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An Integrative Review of Clinical Outcome Assessments Used to Measure Carryover Effects of Exoskeletons and Functional Electrical Stimulation in Spinal Cord Injury

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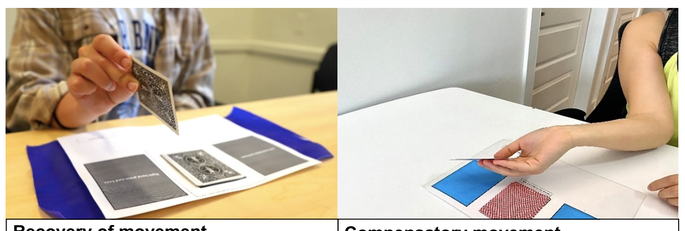
Introduction

- Functional electrical stimulation (FES) and exoskeletons are rehabilitation technologies that provide direct functional ability and potential carryover effects.
- Carryover effects may be due to neuromuscular recovery, behavioral compensation, or a combination of both **(Figure 1)**[1,2,3].
- Clinical outcome assessments (COAs) are used to measure recovery of function with and without the device on.

Figure 1. Example of Recovery of Movement (left) and Compensatory Movement (right)



Recovery of movement	**Compensatory movement**
Grasping the playing card using a 3-jaw chuck, rotate the card face-up via in-hand shifting and place card within designated space on paper via wrist extension with controlled release from fingertips.	Shoulder external rotation to rotate the card face-up.

Purpose

- Identify COAs that have been used to assess carryover effects of FES and exoskeletons in persons with SCI.
- Examine the National Institute of Neurological Disorders and Stroke Common Data Elements (NINDS CDE) for SCI designation for each COA.
- Assess the COAs' ability to distinguish between carryover effects on recovery of function and function due to compensation.

Methods

- Literature search using PubMed and Cochrane Library using all synonyms and relevant MeSH terms.
- Inclusion criteria of studies
  - Written in English
  - Human sample, at least 50% of people with SCI
  - Intervention includes FES and/or exoskeleton
  - Peer-reviewed intervention study
  - Intervention involved repeated training
  - COAs administered without FES/Exoskeleton (carryover)
  - COAs measure motor and/or physical functioning
- Analysis of studies included
  - Name and measurement properties of COAs
  - Ability of COA to distinguish between recovery and compensation
  - NINDS CDE for SCI designation (https://www.commondataelements.ninds.nih.gov/)

Results

- 56 studies met inclusion criteria **(Figure 2).**
- 13 studies on upper limb, 42 studies on lower limb and 1 study on both the upper and lower limb
- 31 studies involved exoskeletons, 23 studies involved FES, and 2 studies involved both exoskeleton and FES
- 38 COAs identified across all studies, counting different versions of the same COA as separate measures.
  - 24 Performance-Based Outcomes (PerfOs) (**Table 1**)
  - 8 Patient-Reported Outcomes (PROs) (**Table 2**)
  - 6 with mode of administration not reported (**Table 3**)
- The 11 most frequently used COAs are shown in **Figure 3**. All other COAs were used in ≤ 3 studies.

Discussion

- Carryover effects of FES and exoskeleton interventions are evaluated in many studies.
- Strengths of COAs reviewed:
  - Wide variety of COAs with constructs measuring motor and physical functioning
  - PerfOs and PROs
- Limitations of COAs reviewed:
  - NINDS CDE for SCI designation for 42.1% of the COAs
  - Few COAs differentiated compensatory movement from recovery of movement (n = 3, 7.89%)
  - Many on ordinal level of measurement
  - Mode of administration not reported for some COAs
- Limitations of the study:
  - Excluded intervention studies other than FES and exoskeletons
  - Integrated review less rigorous than systematic or scoping review

Future Directions and Recommendations

- There is need for COAs with interval scales that distinguish between recovery of function and compensation.
- Studies may want to consider COAs with NINDS CDE designations.
- Studies should be explicit about the mode of COA administration.

Scan this QR code to view the reference list of articles included in this review.

Figure 2. PRISMA Diagram[4]

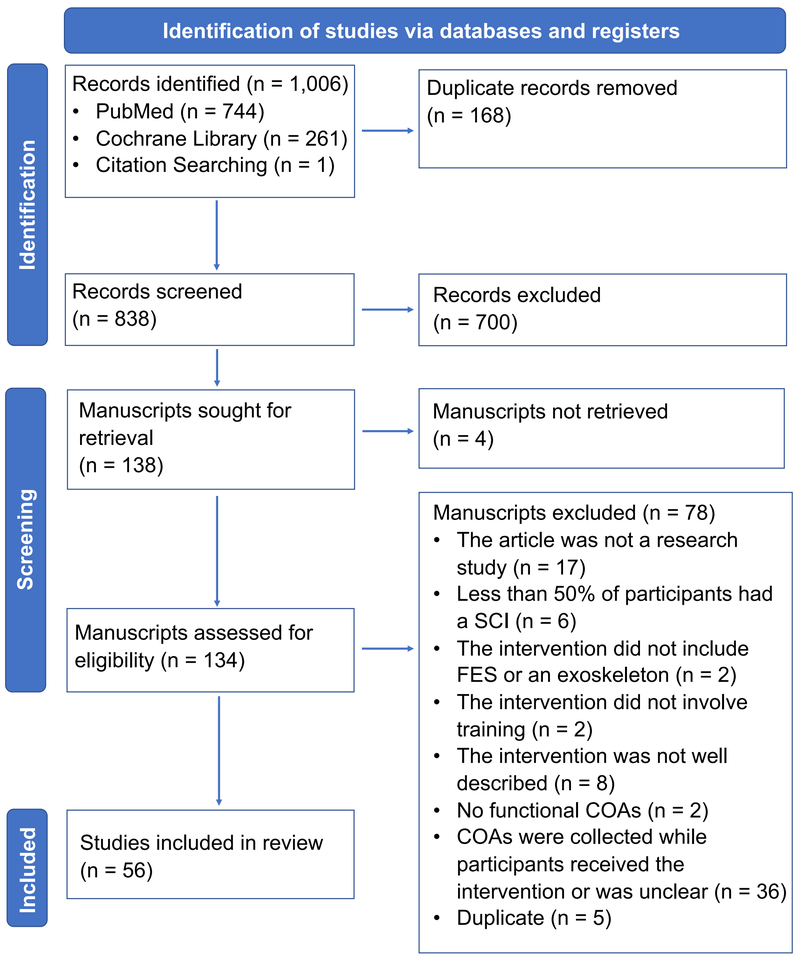


Table 1. Performance-Based Outcomes (PerfOs)

COA	Measurement construct	Scale	Differentiates compensation	NINDS CDE for SCI designation
10 Meter Walk	Gait speed	Ratio	No	Supplemental-Highly Recommended
2 Minute Walk	Endurance	Ratio	No	Supplemental-Highly Recommended
5 Meter Walk	Gait speed	Ratio	No	Not included on CDE for SCI
6 Minute Walk	Endurance	Ratio	No	Supplemental-Highly Recommended
Action Research Arm Test	Upper limb function	Ordinal	No	Not included on CDE for SCI
Activity-Based Balance Level Evaluation	Balance	Ordinal	Not enough information	Not included on CDE for SCI
AuSpinal Test of Hand Function	Unilateral hand function	Nominal and ordinal	Not enough information	Not included on CDE for SCI
Berg Balance Scale	Balance	Ordinal	No	Supplemental
Box and Blocks Test	Unilateral manual dexterity	Ratio	No	Not included on CDE for SCI
Capabilities of the Upper Extremity Test	Limitations in physical function	Ordinal	Yes	Supplemental
Chedoke Arm and Hand Activity Inventory	Upper limb function	Ordinal	No	Not included on CDE for SCI
Functional Ambulation Category	Functional ambulation	Ordinal	No	Not included on CDE for SCI
Graded Redefined Assessment of Strength Sensibility and Prehension	Sensorimotor and prehension	Ordinal	Yes	Supplemental
Grasp and Release Test	Unilateral hand function	Ratio	No	Exploratory
Jebsen-Taylor Hand Function Test	Unilateral hand function	Ratio	No	Supplemental
Mini Balance Evaluation Systems Test	Dynamic balance	Ordinal	No	Exploratory
Modified Action Research Arm Test	Upper limb function	Ordinal	No	Not included on CDE for SCI
Modified Functional Reach Test	Dynamic balance	Ratio	No	Not included on CDE for SCI
Nine Hole Peg Test	Hand dexterity	Ratio	No	Exploratory
Rancho Los Amigos Gait Analysis Assessment	Gait quality	Nominal	Not enough information	Not included on CDE for SCI
Timed Up and Go	Gait function	Ratio	No	Supplemental
Toronto Rehabilitation Institute Hand Function Test	Hand function and grip force	Ordinal and ratio	No	Exploratory
Walking Index for Spinal Cord Injury I&II	Assistance during walking	Ordinal	No	Supplemental (Walking Index for Spinal Cord Injury-II)

Table 2. Patient-Reported Outcomes (PROs)

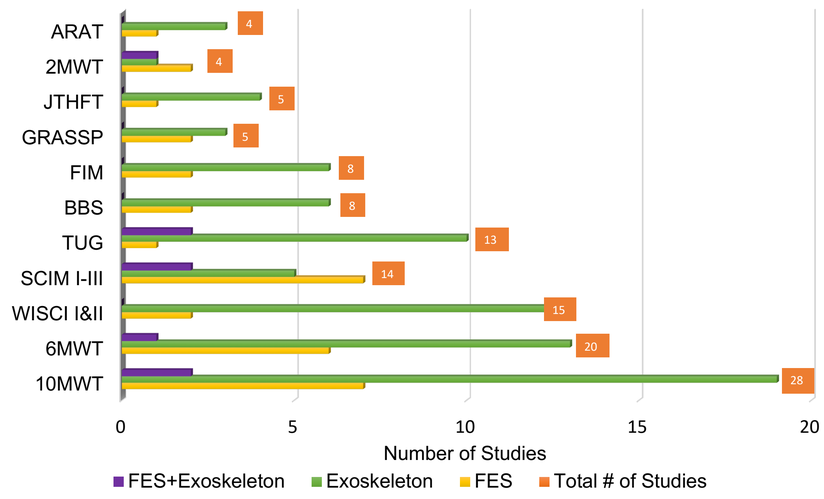
COA	Measurement construct	Scale	Differentiates compensation	NINDS CDE for SCI designation
Canadian Occupational Performance Measure	Performance and satisfaction with activities	Ordinal	No	Supplemental
Goal Attainment Scale	Extent to which a goal is achieved	Ordinal	No	Not included on CDE for SCI
Lawton Instrumental Activities of Daily Living Scale	Functional independence with instrumental activities of daily living	Ordinal	No	Not included on CDE for SCI
Motor Activity Log	Upper limb function	Ordinal	No	Not included on CDE for SCI
Patient's Global Impression of Change Scale	Efficacy of treatment	Ordinal	No	Not included on CDE for SCI
Reintegration to Normal Living Index	Reintegration into activities	Ordinal	No	Not included on CDE for SCI
Spinal Cord Independence Measure-III	Functional status with activities of daily living/ mobility	Ordinal	No	Supplemental-Highly Recommended
Spinal Cord Injury Functional Ambulation Inventory[a]	Functional walking ability	Nominal, ratio, or ordinal	Yes	Supplemental

[a] Spinal Cord Injury Functional Ambulation Inventory has one performance-based item.

Table 3. COA With Mode of Administration Not Reported

COA	Measurement construct	Scale	Differentiates compensation	NINDS CDE for SCI designation
Barthel Index	Level of independence in activities of daily living (ADLs)	Nominal and ordinal	No	Not included on CDE for SCI
Functional Independence Measure	Level of independence in ADLs	Ordinal	No	Not included on CDE for SCI
Modified Barthel Index	Level of Independence in ADLs	Nominal and ordinal	No	Not included on CDE for SCI
Spinal Cord Independence Measure (SCIM I-III)	Functional status with ADLs/mobility	Ordinal	No	Supplemental-Highly Recommended (SCIM-III)

Figure 3. Most Common Functional COAs Reported



Abbreviations: ARAT, Action Research Arm Test; 2MWT, 2 Minute Walk Test; JTHFT, Jebsen-Taylor Hand Function Test; GRASSP, Graded Redefined Assessment of Strength Sensibility and Prehension; FIM, Functional Independence Measure; BBS, Berg Balance Scale; SCIM I-III, Spinal Cord Independence Measure I-III; TUG, Timed Up and Go; WISCI I&II, Walking Index for Spinal Cord Injury I&II; 6MWT, 6 Minute Walk Test; 10MWT, 10 Meter Walk Test.

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