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Neurological and functional capacity outcome measures: Essential to spinal cord injury clinical trials

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Abstract—We intend to demonstrate that future treatment strategies in spinal cord injury (SCI) rehabilitation to restore function (SCI rehabilitation) should be based on the success of rigorous clinical trials with demonstrated effective interventions. Knowing the course of neurological recovery, its mechanism, and its measures will be essential in designing and executing these trials. We reviewed selected recovery outcomes and measures from multicenter studies and a large SCI database. The accuracy of baseline examinations in the first days following injury is critical to demonstrating changes in neurological recovery. Recovery of one neurologic level in subjects with tetraplegia depends on the severity of the injury, the initial level of the injury, and the strength of muscles below the level of injury. Motor recovery of the upper limbs typically correlates with self-care function. Neurological recovery following SCI often correlates with an increase in function and walking in addition to self-care. In subjects with paraplegia, predicting recovery of walking is possible based on the initial 1-week sensory and motor examination. Although initial neurological findings correlate with neurological and functional-recovery outcomes in large populations of 3,500 subjects reported by the Model SCI System centers in the United States, improved outcome measures for walking are needed. The Walking Index for Spinal Cord Injury (WISCI) has recently demonstrated criterion validity and increased sensitivity and responsiveness to change in neurological/walking function in subjects with SCI. The WISCI scale correlated well with measures in use to determine improved walking function regarding walking speed, lower-limb motor scores, and other measures. Demonstrating improved neurologic and functional outcomes following SCI requires accurate neurologic and sensitive functional measures.

Key words: body-weight support training, clinical trials, lower limb, outcome, outcome measures, recovery, rehabilitation, self-care, spinal cord injury, walking, walking index, upper limb.

INTRODUCTION

New physical restoration and rehabilitation treatments introduced recently for spinal cord injury (SCI) include, but are not limited to, neurological enhancement and regeneration trials [1]; physical training trials and applications of functional electrical stimulation (FES) to improve the bladder, the bowel, self-care [2], and walking function; and assistive technology to enhance mobility. Since the range of new interventions and trials is varied

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Abbreviations: AIS = ASIA Impairment Scale, ASIA = American Spinal Injury Association, CUE = Capabilities of Upper Extremity, FES = functional electrical stimulation, FIM = Functional Independence Measure, ICCP = International Campaign for Cure of Paralysis, LEMS = lower extremity motor scores, NMS = no motor strength, SCI = spinal cord injury, SCIM = Spinal Cord Independence Measure, SMS = some motor strength, WISCI = Walking Index for Spinal Cord Injury.

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and numerous, only interventions or trials dealing with neurological recovery and physical training are examined here.

The treatment strategies relevant to this discussion that have emerged over the past 10 years are based on the renewed appreciation of neurological and functional recovery. These treatments propose to exploit neural plasticity in physical training based on the concept of the central pattern generator [3]. Regeneration of the central nervous system can be facilitated if the inhibition of neural growth and scar formation is limited and axon growth with cell lines and growth factors is promoted. Currently completed SCI trials or those in progress were presented in February 2004 at a Clinical Trials Workshop sponsored by the International Campaign for Cure of Paralysis (ICCP) conference [4]. Researchers from around the world reported on experiences with interventions that used 4-aminopyridine, stem cells, olfactory ensheathing cells, activated macrophages, and locomotor training. All the studies used the International Standards for Neurological Classification of SCI, developed by the American Spinal Injury Association (ASIA)* [5] for classification, stratification, and/or neurological recovery end points. Additional outcome measures offered included autonomic-function, neurophysiologic, functional-capacity, and disability tests. The workshop explored consensus on future trials and concluded that this workshop was the beginning of a process with many unknowns.

Although we stand on the threshold of major discoveries that will hopefully restore function and quality of life to those disabled by SCI, we must cross the portal cautiously. Randomized multicenter clinical trials offer the preferred approach [6], but essential to successfully executing these trials are a sufficient study population and an appreciation of known recovery patterns to be improved on by new treatments. Although uniformity of classification is highly desirable for multicenter trials and comparison between trials, the strategy for evaluating new interventions will require recognizing additional factors. Precise and meaningful end points are required, with special attention to an accurate baseline and repeated measures. Statistical analysis must be sufficiently powered to detect a clinically significant effect.

This paper, therefore, carefully examines several of these factors, such as (1) the accuracy/stability of the initial neurological examination; (2) upper- and lower-limb motor recovery, including the functional correlations of self-care and mobility; and (3) the validity/reliability of functional-capacity scales such as the Walking Index for Spinal Cord Injury (WISCI). We attempt to illustrate several examples that we have found to be most challenging, but do not provide a comprehensive review of the subject. A recent publication reviews existing and proposed clinical and physiological outcome measures for SCI trials [7].

MOTOR RECOVERY (INITIAL EXAMINATION)

When the initial neurological examination is compared with subsequent examinations in a clinical trial, its stability and accuracy are critical for demonstrating improvement. Stability and accuracy of the initial examination are particularly important with stratification of the severity of the lesion by level (cervical, thoracic, lumbar) and the ASIA Impairment Scale (AIS) (**Table 1**). Since improvement of

Table 1.
Walking Index for Spinal Cord Injury, version II (WISCI II) levels. (*Source*: Ditunno PL, Ditunno JF Jr. Walking index for spinal cord injury (WISCI II): scale revision. Spinal Cord. 2001;39:654–56.)

WISCI Level	Device	Braces	Assistance (No. of Persons)
0	—	—	—
1	Parallel bars	Braces	2
2	Parallel bars	Braces	2
3	Parallel bars	Braces	1
4	Parallel bars	No braces	1
5	Parallel bars	Braces	None
6	Walker	Braces	1
7	Two crutches	Braces	1
8	Walker	No braces	1
9	Walker	Braces	None
10	One cane/crutch	Braces	1
11	Two crutches	No braces	1
12	Two crutches	Braces	None
13	Walker	No braces	None
14	One cane/crutch	No braces	1
15	One cane/crutch	Braces	None
16	Two crutches	No braces	None
17	No devices	No braces	1
18	No devices	Braces	None
19	One cane/crutch	No braces	None
20	No devices	No braces	None

Note: Level 0 = unable to walk, level 1 = walking less than 10 m, and levels 2 to 20 = walking 10 m.

*In cooperation with the International Spinal Cord Society (ISCoS).

both the neurological lesion level and AIS can be anticipated as part of the typical recovery pattern following acute injury (as will be discussed), unreliable initial examinations can be extremely misleading.

In a recent publication, Burns et al. examined the reliability and stability of the initial neurological examination performed within the first 48 hours on individuals who tested as having motor- and sensory-complete injuries (AIS grade A) [8]. Of 103 subjects in which 51 percent were regarded as reliable because they were cognitively intact (that is, not on a ventilator or medications, which would make the examination difficult to interpret), the examination of 66 percent at 1 year showed no volitional recovery (the subjects remained AIS A or B). However, Burns et al. also found that of the group of subjects "with factors affecting exam reliability, 17.4 percent (4/23) of AIS grade A subjects converted to incomplete status and 13 percent (3/23) regained motor function by 1 year (AIS C or D)." These findings suggest that when an intervention is planned for the first several days after injury, a subset may be identified in which the initial examination is very reliable. On the other hand, if a large number of subjects do not properly randomize because of an unreliable examination, the apparent improvement may be related to factors other than the intervention.

MOTOR RECOVERY/FUNCTION OF THE LIMBS

In the design of a clinical trial, knowledge of the usual course of recovery is important for several reasons. First, the extent of the recovery by level and motor score anticipated without an intervention should serve as the "historical control" for planning. Second, the intervals between initial injury and the subsequent improvement windows can be anticipated for timing evaluations. Third, in the situation of an adverse advent, which results in a change in neurological status, previous experience with patterns of recovery or worsening can be helpful. Very detailed information on motor and functional recovery has been reported in prior articles and book chapters [9–10]. Therefore, we will review mostly data from large studies.

NEUROLOGICAL RECOVERY OF THE ARMS AND SELF-CARE FUNCTION IN SUBJECTS WITH TETRAPLEGIA

In Stauffer's original work on prognosis for cervical lesions in which the neurological level was normal (defined as muscle grade 5) and not the 3/5 or better muscle grade used in the definition of the ASIA standards, all subjects with complete injuries recovered a full level [11]. Although it was based on one center and grouped all cervical lesions, this work was an important contribution because it provided the basis for clarifying recovery based on the specific level and the amount of strength present or absent at the level anticipated to improve.

The first multicenter study of recovery of arm strength of 150 subjects from four centers (reported in 1992) [12] demonstrated that 70 to 80 percent of motor-complete tetraplegia subjects with some motor strength (SMS), (which equals grades 1 to 2) at the injury level at 1 week post-injury would recover to the next neurologic level within 3 to 6 months. However, those with no motor strength (NMS), (which equals grade 0/5) at that level would show far less recovery, with only 30 to 40 percent gaining a level during the same period. Waters et al., who had similar findings, observed that no significant motor recovery occurred after 1 month if no improvement occurred before that period [13]. Our group has published a mathematical model for accurately prognosticating for groups of patients within the first week of injury [14]. Using a generalized estimating equation and subjects from five centers, Ditunno et al. found that prognosis for complete compared with incomplete tetraplegia patients in one study and 221 subjects with motor-complete tetraplegia in a second study can be made with a 90 percent confidence level at 1 week [10]. These studies showed that a significant difference existed between complete and incomplete subjects at the C4 and C5 levels for those who would gain a motor level. Although this finding confirmed earlier reports, the authors found no significant difference at C6, which was not expected. Ditunno et al. also found that while individuals with complete lesions may improve one and sometimes two levels, subjects with incomplete lesions often have recovery at multiple levels below the injury site [10]. When the data from several of these multicenter studies were examined, motor function of patients with incomplete cervical injuries recovered a level faster at 9 to 12 months, while the motor recovery of those with complete lesions did not plateau for 12 to 18 months [12,14].

The functional recovery associated with the recovery of muscle strength in the arms is usually determined by improvements in self-care, particularly in feeding oneself. The National Acute Spinal Cord Injury Study 3 (NASCIS 3) of 499 subjects showed a correlation of motor score to self-care [15], and the Model SCI Systems centers reported for 2,500 subjects a strong correlation of improvement in Functional Independence Measure (FIM) scores with improvement of neurological level [16]. Typically, the measure of self-care most often referred to in these studies is the FIM, which indicates on a seven-level scale the amount of assistance required for feeding, dressing, grooming, dressing, etc. Zafonte et al. found that individuals with motor C7 level on one side could be completely independent in feeding [17]. On the basis of these findings, we can now further qualify Stauffer's initial observation. "Recovery of one neurologic level in subjects with tetraplegia depends on severity, initial level of the injury and the strength of muscles below the level of injury" [11]. Motor recovery of the upper limbs typically correlates with self-care function. Although the mechanisms of recovery are more complicated at the level of the injury, peripheral and central motor sprouting has been suggested [18–19], but to date no interventions based on this mechanism have been offered.

MOTOR RECOVERY OF THE LOWER LIMBS AND WALKING

The Model SCI System maintains a very large database on neurological recovery, but the information on walking is limited because of inadequate quantitative measures in the past [20]. Marino et al. found that patients admitted to the Model SCI System centers within 1 week of injury who have clinically complete lesions (Frankel/AIS A) show only 2 to 3 percent improvement to Frankel/AIS D by 1 year [16]. Furthermore, they found that this improvement in individuals with clinically complete injuries apparently has not changed over the past 10 years. However, their data neither reveal how many of the 2 to 3 percent will be ambulatory nor distinguish between tetraplegia and paraplegia. The Frankel classification used an incomplete injury scale in which Frankel D equated to muscles that were functional, but Frankel regarded "functional" as the ability to walk.* However, this interpretation of "functional" as the ability to walk was never incorporated into the Frankel Scale, and the current modification known as AIS—which defines an AIS D as at least half of the key muscles below the level of the lesion having a grade of 3 or greater—does not refer to walking. Before 1987, no valid global disability scale existed that included the measure of walking. The emergence of the FIM [21], with a subscale for walking, has several limitations when it is applied to SCI [20,22].

Waters showed that a very small percentage (5%) of his paraplegic subjects with complete injuries ambulated [23], but this study included subjects with low-level lesions, who walked with the use of long leg braces and crutches in which ambulation is possible in the presence of complete paralysis of the leg muscles below the level of the lesion.

However, recovery of strength in the legs is common in incomplete injuries in both tetraplegia and paraplegia, and Bosch et al. reported in 1971 that recovery in Brown-Séquard and central cord injuries was excellent, but in Anterior Cord Syndrome, very poor [24]. A number of smaller studies have shown that recovery in incomplete tetraplegia may depend on age and the AIS. For 105 subjects with incomplete tetraplegia admitted within 1 week to an SCI center, Burns et al. reported that all AIS D subjects ambulated 200 ft by discharge from the hospital [25]. Only 40 percent of AIS C subjects who were over age 50 achieved a similar level of ambulation, but 90 percent of those younger than age 50 ambulated.

One AIS grade exists in which motor recovery and walking depend on the sensation present within the initial days or weeks. AIS B patients (motor-complete paralysis but sensory-incomplete) have a subgroup with preserved pin sensation, and this group has a greater than 50 percent chance of walking [26].

The mechanism for recovery of these completely paralyzed limbs in sensory-incomplete subjects has been studied in animals, but has been only speculated in subjects with Brown-Séquard. The central pattern generator, which has been known for many years in animals, has become an area of increased interest in the past 10 years in clinical research. The methodology publication of a large clinical trial on the Spinal Cord Injury Locomotor Trial emphasized that the basis for the intervention was established by animal work [27]. The methodology further emphasized the need for rigorous control, designed to reduce bias with predetermined outcome measures. In our opinion, this study serves as a model that future treatment strategies need to emulate.

VALIDITY/RELIABILITY OF FUNCTIONAL CAPACITY SCALES

While the previous sections dealt with impairment measures [5,28] and disability scales (FIM), functional

*Personal communication with H. Frankel; National Spinal Injury Centre, Stroke Mandeville Hospital, Aylesbury, UK; 2001.

capacity scales are a bridge between the two [29]. The Capabilities of Upper Extremity (CUE) instrument reported by Marino et al. measures grasp, release, and reaching actions [16], most of which are required for self-care. CUE is typically a functional-limitation [29] or capacity [30] measure because it does not include devices or personal assistance and is tested in a standardized environment. The new WISCI [20,31] also measures walking activity in a standardized environment (10 m/level surface) and in that sense is a functional-capacity measure as defined by the World Health Organization (WHO) [30]. The WISCI describes walking function on a 21-level scale that integrates walking-aid devices such as walkers/canes and lower-limb stabilization devices such as braces and physical assistance and therefore has features of a disability scale as defined by WHO [30]. The ranking of the WISCI (levels 0–21) (**Table 1**) among international SCI experts was based on the improvement in the impairment (hierarchical) rather than simply independent function; thus, walking independently with a walker (WISCI level 9) or in the parallel bars (WISCI level 5) would be rated lower than walking with no devices and the assistance of one person (WISCI level 17). However, the FIM (global and locomotor subscale 1–7) is almost completely driven by independent walking based on the level of physical assistance (levels 2, 3, and 4) except for level 6 (walking independently with a device) and level 7 (walking independently with no device). Level 6, however, offers no distinction between a device represented by two leg braces in the parallel bars or walker and walking independently either with a short leg brace or a cane alone.

Table 2 shows the difference in focus between the WISCI and the FIM. FIM level 4 is defined as walking with minimal assistance, irrespective of bracing and assistive devices. FIM level 4 includes the following WISCI levels: WISCI level 6 (walker, braces, one-person assistance), level 8 (walker, no braces, one-person assistance), level 14 (one cane/crutch, no brace, one-person assistance), and level 17 (no device, no brace, one-person assistance). This definition is totally consistent with the burden-of-care focus of the FIM. However, the WISCI, which focuses on capacity, rates ambulation higher since less bracing and fewer assistive devices are required. On the other hand, WISCI levels with one-person assistance span FIM levels 1 to 5, indicating various amounts of assistance required.

The new Spinal Cord Independence Measure (SCIM) has three walking subscales, which include three diferent distances, and as a global disability scale, SCIM has been reported as more precise than the FIM when tested on an SCI population [22]. Although neither the FIM nor SCIM has validated its subscales for walking, they are validated as global scales. The SCIM also lacks one of the most commonly scored WISCI levels (WISCI = 13 = walker, no braces, no assistance) [32] and has a more limited number of levels compared with the WISCI [33]. In a preliminary report, 80 acutely injured SCI subjects were examined at the same time as they progressed in their rehabilitation program for lower extremity motor scores (LEMS), WISCI levels, and locomotor FIM levels [34]. Seven different WISCI levels (12–13, 15–17, and 19–20) were recorded for the same locomotor FIM level of 5 (supervision), suggesting that less discrimination may exist in this subscale of the FIM than in the WISCI (**Table 2**). This study also shows that LEMS and WISCI levels correlate and that the progression of the subjects in recovering from SCI follows the hierarchical ranking of

Table 2.
Scores of Locomotor Functional Independence Measure (FIM) and Walking Index for Spinal Cord Injury, version II (WISCI II) performed at 255 evaluations at same time on same 80 subjects.

WISCI Level	FIM Level							Total
	1	2	3	4	5	6	7	
0	89	1	—	1	1	43	—	135
1	2	—	—	—	—	—	—	2
2	—	—	—	—	—	—	—	0
3	—	—	—	—	—	—	—	0
4	4	—	—	—	—	—	—	4
5	—	—	—	—	—	—	—	0
6	—	3	—	4	—	—	—	7
7	—	—	—	2	—	—	—	2
8	3	9	2	6		—	—	20
9	—	1	—	—	—	—	—	1
10	—	—	—	—	—	—	—	0
11	—	—	—	3	—	—	—	3
12	—	—	—	—	2	—	—	2
13	—	—	—	1	8	2	—	11
14	—	—	—	1		—	—	1
15	—	—	—	—	1	1	—	2
16	—	—	—	—	3	4	—	7
17	1	3	2	9	5	—	—	20
18	—	—	—	—	—	—	—	0
19	—	—	—	—	2	4	1	7
20	—	1	—	—	8	1	21	31

the WISCI, except for subjects who progressed too rapidly to the next level.

The WISCI scale has shown face validity [20,31], criterion validity [32], and responsiveness to change* and has been accepted as the standard for evaluation of walking function by the European Clinical Trial Group [35].

CONCLUSION

The WISCI is an instrument designed for measuring progress and improvement in a specific functional capacity (under standardized conditions of task complexity), simple to handle, and usable without need for complex instruction. New and exciting clinical trials will provide opportunities for SCI rehabilitation clinicians to participate in research leading to evidence-based medical practice in the future. Understanding the clinical course of recovery, recognizing accurate examination skills, and appropriately using outcome end points are some of the necessary tools for participation in these trials.

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