking outcomes may more accurately determine response to therapy or recovery from injury, and multiple outcome measures may be necessary to capture the rate of change.

APPENDIX 1: WITHIN-CLUSTER RESAMPLING

Here we provide a description of the within-cluster resampling algorithm through an NRN-specific example and a formal (mathematical) description of the marginal correlation being estimated by within-cluster resampling. Consider 2 outcome measures, say the 6-minute walk and 10-meter walk, for which we are interested in estimating the correlation. Given the longitudinal nature of the data, there were 2 challenges involved in estimating this correlation: (1) repeated observations on a single participant were likely dependent, and (2) the number of observations per patient was related to the outcome measures themselves. The first challenge is well known; many methods for assessing correlation require independent observations. The second challenge is less well known, which we describe here. In the NRN, the duration of enrollment, and hence the number of evaluations, was strongly related to a patient's level of recovery at enrollment; more impaired patients tended to remain enrolled longer and therefore contribute more observations to the data set. By extension, 6-minute walk distances and 10-meter walk speeds themselves were related to the number of observations contributed by a patient; more impaired patients contributed not only more observations, but observations with lower distances and speeds. When estimating a marginal quantity like a correlation coefficient in such a situation, improper weight may be placed on more severely impaired patients, since they have contributed more observations to the data set than those less severely impaired. This subsequently may bias the estimation of the marginal correlation between 2 outcome measures.

The within-cluster resampling algorithm circumvents this problem by giving equal weight to each patient (rather than to each observation) through its random resampling scheme, eliminating the need to model the dependence structure among repeated observations and the cluster size. The within-cluster resampling algorithm randomly selects a single, paired observation (6-minute walk, 10-meter walk) from each of the patients (ie, clusters) to produce a "resampled" data set of paired observations, 1 observation per patient. Since the patients are independent, these resampled observations form a data set of independent observations and a standard correlation coefficient (Pearson, Spearman, Kendall, etc) can be calculated on the resampled data set. Further, each patient in the data set is equally represented in the resampled data set, and the effect of the cluster size on the outcome measures is mitigated—that is, each patient is represented once in the resampled data set regardless of how many observations he or she contributed to the original data set.

The correlation coefficient calculated on the resampled data set inefficiently uses the available data—only 1 observation per cluster is used—and is itself random, so the resampling process is repeated many times with replacement for each patient, and a correlation coefficient is calculated for each resampled data set. The average of these resampled correlation coefficients then provides a consistent estimate of the marginal correlation in which we are interested. An estimate of the asymptotic variance for the correlation coefficient can also be calculated as detailed by Hoffman et al,[22] to allow for statistical inference (CIs and hypothesis tests).

The following is a mathematical description of the marginal correlation that is estimated by within-cluster resampling. Let (X_{ij}, Y_{ij}) be a bivariate functional outcome measure collected on the i^{th} individual during his or her j^{th} evaluation, $1 \leq j \leq n_i$, $1 \leq I \leq M$. For example, X could be the 6-minute walk distance and Y the 10-meter walk speed received by an individual in a given evaluation. Here, M denotes the total number of patients in our sample and, for a given patient i, n_i denotes the number of evaluations received by that patient. The data for patient i are clustered and, as noted above, the size of the cluster (n_i) is related to the severity of injury and therefore should be treated as potentially informative for the outcome measures.[22,49]

The following inverse cluster size–weighted bivariate distribution function corresponds to the empirical or sampling distribution of a typical paired measurement (chosen at random from all the paired measurements on the same individual) received by a typical individual (chosen at random from the study population of SCI patients):

$$\hat{F}(x, y) = \frac{1}{M}\sum_{i=1}^{M}\frac{1}{n_i}\sum_{j=1}^{n_i} I(X_{ij} \leq x, Y_{ij} \leq y).$$

Let $F(x, y) = E(\hat{F}(x, y))$ be the population bivariate, marginal distribution function that is being estimated by $\hat{F}(x, y)$. Here E stands for expectation on the outcome variables X_{ij} and Y_{ij} as well as the random cluster sizes n_i. Let ρ be the correlation coefficient corresponding to the marginal bivariate distribution function F given by

$$\rho = \frac{\iint (x-\mu_F)(y-\upsilon_F)dF(x,y)}{\left[\left\{\iint (x-\mu_F)^2 dF(x,y)\right\}\left\{\iint (y-\upsilon_F)^2 dF(x,y)\right\}\right]^{1/2}},$$

with $\mu_F = \iint x \, dF(x, y)$ and $\nu_F = \iint y \, dF(x, y)$. It can be shown following Williamson et al[49] that within-cluster resampling estimates this marginal correlation ρ.

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