

AWARD NUMBER: W81XWH-21-1-0922

TITLE: Dosing of Overground Robotic Gait Training with Functional Outcomes and Neuroplasticity After Spinal Cord Injury (DOOR SCI)

PRINCIPAL INVESTIGATOR: Chad Swank, PT, PhD

CONTRACTING ORGANIZATION: Baylor Scott & White Research Institute, Dallas, TX

REPORT DATE: October 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) October 2023		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 15Sep2022-14Sep2023
4. TITLE AND SUBTITLE Dosing of Overground Robotic Gait Training with Functional Outcomes and Neuroplasticity After Spinal Cord Injury (DOOR SCI)			5a. CONTRACT NUMBER W81XWH-21-1-0922	
			5b. GRANT NUMBER	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Chad Swank, PT, PhD Christa Ochoa, MPH Faith Meza, MPH			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Baylor Scott & White Research Institute 909 N. Washington Ave., Suite 232 Dallas, TX 75246			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution is unlimited.				
13. SUPPLEMENTARY NOTES				
14. ABSTRACT The goals of this project are 1) to conduct a randomized controlled trial to prospectively examine whether the dosing frequency [24 sessions delivered as high, moderate, or low frequency, defined by number days/week (4, 3, or 2 days/week over 6, 8, 12 weeks)] of robotic gait training (RGT) therapy provided during the acute/subacute recovery phase after incomplete SCI impacts outcomes compared to usual care only; 2) investigate the difference over 9 months of the neuroplastic effect of RGT dosing as measured by single pulse TMS; and 3) evaluate the safety, tolerability, and feasibility of delivering different dosing frequency levels of RGT from inpatient to outpatient rehabilitation settings. Over year 2 of the project, we achieved all IRB and HRPO approvals, engaged our advisory board and DSMB in quarterly meetings, continued participant recruitment and data collection, and participated in dissemination efforts. By grant year 2 end, we had enrolled 41 participants.				
15. SUBJECT TERMS spinal cord injury; robotic gait training; exoskeleton; transcranial magnetic stimulation				
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES
a. REPORT	b. ABSTRACT	c. THIS PAGE		
Unclassified	Unclassified	Unclassified	Unclassified	79
			19a. NAME OF RESPONSIBLE PERSON USAMRDC	
			19b. TELEPHONE NUMBER (include area code)	

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1. INTRODUCTION:

Emerging evidence indicates that robotic exoskeleton use results in positive outcomes for those with chronic SCI, yet limited evidence exists for the acute setting. The potential benefit of robotic gait training (RGT) initiated during inpatient rehabilitation when recovery is greatest is unknown yet appears promising due to established principles of neuroplasticity and the fact that RGT incorporates the critical components of gait training. As a result of the lack of evidence, no clinical practice guidelines exist that delineate which gait retraining approach or dose during early phases of recovery results in the best outcomes for people with motor incomplete SCI. This project will be the first to (1) generate efficacy data concerning the dose of RGT initiated during early phases of recovery in people with SCI, (2) provide mechanistic data of neuroplasticity based on RGT dose, and (3) confirm that the intervention is safe, tolerable, and feasible to administer across inpatient and outpatient rehabilitation settings. Findings will directly impact rehabilitation clinical practice and patient outcomes for people with motor incomplete SCI.

2. KEYWORDS:

spinal cord injury; robotic gait training; exoskeleton; transcranial magnetic stimulation

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Study Specific Aims:

Aim 1: Using a randomized controlled trial, prospectively examine whether the dosing frequency [24 sessions delivered as high, moderate, or low frequency, defined by number days/week (4, 3, or 2 days/week over 6, 8, 12 weeks)] of RGT therapy provided during the acute/subacute recovery phase after incomplete SCI impacts outcomes compared to usual care only.

Aim 2: Investigate the difference over 9 months of the neuroplastic effect of RGT dosing as measured by single pulse TMS.

Aim 3: Evaluate the safety, tolerability, and feasibility of delivering different dosing frequency levels of RGT from inpatient to outpatient rehabilitation settings.

	Timeline [Year(Quarter)]	Status (Percent complete)
Major Task 1: Achieve IRB Approval		
Coordinate with Sites for clinical trial agreements (CTAs) submission	Y1(Q1)	Complete (100%)
Coordinate with Sites for nondisclosure agreements (NDAs).	Y1(Q1)	Complete (100%)
Refine eligibility criteria, exclusion criteria, screening protocol	Y1(Q1)	Complete (100%)

Finalize consent form & human subjects protocol	Y1(Q1)	Complete (100%)
Coordinate with Sites for IRB protocol submission	Y1(Q1)	Complete (100%)
Obtain HRPO approval	Y1(Q2)	Complete (100%)
Submit amendments, adverse events and protocol deviations	As Needed	Complete (100%)
Coordinate with Sites for annual IRB report for continuing review	Annually	In progress (50%)
<i>Milestone Achieved: Local IRB approval at BSW and TWU</i>	Y1(Q1)	Complete (100%)
<i>Milestone Achieved: IRB approval at HARPO</i>	Y1(Q2)	Complete (100%)
Major Task 2: Train and Coordinate Study Staff for Clinical Trial		
Training of Study Staff		
Coordinate with Sites for training staff until 100% concordance with study protocol and site-specific demands	Y1-Y4(Q1)	Complete (100%)
<i>Milestone Achieved: Research staff trained</i>	Y1(Q1)	Complete (100%)
Major Task 3: Patient Recruitment and Enrollment		
Subtask 1: Recruitment of 144 patients admitted to BSW for inpatient rehabilitation	Y1(Q2)-Y4(Q1)	In progress (~28%) <i>41 of 144 participants enrolled</i>
<i>Milestone Achieved: Maintained ongoing recruitment procedure throughout duration of clinical trial</i>	Y1(Q2)-Y4(Q1)	In progress: (~55%) <i>6 of 11 quarters completed</i>
Subtask 2: Enrollment of 144 patients into study		
Patients complete assigned dosing group intervention during inpatient and outpatient rehabilitation. High frequency group: 4 sessions/week x 6 weeks (n=36) Moderate frequency group: 3 sessions/week x 8 weeks (n=36) Low frequency group: 2 sessions/week x 12 weeks (n=36) Control group: usual care only, no RGT sessions (n=36)	Y1(Q3)-Y4(Q1)	In progress (~22%)
Patients complete clinical assessments including but not limited to WISCI-II, 10MWT, and SCIM. Assessments for the RGT groups will be conducted on 5 occasions: (1) admit to and (2) discharge from inpatient rehabilitation, (3) completion of 24 sessions, (4) 1-month post RGT, and (5) 9-months post-SCI. The control would complete assessments at 5 timepoints corresponding to the RGT groups	Y1(Q3)-Y4(Q3)	In progress (~9%)

[(1) inpatient admit (2) inpatient discharge, (3) 1-month post inpatient discharge, 4) 2-months post inpatient rehabilitation discharge, and (5) 9-months post-injury].		
Patients complete research self-report assessments, including but not limited to NPRS, FSS, PSFS, PHQ-9, and LiSAT9. Assessments will be conducted on 5 occasions: (1) admit to and (2) discharge from inpatient rehabilitation, (3) completion of 24 sessions, (4) 1-month post RGT, and (5) 9-months post-SCI.	Y1(Q3)-Y4(Q3)	In progress (~9%)
Patients complete transcranial magnetic stimulation (TMS) assessments during inpatient and outpatient rehabilitation	Y1(Q3)-Y4(Q3)	In progress (~8%)
<i>Milestone Achieved: Report quarterly patients enrolled and findings from patients completing study</i>	Y1(Q3)-Y4(Q3)	In progress (25%)
Major Task 4: Data Analysis		
<i>Subtask 1: Amalgamate site specific assessments for data analysis</i>		
Coordinate TMS data sharing from TMS assessments	Y1(Q3)-Y4(Q4)	In progress (50%)
Build database consistent with outcomes	Y1(Q3)	Completed (100%)
Clean and manage data for analysis	Y1-4(Q4)	In progress (25%)
Subtask 2: Conduct data analysis using methodologies including but not limited to general linear mixed effects models to assess the differences between groups and over time, as well as the time by group interaction.	Y1-4(Q4)	Pending (0%)
<i>Milestone Achieved: Report findings from Outcomes assessments</i>	Y1-4(Q4)	Pending (0%)
Major Task 5: Dissemination		
<i>Subtask 1: Scientific & Peer Reviewed Efforts</i>		
Generate presentation(s) for national conferences	Y1-4(Q4)	In progress (30%)
Generate manuscript(s) for submission to peer reviewed journals	Y1-4(Q4)	Pending (5%)
Generate plain language summaries for consumers/policymakers	Y1-4(Q4)	Pending (0%)
<i>Subtask 2: Non-Refereed Activities</i>		
Conduct Consumer Seminar	Y3(Q4)	Pending (15%)
Conduct VA Educational Meeting	Y3(Q4)	Pending (15%)
Conduct VA Educational Meeting	Y3(Q4)	Pending (10%)
Conduct Clinician-Researcher workshops	Y4(Q4)	Pending (10%)

<i>Milestone Achieved: Report findings (agendas, meeting summaries/notes/minutes) from non-refereed activities</i>	Y3-4(Q4)	Pending (0%)
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What was accomplished under these goals?

Over the past year, we have achieved the following:

1. Obtained Continuing Review approvals (Major Task 1).
 - a. Baylor Scott & White (BSW) IRB approval on 7/21/2022 (CY21-22); 7/20/2023 (CY22-23)
 - b. TWU IRB approval on 8/9/2022 (CY21-22); 7/26/2023 (CY22-23)
 - c. OHRO IRB Approval on 1/6/2023
2. Convened our Advisory Board including individuals with SCI Lived Experience on 10/17/2022, 2/27/2023, and 7/11/2023 (Major Task 2).
 - a. The purpose of these meetings is to review the project goals, protocol, and progress with the stakeholders in addition to obtaining their feedback related to potential recruitment and retention issues.
3. Convened our quarterly DSMB meetings to review study progress on 10/19/2022, 1/18/2023; 4/26/2023; and 7/12/2023.
4. Continued conversations with the VA North Texas Health Care System, stakeholders with SCI lived experience, and BSW administrators to develop educational workshops for study years 3 and 4 (Major Task 5).
 - a. We established a monthly standing meeting to make steady progress towards this deliverable. We are planning to host the Year 3 workshop on October 31, 2024.
5. Conducted ongoing staff training on study procedures, study protocol, TMS and SCI transfers.
6. Completed database development and conducted quarterly data and source document checks.
7. Maintained our Standard Operating Procedures and Data Management Plan.
8. Engaged in continued Patient Recruitment & Enrollment efforts (Major Task 3).
 - a. As of 9/14/2023:
 - i. Screened 244 admissions with SCI for study eligibility.
 - ii. Of the 65 eligible patients, we enrolled 41 participants into the study and continued data collection.
9. Coordinated TMS data sharing between BSW and TWU.
10. Delivered scientific presentations at the following conferences: American Spinal Injury Association (ASIA) Conference 2022, Combined Sections Meeting, American Physical Therapy Association (2023) Conference, American Society of Neurorehabilitation (2023) Annual Meeting, American Spinal Injury Association Annual (2023) Scientific Meeting, American College of Sports Medicine (2023) Annual Meeting, Rehabilitation Engineering and Assistive Technology Society of North America (2023) Conference, and Academy of Spinal Cord Injury Professionals (2023) Conference (Major Task 5).
11. Submitted five manuscripts related to SCI and robotic gait training for publication to peer reviewed journals (Major Task 5).

- a. Gillespie, J, Arnold, D, Trammell, M, Bennett, M, Ochoa, C, Driver, S, Callender, L, Sikka, S, Dubiel, R & Swank, C. Utilization of overground exoskeleton gait training during inpatient rehabilitation – a descriptive analysis. *Journal of Neuroengineering and Rehabilitation*. 20.1 (2023): 102.
- b. Bosteder, K, Moore, A, Weeks, A, Dawkins, J, Trammell, M, Driver, S, Hamilton, R, & Swank, C. Intensity of overground robotic exoskeleton training in two persons with complete tetraplegia: a case series. *Spinal Cord Series and Cases*. 9(1) (2023): 24.
- c. Arnold, D, Gillespie, J, Bennett, M, Callender, L, Sikka, S, Hamilton, R, Driver, S & Swank, C. Clinical delivery of overground exoskeleton gait training in persons with spinal cord injury across the continuum of care: a retrospective analysis. *Topics in Spinal Cord Injury Rehabilitation*. (in press).
- d. Shih, H-T, Goh, H-T, Sikka, S, Hamilton, R, & Swank, C. Regaining walking and restoring corticospinal tract excitability after neuromyelitis optica spectrum disorder: a case report. *Neuroimmunology Reports*. (submitted – under review).
- e. Holden, A, Ochoa, C, Driver, S, Sikka, S, Hamilton, R, Goh, H-T, Callender, L, Bennett, M, Shih, H-T, & Swank, C. Dosing Overground Robotic Gait Training after Spinal Cord Injury: A Randomized Clinical Trial Protocol. *Spinal Cord*. (submitted – under review).

What opportunities for training and professional development has the project provided?

Members of the study team attended the following conferences:

2022 (Nov) American Congress of Rehabilitation Medicine Progress in Rehabilitation Research Annual Conference in Chicago, IL:

- Chad Swank, PT, PhD (PI)
- Rita Hamilton, DO (Co-I)
- Seema Sikka, MD (Co-I)
- Jaime Gillespie, PT, DPT (Study Therapist)
 - Presented “Elevating Current Practice with Exoskeletons: Overground Robotic Gait Training During Inpatient Rehabilitation” (symposium)
- Danae Arnold, PT, DPT (Study Therapist)

2023 (Feb) Combined Sections Meeting, American Physical Therapy Association in San Diego, CA.

- Chad Swank, PT, PhD (PI)
- Jaime Gillespie, PT, DPT (Study Therapist)

- Presented “Elevating Current Practice with Exoskeletons: Overground Robotic Gait Training During Inpatient Rehabilitation” (symposium)
- Danna Arnold, PT, DPT (Study Therapist)
 - Presented “Survey says: Therapists’ Clinical Decisions Guiding Overground Exoskeleton Gait Training during Inpatient Rehabilitation.” (poster)

2023 (March) American Society of Neurorehabilitation Annual Meeting in Charleston, SC.

- Chad Swank, PT, PhD (PI)
- Hui-Ting Goh, PT, PhD (Co-I)
 - Presented: “Tracking walking recovery in individuals with motor incomplete spinal cord injury with transcranial magnetic stimulation: preliminary findings.” (poster)
- Hui-Ting Shih, PT, PhD (Post-doctoral Fellow)

2023 (April) American Spinal Injury Association Annual Scientific Meeting in Atlanta, GA

- Chad Swank, PT, PhD (PI)
- Simon Driver, PhD (Co-I)
- Rita Hamilton, DO (Co-I)
- Seema Sikka, MD (Co-I)
- Hui-Ting Shih, PT, PhD (Post-doctoral Fellow)
 - Presented: “Transcranial Magnetic Stimulation Assessment in Patients with Subacute Spinal Cord Injury during Inpatient Rehabilitation.” (platform)
- Faith Meza, MPH (Study Coordinator)
 - Presented: “Spinal Cord Injury Enrollment Experiences in Studies Using Overground Exoskeleton Gait Training During Inpatient Rehabilitation.” (poster)

2023 (May) American College of Sports Medicine Annual Meeting, World Congress on Exercise is Medicine in Denver, CO

- Chad Swank, PT, PhD (PI)
 - Presented: “Intensity of Overground Robotic Exoskeleton Exercise Training Conditions in an Adult with Chronic, Motor-Complete Tetraplegia.” (poster)
 - Presented: “Intensity Of Overground Robotic Exoskeleton Gait Training in Patients with Spinal Cord Injury During Inpatient Rehabilitation.” (poster)
- Simon Driver, PhD (Co-I)

2023 (July) Rehabilitation Engineering and Assistive Technology Society of North America Conference in New Orleans, LA.

- Danna Arnold, PT (Study Therapist)
 - Presented: “Is there a place for robotic exoskeletons to improve health and function of persons with SCI undergoing rehabilitation?” (symposium)

2023 (Sept) Academy of Spinal Cord Injury Professionals in San Diego, CA.

- Chad Swank, PT, PhD (PI)
 - Presented: “Is there a place for Overground Robotic Exoskeletons in Rehabilitation?” (symposium)
- Danna Arnold, PT (Study Therapist)
 - Presented: “Clinical reasoning and user experience of exoskeleton-assisted therapy in inpatient rehabilitation.” (symposium)
- Lindsey Wynne, PT (Study Therapist)

How were the results disseminated to communities of interest?

Presentations (oral and poster) at scientific meetings.

What do you plan to do during the next reporting period to accomplish the goals?

We intend to continue to screen and enroll participants into the study while conducting data collection across all assessment periods (Major Task 3). We have developed a working group including our partners with SCI lived experience to develop the educational workshops for Year 3 & 4 in collaboration with the VA (Major Task 5). We intend to conduct our Year 3 workshop in October 2024. We will also continue to engage in dissemination efforts including publication of SCI and robotic exoskeleton-related manuscripts and presentations at scientific conferences. (Major Task 5).

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The findings from this study will provide the first evidence-based guidelines for RGT dosing (including outcomes related to walking function, neuroplasticity and feasibility) during inpatient and outpatient rehabilitation during the subacute phase of recovery after SCI. The principal discipline to benefit from the findings of this study is physical therapy. Physical therapists within BSW, members of our Advisory Board and DSMB have reported considerable interest in our study topic and findings. Additionally, physical therapy colleagues at scientific conferences CSM2023, ASNR2023, ASIA2023, RESNA2023, and ASCIP2023 indicate interest in our pending study findings and scheduled educational workshop(s).

What was the impact on other disciplines?

Rehabilitation is a team sport and this study takes place within inpatient and outpatient rehabilitation settings. The allied health providers (physician, nursing, occupational therapy, speech therapy) within BSW have collectively supported this study by helping identify interested patients and sharing IRB approved study flyers with patients. In addition, case

managers have provided transportation options with study participants for return to the outpatient setting to complete study activities.

Beyond the walls of BSW, conversations with colleagues at the VA North Texas Health Care System to develop educational workshops indicate interest in our pending study findings. Additionally, allied health colleagues at scientific conferences CSM2023, ASNR2023, ASIA2023, RESNA2023, and ASCIP2023 indicate interest in our pending study findings. Overall, the study has been well-received by our colleagues in the scientific and clinical community.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

We have engaged in conversations with robotic exoskeleton industry providers Ekso Bionics and ReWalk to strengthen our developing relationship. The goal of these conversations with the robotic exoskeleton industry whereby study findings can inform the 'next generation' of robotic exoskeleton technology. We hope to leverage this relationship with industry to facilitate 'next generation' of robotic exoskeletons to maximize outcomes for people after SCI. We have invited Ekso Bionics and ReWalk to participate in our educational workshops alongside researchers, clinicians and individuals with SCI lived experience.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Our original randomized control trial lacked a true (no RGT) control group. Based upon the recommendation of the Reviewers, our Advisory Board of individuals with SCI lived experience, and the DSMB, our study team met with our biostatistician Dr. Monica Bennett to explore the inclusion of a true control group as a fourth group. As a team, we arrived at consensus for the following proposed amendments to the study protocol. This change to the protocol was approved in a revised Statement of Work and by HRPO, in addition to our local IRB, in grant year 1. There have been no subsequent changes in approach.

Actual or anticipated problems or delays and actions or plans to resolve them

As planned, we initiated recruitment and enrollment during Y1Q3. During the Y1Q3-Y2Q4, recruitment has been slower than initially anticipated (n=13 patients/quarter). This slower recruitment rate is partially explained by not initiating recruitment until the second month of Y1Q3 as we awaited IRB approval for the addition of the control arm to the study. Other potential reasons for the slower recruitment may include:

- Ineligibility of patients screened to date (n=244). Common reasons for exclusion include:
 - Not AIS level C or D (n=135)
 - *Patient lives >90 miles away from the rehabilitation facility (n=22) → removed in protocol V1.9*
 - Not within the acute/subacute recovery period (i.e. greater than 6-months post-injury) (n=40)
 - Patient did not meet Ekso manufacturer device requirements (n=48)
- Fewer SCI admissions compared to prior calendar years.
- Internal enrollment processes.

As of 9/15/2022, 65 patients met the eligibility criteria and were approached to participate in the study. However, 24 patients declined to participate. Commonly expressed reasons for declined to participate were 1) having no interest in study participation, 2) feeling overwhelmed, 3) not wanting to risk being randomized to the control group, 4) concerns over access to transportation (for post-inpatient rehabilitation RGT sessions and assessments), 5) unease over additional caregiver burden, and 6) desire to prioritize other activities.

We are undertaking the following action steps to identify solutions to increase enrollment:

- We are examining our internal screening and recruitment processes.
- We are engaging with our advisory board including stakeholders with SCI Lived Experience to address above stated reasons for declining to participate including providing opportunities for peer mentoring conversations between our stakeholders with SCI Lived Experience and study participants.
- We are engaging with our DSMB.
- We are working with our institutional liaison coordinator to specifically facilitate SCI admissions from local Level 1 trauma centers to our rehabilitation institution.
- We worked with our PM&R physician group to support the hiring of a new SCI physician. A strong candidate was identified and hired as staff SCI physician to provide inpatient and outpatient service. He started in September 2023 following completion of his SCI fellowship at University of Miami.

We are encouraged by the results of implementing prior recommendations from our advisory board (including persons with SCI lived experience) and DSMB. Specifically, the average quarterly enrollment over the last 3 quarters has improved (n=10) compared to the initial 3 quarters (n=4).

Changes that had a significant impact on expenditures

None to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

None to report.

Significant changes in use or care of human subjects

None to report.

Significant changes in use or care of vertebrate animals

N/A.

Significant changes in use of biohazards and/or select agents

None to report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

- Gillespie, J, Arnold, D, Trammell, M, Bennett, M, Ochoa, C, Driver, S, Callender, L, Sikka, S, Dubiel, R & **Swank, C**. Utilization of overground exoskeleton gait training during inpatient rehabilitation – a descriptive analysis. *Journal of Neuroengineering and Rehabilitation*. 20.1 (2023): 102.
- Bosteder, K, Moore, A, Weeks, A, Dawkins, J, Trammell, M, Driver, S, Hamilton, R, & Swank, C. Intensity of overground robotic exoskeleton training in two persons with complete tetraplegia: a case series. *Spinal Cord Series and Cases*. 9(1) (2023): 24.
- Arnold, D, Gillespie, J, Bennett, M, Callender, L, Sikka, S, Hamilton, R, Driver, S & **Swank, C**. Clinical delivery of overground exoskeleton gait training in persons with spinal cord injury across the continuum of care: a retrospective analysis. *Topics in Spinal Cord Injury Rehabilitation*. (in press).

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Conference Presentations:

Wynne, L, Arnold, D, Gillespie, J, Trammell, M, & Swank, C. (September 2022) Dynamic variable exoskeleton gait training following spinal cord injury in inpatient rehabilitation: A case series. Academy of Spinal Cord Injury Professionals. Kansas City, MO.

Arnold, D, Gillespie, J, Trammell, M, Stevens, C, Bennett, M, Callender, L, Sikka, S, & Swank, C. (September 2022) Clinical delivery of overground exoskeleton gait training in persons with spinal cord injury across the continuum of care: a retrospective analysis. Academy of Spinal Cord Injury Professionals. Kansas City, MO. (oral presentation).

Brown, K, Trammell, M, Moore, A, Weeks, A, Wynne, L, Gilliland, T, Reynolds, M, McShan, E, Driver, S, Sikka, S, Hamilton, R, & Swank, C. (September 2022) Metabolic testing for exercise intensity during overground robotic exoskeleton gait training in two persons with complete tetraplegia. Academy of Spinal Cord Injury Professionals. Kansas City, MO.

Gillespie, J, Trammell, M, Arnold, D, Sikka, S, Dubiel, R, & Swank, C. (November 2022) Elevating Current Practice with Exoskeletons: Overground Robotic Gait Training During Inpatient Rehabilitation. American Congress of Rehabilitation Medicine Progress in Rehabilitation Research Annual Conference. Chicago, IL. (symposium).

Arnold, D, Gillespie, J, Ochoa, C & Swank, C (February 2023) Survey says: Therapists' Clinical Decisions Guiding Overground Exoskeleton Gait Training during Inpatient Rehabilitation. Combined Sections Meeting, American Physical Therapy Association. San Diego, CA.

Sajan, S, Shih, H-T, Parikh, V, Meza, F, Suhalka, A, Swank, C & Goh, H-T (March 2023) Tracking walking recovery in individuals with motor incomplete spinal cord injury with transcranial magnetic stimulation: preliminary findings. 2023 American Society of Neurorehabilitation Annual Meeting. Charleston, SC.

Meza, F, Gillespie, J, Arnold, D, Sikka, S, & Swank, C (April 2023) Spinal Cord Injury Enrollment Experiences in Studies Using Overground Exoskeleton Gait Training During Inpatient Rehabilitation. American Spinal Injury Association 2023 Annual Scientific Meeting. Atlanta, GA.

Shih, HT, Goh, HT, Ochoa, C, Driver, S, Sikka, S, Hamilton, R, & Swank, C (April 2023) Transcranial Magnetic Stimulation Assessment in Patients with Subacute Spinal Cord Injury during Inpatient Rehabilitation. American Spinal Injury Association 2023 Annual Scientific Meeting. Atlanta, GA (oral presentation).

Brown, K, Elliot, C, McCorkle, M, Wynne, L, Gillespie, J, Arnold, D, Sikka, S, Driver, S, & Swank, C. (May 2023) Intensity Of Overground Robotic Exoskeleton Gait Training in Patients with Spinal Cord Injury During Inpatient Rehabilitation. American College of Sports Medicine Annual Meeting, World Congress on Exercise is Medicine. Denver, CO (poster)

Swank, C, Brown, K, McCorkle, M, Elliot, C, Gillespie, Trammell, M, Arnold, D, Hamilton, R, & Driver, S. (May 2023) Intensity of Overground Robotic Exoskeleton Exercise Training Conditions in an Adult with Chronic, Motor-Complete Tetraplegia. American College of Sports Medicine Annual Meeting, World Congress on Exercise is Medicine. Denver, CO (poster)

Arnold, D, Gillespie, J, Shih, H-T, & Swank, C. (July 2023) Is there a place for robotic exoskeletons to improve health and function of persons with SCI undergoing rehabilitation? Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) 2023 Conference. New Orleans, LA. (symposium).

Arnold, D, Shih, H-T, Gillespie, J, Wynne, L, & Swank, C. (Sept 2023) Clinical reasoning and user experience of exoskeleton-assisted therapy in inpatient rehabilitation. Academy of Spinal Cord Injury Professionals. San Diego, CA. (symposium).

Nolan, KJ, Swank, C, & Tefertiller, C (Sept 2023) Is there a place for Overground Robotic Exoskeletons in Rehabilitation? Academy of Spinal Cord Injury Professionals. San Diego, CA. (symposium).

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Chad Swank, PT, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): [0000-0002-7865-179X](https://orcid.org/0000-0002-7865-179X)
Nearest person month worked: 3.0

Contribution to Project: Dr. Swank oversees all aspects of the project including scientific oversight and management of day-to-day issues that arise (e.g., leading weekly meeting, budget, IRB, recruitment), attends weekly meetings, provides training and supervision on assessments of functional measures (10-meter walk test, WISCI-II), and oversees recruitment strategies, Consumer Advocates, data collection, results, and dissemination activities.

Name: Simon Driver, PhD
Project Role: Co- Investigator
Researcher Identifier (e.g. ORCID ID): [0000-0003-2356-432X](#)
Nearest person month worked: 1.2
Contribution to Project: Dr. Driver attends weekly meetings, supports Dr. Swank with study administration including actigraphy, assists with recruitment strategies, protocol for treatment fidelity, data collection, results, and dissemination activities.

Name: Rita Hamilton, DO
Project Role: Co- Investigator
Researcher Identifier (e.g. ORCID ID): [0000-0002-8893-2739](#)
Nearest person month worked: 1.2
Contribution to Project: Dr. Hamilton attends weekly meetings, provides medical oversight, rehabilitation hospital administrative assistance, and assists with screening, recruitment, results, and dissemination activities.

Name: Seema Sikka, MD
Project Role: Co- Investigator
Researcher Identifier (e.g. ORCID ID): [0000-0003-4918-4480](#)
Nearest person month worked: 1.2
Contribution to Project: Dr. Sikka attends weekly meetings, provides medical oversight, and assists with screening, recruitment, results, and dissemination activities.

Name: Hui-Ting Goh, PT, PhD
Project Role: Co- Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0001-9460-9869
Nearest person month worked: 3.0
Contribution to Project: Dr. Goh oversees the TWU subaward, attend weekly meetings, administers TMS assessments, processes and analyzes TMS data, trains staff for assisting with TMS assessments, and assists with results and dissemination activities.

Name: Hui-Ting Shih, PhD
Project Role: Postdoctoral Researcher
Researcher Identifier (e.g. ORCID ID): 0000-0002-1757-9691
Nearest person month worked: 5.0
Contribution to Project: Dr. Shih has completed training on the study protocol including with Dr. Goh to collect TMS data and troubleshoot issues. Dr. Shih attends weekly meetings, assists with recruitment strategies, protocol for treatment fidelity, data collection,

results, and dissemination activities. She completed her post-doctoral fellowship in July 2023 under the mentorship of Drs. Swank (PI) and Driver (Co-I).

Name: Alexandria Suhalka
Project Role: Lead Project Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0001-9533-9872
Nearest person month worked: 12.0
Contribution to Project: Ms. Suhalka, formerly Ms. Holden, serves as the project coordinator and is responsible for recruitment and project management.

Name: Christa Ochoa
Project Role: Project Coordinator
Researcher Identifier (e.g. ORCID ID): [0000-0002-9252-5247](#)
Nearest person month worked: 7.2
Contribution to Project: Ms. Ochoa has provided data management/quality assurance and database maintenance during the study-startup phase and initial recruitment/enrollment period. She has also handled all IRB and DoD correspondence.

Name: Librada Callender
Project Role: Project Manager
Researcher Identifier (e.g. ORCID ID): [0000-0002-8655-6952](#)
Nearest person month worked: 0.6
Contribution to Project: Ms. Callender has worked with coordinators and Dr. Swank to ensure progress of the project towards the quarterly goals has been achieved.

Name: Faith Meza
Project Role: Project Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.0
Contribution to Project: Ms. Meza has assisted with study screening, enrollment, and recruitment. She is also currently working on scheduling, data collection, data entry, and planning for the Years 3 and 4 workshops.

Name: Sara Baltz
Project Role: Project Coordinator Assistant
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.0
Contribution to Project: Ms. Baltz joined the study team in March 2023 and has assisted with study screening, enrollment, and recruitment. She is also currently working on scheduling, data collection, and data entry.

Name: Elliot Forst
Project Role: Project Coordinator Assistant
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.0

Contribution to Project: Mr. Forst joined the study team in August 2023 and has assisted with study screening, enrollment, and recruitment. He is also currently working on scheduling, data collection, and data entry.

Name: Danae Arnold
Project Role: Research Physical Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.0
Contribution to Project: Ms. Arnold has completed study-related training and assisted with study recruitment, assessments, and intervention delivery.

Name: Jaime Gillespie
Project Role: Research Physical Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.0
Contribution to Project: Ms. Gillespie has completed study-related training and assisted with study recruitment, assessments, and intervention delivery.

Name: Lindsey Wynne
Project Role: Research Physical Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.0
Contribution to Project: Ms. Wynne joined the study team in February 2023 and has completed study-related training and assisted with study recruitment, assessments, and intervention delivery.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report.

What other organizations were involved as partners?

Organization Name: Texas Woman's University
Location of Organization: Dallas, Texas
Partner's contribution to the project: Collaboration with Dr. Hui-Ting Goh

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable.

QUAD CHARTS: See Appendix III.

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

APPENDIX I. ABSTRACTS FROM SCIENTIFIC PRESENTATIONS

ASIA 2022 Conference Abstract, presented May 2022

Title: Dosing Overground Robotic Gait Training after Spinal Cord Injury: Department of Defense Protocol

Presenter: Alexandria Holden, MPH

Authors: Alexandria Holden, Rita Hamilton, Seema Sikka, Hui-Ting Goh, Simon Driver, Chad Swank,

Abstract/Course Body Background: Robotic exoskeletons have changed rehabilitation care available to people after spinal cord injury (SCI). Our pilot data suggest that using overground robotic gait training (RGT) can be feasibly integrated into acute clinical practice, yield greater improvements in gait than usual care, and enable a dose of 140% more minutes walking than usual care. Yet, the current evidence base is insufficient to identify the optimal dose and neurophysiological mechanism of RGT as an effective rehabilitation approach. We will 1) examine whether the frequency of RGT after motor incomplete SCI impact's function and health outcomes, 2) analyze the difference of the neuroplastic effect of RGT dose as measured by transcranial magnetic stimulation (TMS), 3) evaluate the safety (rate of adverse events), tolerability (visual analog scale), and feasibility (treatment completion rate) of delivering different RGT dose. Study Design: We will randomize 138 patients with motor incomplete SCI into 1 of 3 RGT frequency groups (high, moderate, or low) based on injury severity and level. Patients will complete assessments at 5 time points: inpatient admission and discharge, after completing 24 RGT sessions, 1-month post-RGT, and 9-months post-SCI. RGT sessions will use the Ekso econdary outcomes are gait speed, Spinal Cord Independence Measure, Numeric Pain Rating Scale, Fatigue Severity Scale, Penn Spasm Frequency Scale, Patient Health Questionnaire-9, Life Satisfaction Questionnaire-9, and physical activity. Neurophysiological measures will include MEP amplitudes obtained using TMS. Dosing effects of RGT will be evaluated using general linear mixed effects models to analyze differences between groups, settings, and the interaction. Clinical Impact: Our study tackles critical robotic exoskeleton [class II medical device (United States FDA)]. Our primary outcome is WISCI-II. S questions of dosing gait training interventions for people with SCI during subacute rehabilitation and links dose with neurophysiological markers of neuroplasticity with delivery across rehabilitation care settings. Support: DOD, W81XWH-21-1-0922 The contents of this abstract were developed under a grant from the Department of Defense office of the Congressionally Directed Medical Research Programs (grant number W81XWH2110922). Opinions, interpretations, conclusions, and recommendations are those of the author(s) and are not necessarily endorsed by the Department of Defense.

Learning Objectives: Discuss robotic gait training as a rehabilitation tool and potential impact on neuroplasticity, function, and health outcomes.

ASCIP 2022 Conference & Expo, presented September 2022

Title: Dynamic variable exoskeleton gait training following spinal cord injury in inpatient rehabilitation: A case series.

Authors: Lindsey Wynne, PT, DPT, NCS1; Danna Arnold, PT, DPT, ATP2; Jaime Gillespie, PT, DPT; Molly Trammell, PT1; Seema Sikka, MD1; Faith Meza, BS2; Angelo Abis, SPT1; Chad Swank, PT, PhD, NCS

Context: Promoting gait adaptability is critical for improving gait following spinal cord injury (SCI). Recent advances in exoskeleton technology allow for dynamic stepping tasks (e.g. multidirectional stepping, challenging stability by reducing device assistance, adding resistance to step trajectory) during overground exoskeleton gait training (OEGT). This case series describes incorporating dynamic stepping tasks during OEGT for three individuals with incomplete SCI during inpatient rehabilitation. Outcomes included OEGT session metrics [step count and walk duration], walking measures [Walking Index for Spinal Cord Injury-revised (WISCI-II) and 10-meter walk test (10mWT)], and cardiovascular intensity [heart rate (HR), rate of perceived exhaustion (RPE)].

Findings: Patients [males, aged 29 to 51 years, with tetraplegia, ASIA Impairment Scale D (AIS D)] completed OEGT [sessions Patient A=2, Patient B=4, Patient C=3; walk duration (average minutes) A=21:03, B=18:24, C=21:40; step count A=1290, B=835, C=664] during inpatient rehabilitation. Positive changes were observed in WISCI-II (A=12 levels, B=20, C=20 and gait speed (A=3.16m/s, B=2.12m/s, C=1.26 m/s). Moderate HR intensity (A=34% of OEGT session, B=75%, C=36%) and high HR intensity (A=1%, B=2.5%, C=22%) were observed during OEGT sessions. Patients generally perceived attaining moderate intensity (RPE: A=2, B=6, C=5).

Clinical Relevance: Contemporary exoskeleton devices allow for dynamic stepping tasks beyond active assistance gait training. Dynamic stepping tasks were incorporated during OEGT for 3 patients with AIS D tetraplegia SCI to maximize gait training progression during inpatient rehabilitation. Physiologic and patient-report indicators of cardiovascular intensity suggest dynamic stepping tasks during OEGT were tolerated without undue burden.

Learning Objectives: (1) Explore dynamic step training within an OEGT for patients with incomplete SCI. (2) Describe methods to increase variability within gait interventions for patients with incomplete SCI. (3) Identify improvements in overground ambulation outcome measures after performing OEGT intervention.

Source of Funding: Baylor Research Institute in collaboration with National Institute on Disability, Independent Living, and Rehabilitation Research

Keywords: spinal cord injury; exoskeleton device; gait; heart rate

References:

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2. Bach Baunsgaard C, Vig Nissen U, Katrin Brust A, Frotzler A, Ribeill C, Kalke YB, León N, Gómez B, Samuelsson K, Antepohl W, Holmström U, Marklund N, Glott T, Opheim A, Benito J, Murillo N, Nachtegaal J, Faber W, Biering-Sørensen F. Gait training after spinal cord injury: Safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics. *Spinal Cord*. 2018; 56(2):106–116.
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4. Leech K, Kinnaird C, Holleran C, Kahn J, Hornby T. Effects of locomotor exercise intensity on gait performance in individuals with incomplete spinal cord injury. *Physical Therapy Journal*. 2016; 96-(12):1919-1929.
5. Sohn WJ, Tan AQ, Hayes HB, Pochiraju S, Deffeyes J, Trumbower RD. Variability of leg kinematics during overground walking in persons with chronic incomplete spinal cord injury. *J Neurotrauma*. 2018;35(21):2519-2529.

Title: Exoskeleton gait training across the continuum of care following spinal cord injury: a retrospective analysis.

Authors: Danna Arnold, PT, DPT, ATP1, 2; Jaime Gillespie PT, DPT1, 2; Molly Trammell, PT1; Christi Stevens, PT1; Monica Bennett, PhD2; Librada Callender, MPH1,2; Seema Sikka, MD1,3; Chad Swank, PT, PhD, NCS1,2

Affiliations: 1Baylor Scott & White Institute for Rehabilitation; 2Baylor Scott & White Research Institute; 3Baylor Scott & White University Medical Center

Background: After spinal cord injury (SCI), rehabilitation begins during inpatient (IP) and continues through outpatient (OP) settings. Overground exoskeleton gait training (OEGT) is feasible in both settings, yet no guidelines exist for its use across the continuum.

Objective: To describe the clinical use of OEGT initiated during IP and continued through OP. Design: Retrospective review of medical records from 2018-2021 of patients with SCI who completed at least one OEGT session during IP and OP.

Methods: Demographic data, clinical outcomes, and OEGT session details [frequency, “walk” time, “up” time, step count, and device assistance settings] were extracted from the medical record.

Results: Eighteen patients met criteria: male (83%), white (61%), aged 37.4 ± 15 years, tetraplegic (53%), ASIA Impairment Scale A (22%), B (28%), C (39%), D (11%). OEGT sessions (IP= 8.8 ± 5.3 ; OP= 11.5 ± 8.9) were completed over 17.7 ± 7.3 weeks. Across sessions, “walk” time ($11:49 \pm 7:06$ minutes to $26:43 \pm 13:36$), “up” time ($16:39 \pm 6:12$ minutes to $31:34 \pm 15:46$), and step count (361.7 ± 249.6 to 792.4 ± 466.5) increased while assistance for left (78.4 ± 7.3 to 70.1 ± 10.5) and right (79.4 ± 8.1 to 67.6 ± 11.7) step decreased. Initially, the most common exoskeleton software setting was “Bilateral Adapt”, indicating device assistance provided as needed for limb swing. As sessions continued, mid-session setting changes became more frequent to encourage reduced device assistance. Session details were communicated from IP to OP allowing uninterrupted progression of OEGT.

Conclusions: OEGT was integrated into clinical practice following SCI across IP and OP, though more sessions were completed during OP. Coordinated communication between IP and OP contributed to seamless session progression.

Source of Funding: Baylor Scott & White Foundation

Keywords: Neurological Rehabilitation; Exoskeleton Device; Spinal Cord Injury; Physical Therapy; Walking.

Learning Objectives: (1) Describe the use of overground exoskeleton gait training across inpatient and outpatient rehabilitation settings. (2) Examine the clinical results associated with overground exoskeleton gait training following spinal cord injury. (3) Discuss progression of gait training using an exoskeleton device across the continuum of care.

References:

Delgado AD, Escalon MX, Bryce TN, Weinrauch W, Suarez SJ, Kozlowski AJ. Safety and feasibility of exoskeleton-assisted walking during acute/sub-acute SCI in an inpatient rehabilitation facility: A single-group preliminary study. *The journal of spinal cord medicine*. 2020;43(5):657-666.

Esquenazi A, Talaty M, Jayaraman A. Powered exoskeletons for walking assistance in persons with central nervous system injuries: a narrative review. *PM&R*. 2017;9(1):46-62.
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Kaiser A, Chan K, Pakosh M, Musselman KE. Characteristics of activity-based therapy interventions for people living with spinal cord injury or disease across the continuum of care: a scoping review protocol. *BMJ open*. 2020;10(7):e040014.

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Miller LE, Zimmermann AK, Herbert WG. Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis. *Medical devices (Auckland, NZ)*. 2016;9:455.

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Wallace MA, Kendall MB. Transitional rehabilitation goals for people with spinal cord injury: looking beyond the hospital walls. *Disability and rehabilitation*. 2014;36(8):642-650.

Title: Metabolic testing for exercise intensity during overground robotic exoskeleton gait training in two persons with complete tetraplegia.

Presenter: Katelyn Brown

Authors: Katelyn Brown^{1,3}, MS, Molly Trammell², PT, DPT, Ashlyn Moore², PT, DPT, Ariana Weeks², PT, DPT, Lindsey Wynne², PT, DPT, NCS, Taylor Gilliland^{1,3}, MS, Chol Ho James Kim^{1,3}, BS, BA, Megan Reynolds^{1,3}, MS, Evan McShan^{1,3}, MS, Simon Driver^{1,2, 3}PhD, Seema Sikka², MD, Rita Hamilton², DO, Chad Swank^{2, 3}, PT, PhD

Affiliations: ¹Baylor Scott & White Sports Therapy & Research Center, Frisco, TX, USA, ²Baylor Scott & White Institute for Rehabilitation, Dallas, TX, USA, ³Baylor Scott & White Research Institute, Dallas, TX, USA

Context: Participation in moderate-to-vigorous intensity physical activity (MVPA) is recommended to reduce chronic disease risk in individuals following spinal cord injury (SCI). Assessing exercise intensity using traditional methods (e.g., heart rate, rate of perceived exertion) may be inaccurate in patients with tetraplegia due to neuromuscular and autonomic dysfunction. Direct gas analysis may be more accurate. Overground robotic exoskeleton gait training (OEGT) can be physiologically demanding. Yet, its utility in facilitating MVPA in patients with chronic and acute complete tetraplegia has not been explored. We present the results of two participants who completed one OEGT session with intensity assessed using a portable metabolic system and expressed in metabolic equivalents (METs).

Findings: METs were calculated using a rolling 30-second average with 1 MET defined as 2.7 mL/kg/min and MVPA defined as MET $\geq$ 3.0. Participant A (28-year-old male, BMI 16.7) with a chronic (>10 yrs) SCI (C5-C6, AIS A) completed 37.39 min of OEGT (28.9 min walking) achieving 1,047 steps. Peak METs were 2.9 (average 2.3). Participant B (21-year-old male, BMI 17.3) with an acute (<3 months) SCI (C4, AIS A) completed 42.33 min of OEGT (40.5 min walking) achieving 1,023 steps. Peak METs were 3.3 (average 2.5) with 12% of walk time spent in MVPA. Both participants tolerated activity well without observed adverse responses to activity.

Clinical Relevance: OEGT may be an effective training modality to attain moderate intensity exercise patients with acute tetraplegia. However, chronicity of SCI may play a role in exercise intensity achieved.

Source of Funding: None

Keywords: Ekso, spinal cord injury, metabolic testing, oxygen consumption, rehabilitation

ACRM 2020 Conference, presented November 2022

Title: Elevating Current Practice with Exoskeletons: Overground Robotic Gait Training During Inpatient Rehabilitation

Presenters: Molly Trammell, Danae Arnold

Authors: Jaime Gillespie*,^{1,2} Molly Trammell,² Danae Arnold,^{1,2} Simon Driver,^{1,2} Librada Callender,^{1,2} Sikka Seema,^{1,2} Rosemary Dubiel,^{1,2} Chad Swank^{1,2}

Affiliations: ¹Baylor Scott & White Research Institute; ²Baylor Scott & White Institute for Rehabilitation

Purpose: Stroke, spinal cord injury (SCI), and traumatic brain injury (TBI) can have lasting effects on patients' functional abilities, mental health, independence, overall quality of life, and yield increased risk of future medical morbidity. Patients who have experienced these neurologic events are often admitted to inpatient rehabilitation during the subacute window of recovery where the ability to regain walking function is a highly prioritized goal for patients and clinicians alike. With advancing technology, use of overground exoskeleton gait training (OEGT) to address mobility deficits is becoming more prevalent. Initial data suggests OEGT benefits include reduced pain and spasticity, and improved emotional well-being, bowel and bladder function, and functional mobility.

Yet, there remain no guidelines for utilization of OEGT during inpatient rehabilitation (e.g., initiation, delivery, progression and termination). Consequently, OEGT usage is variable during inpatient rehabilitation and our preliminary data suggests a 'one size fits all' approach to the use of OEGT does not account for individual differences or diagnosis-specific considerations. Therefore, the primary purpose of this presentation is to describe the clinical lessons learned from incorporation of OEGT into the physical therapy clinical plan of care for patients after stroke, SCI, and TBI during inpatient rehabilitation. A secondary aim is to highlight the clinical decision-making process of the clinicians utilizing OEGT during inpatient rehabilitation.

Method: In 2016 we integrated OEGT using the Ekso Bionics exoskeleton device into clinical practice at our inpatient rehabilitation program sequentially. First, we examined the feasibility of integrating OEGT into inpatient rehabilitation for use with patients after stroke, SCI, or TBI who met the manufacturer's criteria for use of the exoskeleton (e.g., height, weight, orthopedic considerations) and had the potential to benefit from gait training interventions. Second, we conducted a focus group with 10 therapists who use OEGT in our inpatient rehabilitation setting to discuss clinical experiences, clinical decision making, and safety related adverse/medical events. Third, we retrospectively reviewed medical records for patients who completed a minimum of one OEGT session during inpatient rehabilitation due to stroke, TBI, or SCI to examine whether there were observable differences in OEGT session performance during inpatient rehabilitation. Hospital institutional review board approval was obtained prior to initiating data collection procedures. Patient and clinical data, stratified by diagnosis, included: patient

demographics, length of stay (LOS), and functional data (initially Functional Independence Measure [FIM] scores with transition to Continuity Assessment and Record Evaluation [CARE] scores as mandated by the Center for Medicare and Medicaid Services). OEGT session details included: total OEGT session count during inpatient rehabilitation, time “up” and time “walking” in device, step count per session, and assistance provided by the exoskeleton device. Additionally, therapist determined assistance modes and settings were recorded to characterize clinical changes made with individual patient progress.

Results: In our first study, integration of OEGT into use during inpatient rehabilitation was found to be feasible and safe, but not without challenges. Overcoming barriers to implementation required administrative support and clinician persistence over several months. In our second study, therapists reported collective experiences working with 186 patients (including 93 diagnosed with stroke) over 3 years and 716 unique OEGT sessions. Lessons learned included clinical characteristics critical to determine patient suitability for OEGT and recognition that a lack of guidelines for utilization of OEGT led to heterogeneity of clinical decision-making regarding initiation, delivery, progression, and termination of OEGT.

In our third study, data from 194 patients [96 with stroke (median LOS 35 days), 73 SCI (43 days), 25 TBI (40 days)] were analyzed. Patients after stroke averaged 5.9 ± 4.5 total OEGT sessions during their LOS. Patients increased “up” time (admit $13:14 \pm 8:01$ minutes; discharge $20:22 \pm 7:07$), “walk” time (admit $5:38 \pm 4:23$ minutes; discharge $15:03 \pm 4:57$), steps per session (admit 139.2 ± 117.7 ; discharge 409.1 ± 123), while assistance required for left step (admit $89.5\% \pm 16.4$; discharge $71.5\% \pm 26.1$) and right step (admit $89.9\% \pm 15.8$; discharge $73.2\% \pm 22.9$) decreased.

Patients after SCI averaged 6.2 ± 4 total OEGT sessions during their length of stay. Patients increased “up” time (admit $16:20 \pm 6:24$ minutes; discharge $23:49 \pm 5:48$), “walk” time (admit $9:48 \pm 5:34$ minutes; discharge $20:17 \pm 6:20$), steps per session (admit 286.1 ± 180.6 ; discharge 692.2 ± 274.2 steps), while assistance required for left step (admit $92.7\% \pm 7.7$; discharge $73.2\% \pm 26.7$) and right step (admit $93.1\% \pm 7.5$; discharge $77.7\% \pm 24.6$) decreased.

Patients after TBI averaged 9.1 ± 5.6 total OEGT sessions during their length of stay. Patients increased “up” time (admit $13:14 \pm 8:01$ minutes; discharge $16:42 \pm 5:58$), “walk” time (admit $5:38 \pm 4:23$ minutes; discharge $9:50 \pm 8:10$), steps per session (admit 139.2 ± 117.7 ; discharge 292.9 ± 364.4 steps), while assistance required for left step (admit $89.5\% \pm 16.4$; discharge $57.6\% \pm 26.8$) and right step (admit $89.9\% \pm 15.8$; discharge $64.1\% \pm 31.6$) decreased.

Details of therapist selected device assistance modes during OEGT sessions were recorded and will be discussed.

Conclusion: Our data suggests implementation of OEGT is feasible during inpatient rehabilitation for appropriate patients with stroke, SCI, and TBI. Additionally, OEGT may be a useful tool to deliver and progress walking interventions through applying select device

assistance modes under the management of a skilled and trained clinician. Termination of OEGT with transition to traditional mobility devices to meet patient-specific walking goals is necessary during inpatient rehabilitation. Linking outcomes to the clinical decision-making process in delivering OEGT is a critical next step.

Keywords: Neurologic Rehabilitation. Robotic Exoskeleton. Physical Therapy. Physical Medicine and Rehabilitation. Walking.

Learning Objectives:

Following completion of this session, the learner will be able to:

- 1) Describe the process of successfully incorporating OEGT into the physical therapy plan of care for patients after neurological injury during inpatient rehabilitation.
- 2) Understand the clinical and functional outcomes associated with OEGT use within the physical therapy plan of care for patients after stroke, SCI, or TBI during inpatient rehabilitation.

Discuss clinical decision making on the initiation, delivery, progression and termination of OEGT during inpatient rehabilitation.

CSM APTA 2023, presented February 2023

Title: Survey says: Therapists' clinical decisions guiding overground exoskeleton gait training during inpatient rehabilitation

Authors: Danna Arnold,^{1,2} Jaime Gillespie,^{1,2} Christa Ochoa,¹ Chad Swank^{1,2}

Affiliations: ¹Baylor Scott & White Research Institute; ²Baylor Scott & White Institute for Rehabilitation

Purpose: Overground exoskeleton gait training (OEGT) use in clinical practice is safe and feasible, with potential benefits including improved mobility, emotional well-being, bowel and bladder function, and reduced pain and spasticity. However, no guidelines exist for OEGT use during inpatient rehabilitation. Our purpose was to describe the clinical decision-making process of physical therapists concerning the initiation, progression, and termination of OEGT for patients admitted with stroke, spinal cord injury (SCI), or traumatic brain injury (TBI) during inpatient rehabilitation.

Subjects: Physical therapists in an inpatient rehabilitation hospital trained in the use of Ekso Bionics robotic exoskeletons.

Methods: Therapists completed a Microsoft Forms survey aimed to inform clinical decision-making surrounding use of OEGT during inpatient rehabilitation. Questions were categorized as “initiation” (e.g. patient selection, readiness), “progression” (e.g. setting changes to facilitate improvement), and “termination” (e.g. discontinuation). The survey included multiple choice and short answer questions to allow for structured and free response to describe clinical practice. **Results:** Seven therapists averaging 8.9 years of clinical experience and 4.5 years with OEGT completed the survey. Two therapists each specialized in stroke, SCI, and TBI, and one in neurological debility. Recovery of walking (n=7), cardiovascular endurance (n=5), and balance/midline positioning (n=5) were the most commonly reported OEGT goals. Key indicators of “initiation” readiness were medical stability (n=6) and ability to tolerate a standing program (n=6). Initial settings were reported as ProStep+ (n=5), bilateral assistance (n=7), adaptive swing assistance (n=6), and flex stance support (n=6). Therapists chose OEGT for patients who “wouldn’t be able to walk any other way.” Important markers of “progression” were increased walk time (n=6), step count (n=4), and decreased swing assist (n=4). Therapists reported monitoring heart rate and adjusting device settings to elicit higher cardiovascular intensity. Reasons for “termination” of OEGT were progression to gait without robotics (n=7), prioritizing discharge preparation (n=5), and OEGT not eliciting enough intensity (n=5). Therapists reported decreased OEGT use when other gait interventions allowed higher stepping repetition, intensity, or variability.

Conclusions: Despite use of OEGT with diverse diagnoses, therapists generally agreed on clinical indicators for initiation, progression, and termination of OEGT during inpatient rehabilitation. Therapists described OEGT as “less physically demanding” than other gait interventions while allowing the “ability to adjust settings based on individualized needs.”

Clinical Relevance: In the absence of defined clinical guidelines, these therapist-informed practice patterns lay a foundation for clinical use of OEGT with patients with stroke, SCI and TBI during inpatient rehabilitation.

References:

Esquenazi A, Talaty M, Jayaraman A. Powered exoskeletons for walking assistance in persons with central nervous system injuries: a narrative review. *PM&R*. 2017;9(1):46-62.

Swank C, Sikka S, Driver S, Bennett M, Callender L. Feasibility of integrating robotic exoskeleton gait training in inpatient rehabilitation. *Disability and Rehabilitation: Assistive Technology*. 2020;15(4):409-417.

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ASNR 2023 Annual Meeting, presented March 2023

Title: Tracking walking recovery in individuals with motor incomplete spinal cord injury with transcranial magnetic stimulation: preliminary findings

Authors: Sheba Sajjan, Hui-Ting Shih, Vyoma Parikh, Faith Meza, Alex Suhalka, Chad Swank, Hui-Ting Goh

Background and Purpose: Transcranial Magnet Stimulation (TMS) measures are useful for assessing motor recovery after stroke but are underutilized in spinal cord injury (SCI). Here, we report preliminary findings from an ongoing randomized controlled trial aimed to determine the effectiveness of overground robotic exoskeleton gait training on walking recovery in individuals with motor incomplete SCI. The purpose of this analysis was to examine change in TMS measures in individuals with motor incomplete SCI across the initial months post-SCI.

Methods: Eligible patients were within 10 days of admission of inpatient rehabilitation with a diagnosis of motor incomplete (ASIA Impairment Scale [AIS] C or D) and without TMS contraindications. Participants underwent structured gait training as determined by the randomized controlled trial protocol. Walking function was assessed by the Walking Index for Spinal Cord Injury - revised (WISCI-II) and the 10 Meter Walk Test (10MWT). TMS assessments measured resting motor threshold (RMT), and active motor threshold (AMT) of tibialis anterior (TA) and rectus femoris (RF) muscles on the stronger side. Motor-evoked potential amplitudes at 120% RMT (resting MEP), 120% AMT (active MEP), and 100% of the stimulator output (maximal MEP) were also obtained. Assessments were completed at admission and discharge from inpatient rehabilitation, completion of gait training, and 1-month follow-up.

Results: Five participants (2 females and 3 males, age = 32.6 ± 5 years, 2 AIS C and 3 AIS D, time since injury = 44 ± 25.78 days) were enrolled. One participant remained non-ambulatory and 4 demonstrated improved walking performance. WISCI-II improved from 3.3 ± 7.6 to 11.6 ± 8.6 points; 10MWT gait speed increased from 0.28 ± 0.62 m/s to 0.60 ± 0.75 m/s. RMT was established in 3 of 5 participants at admission with 2 having a decline in RMT over time and 1 having no change. AMT was established in 2 of 5 participants at admission but was obtained in all participants after the completion of gait training and 1-month follow-up from at least one muscle. AMT declined for 3 participants but remained unchanged for the other 2 participants. MEPs were recorded for all participants but not at all time points. Observed changes in MEPs were highly variable across time. MEPs measured at resting (resting MEP and maximal MEP) did not have a consistent trend whereas MEPs measured under active contraction (active MEP) tended to increase over time. Overall, TMS measures obtained from TA, compared to RF, trended similarly to gait outcomes.

Discussion and Conclusion: Our preliminary analysis suggests that TMS measures, especially when measured under active contraction and from the TA, appear to be sensitive neurophysiological biomarkers to track gait recovery in individuals with motor-incomplete

SCI during the initial months post-injury. We are currently enrolling additional participants into the randomized controlled trial.

ASIA 2023 Conference, presented April 2023

Title: Spinal Cord Injury Enrollment Experiences in Studies Using Overground Exoskeleton Gait Training During Inpatient Rehabilitation

Author: Faith Meza, MPH², Jaime Gillespie, PT, DPT^{1,2}, Danna Arnold, PT, DPT, ATP^{1,2}, Seema Sikka, MD^{1,3}, Chad Swank, PT, PhD, NCS^{1,2}

Affiliation: Baylor Scott & White Institute for Rehabilitation¹; Baylor Scott & White Research Institute²; Baylor Scott & White University Medical Center³

PURPOSE: Advanced technology has facilitated a recent rise in the adoption of overground robotic exoskeletons into clinical practice within the inpatient rehabilitation setting. However, there is limited knowledge regarding the eligibility of patients with subacute spinal cord injury (SCI) to participate in overground exoskeleton gait training (OEGT). Our purpose was to describe the feasibility of enrolling patients with subacute incomplete SCI in clinical studies using OEGT during inpatient rehabilitation.

METHODS: Our large, urban inpatient rehabilitation hospital is currently conducting two investigator initiated randomized controlled trials (RCT) [NCT04781621; NCT05218447] examining the use of OEGT in patients with traumatic and non-traumatic incomplete SCI (American Spinal Injury Association Impairment Scale [AIS] B, C, and D or equivalence score). Inclusion criteria for both studies include patients less than 6 months post-SCI, medically stable as deemed by physician, continence of or on a program for bladder and bowel management, and able to meet manufacturer determined robotic exoskeleton frame limitations. Exclusion criteria include presence of moderate to severe traumatic brain injury, degenerative diagnosis, pre-morbid developmental disability, significant psychological diagnosis, or other cognitive impairment. All patients admitted to our inpatient rehabilitation hospital with a medical diagnosis of SCI are screened with eligible patients approached by a member of the research team for informed consent. Enrollment metrics of admission data, screen failure rate, reasons for screen failures, enrollment rate, and refusals were recorded.

RESULTS: Over the past 16 months 315 patients with a medical diagnosis of SCI were admitted to our inpatient rehabilitation hospital and were screened for eligibility. Seventy-nine percent (n=249) of patients screen failed due to 1) non-incomplete SCI diagnoses [n=153 (49%); AIS A n=70, myelopathy n=33, degenerative disorder n=30, post-orthopedic spine surgery n=20], 2) not meeting exoskeleton frame limitations [n=82 (33%)], and 3) greater than 6 months post-SCI [n=61 (24%)]. Of the patients deemed eligible [n=66 (21%)], we were able to enroll 83% (n=55) into our RCTs. Commonly expressed reasons for refusal to participate were 1) having no interest in study participation, 2) feeling overwhelmed, 3) wanting the opportunity to participate in OEGT (if randomized to control group), 4) concerns over access to transportation (for follow-up appointments), 5) unease of additional caregiver burden, and 6) desire to prioritize other activities. Patients who enrolled into the RCTs were middle aged (49.3±17.7 years), male (84%), non-Hispanic (80%), White (69%), traumatic SCI (67%), tetraplegic (56%), and AIS B (15%), C (27%), D (58%).

CONCLUSION: Patients admitted to inpatient rehabilitation after SCI may demonstrate interest in participation in OEGT trials. While a majority may not be eligible for such trials, those who did meet eligibility criteria were likely to enroll.

Learning Objective: Describe enrollment experiences of patients with SCI into exoskeleton gait training studies during inpatient rehabilitation.

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Title: Transcranial Magnetic Stimulation Assessment in Patients with Subacute Spinal Cord Injury during Inpatient Rehabilitation

Authors: Hui-Ting Shih, PT, PhD¹, Hui-Ting Goh, PT, PhD², Christa Ochoa¹, Simon Driver, PhD¹, Seema Sikka, MD¹, Rita Hamilton, DO¹, Chad Swank, PT, PhD^{1,3}

Affiliations: ¹Baylor Scott & White Research Institute; ²Texas Woman's University; ³Baylor Scott & White Institute for Rehabilitation

Objective: Use of transcranial magnetic stimulation (TMS) to assess corticospinal tract integrity in patients with subacute spinal cord injury (SCI) during inpatient rehabilitation is unreported. Potential concerns for its use include: 1) safety due to medical status and the risk of a TMS-induced adverse event, 2) tolerance of a TMS assessment due to rehabilitation-induced fatigue, and 3) feasibility of obtaining meaningful neurophysiological responses [e.g., motor evoked potential (MEP)] in early phases recovery after SCI. The current study describes the safety, tolerability, and feasibility of performing TMS assessments during inpatient rehabilitation in patients within 90 days of a motor incomplete SCI.

Design/Methods: Consecutive patients with SCI were screened for eligibility to participate in a randomized controlled trial (RCT) evaluating the effectiveness of robotic gait training in which TMS assessment is one of the outcomes. Eligible patients were within 90 days post-SCI, motor incomplete [ASIA Impairment Scale (AIS) C or D], and without TMS contraindications (e.g., pacemaker). TMS assessment was completed within 10 days of admission and scheduled at the end of the therapy day to avoid interference with required therapy. Resting motor threshold (RMT), MEP amplitude at 120% RMT and at maximum stimulator output (MSO; MEP120 & MEPmax) of first dorsal interossei (FDI), rectus femoris (RF), and tibialis anterior (TA) muscles were assessed in a 2-hour TMS session. For the RCT, TA and RF are muscles of interest and FDI serves as a control muscle.

Results: Seven patients were enrolled in the RCT, and 1 was excluded from TMS assessment due to presence of a pacemaker. Six patients [age 31 years (range 25-39); n=2 AIS C, n=4 AIS D; n=2 cervical, n=2 thoracic, n=2 lumbar; time since SCI = 44 days (range 13-70)] completed the TMS assessment. No adverse events were reported during TMS assessments. Due to fatigue, 2 patients required two 1-hour sessions on separate days to complete all assessments. Two patients tolerated 100% MSO poorly and were not assessed for FDI MEPmax. RMT and MEP120 were acquired from the FDI in 5 participants (RMT=60±14.8%MSO, MEP120=1275.8±1371.9µV) but not in 1 participant due to fatigue. We were able to acquire RMT and MEP120 in TA (RMT=59.7±19.5%MSO, MEP120=565.1±72µV) and RF (RMT=55.3±6.8%MSO, MEP120=311.3±108.4µV) in 3 patients whereas the other 3 showed no MEP at rest. Stimulating at the maximal MSO was tolerable and resulted in readable MEP from resting FDI in 5 patients (MEPmax=3310.7±4573.17µV), TA in 4 patients (MEPmax=1045.9±1138.1µV), and RF in 4 patients (MEPmax=708.6±660.3µV). The RMT from our patients with subacute motor incomplete SCI was higher than previously reported in healthy adults (FDI: 60% vs

~40%MSO; RF: 55.3% vs ~47.7%MSO; TA: 59.7% vs ~45%MSO), suggesting a lower corticospinal excitability.

Conclusion: TMS assessment during inpatient rehabilitation with patients within 90 days of motor incomplete SCI was safe. Maximal MSO was tolerable and elicited readable MEP. However, assessments may require flexible scheduling to promote patient tolerance. Neurophysiological biomarkers were feasibly obtained from patients with motor incomplete SCI during inpatient rehabilitation.

Support: DOD, W81XWH-21-1-0922

Learning Objectives: Discuss safety, tolerance, and feasibility of TMS assessment in patients with SCI during inpatient rehabilitation.

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ACSM 2023 Conference Abstract, presented May 2023

Title: Intensity Of Overground Robotic Exoskeleton Exercise Training Conditions In An Adult With Chronic, Motor Complete Tetraplegia

Presenter: Chad Swank

Authors: Chad Swank, Katelyn D. Brown, Megan McCorkle, Chad Elliott, Jamie Gillespie, Molly Trammel, Danae Arnold, Rita Hamilton, Simon Driver. (Sponsor: Jakob Vingren, PhD, FACSM)

Abstract: Overground robotic exoskeletons (ORE) may be a unique modality to allow non-ambulatory individuals with tetraplegia to stand and perform walking exercise. However, the ability of ORE training to elicit moderate to vigorous levels of intensity (MVI) in non-ambulatory individuals with tetraplegia is unknown.

Purpose: To examine the level of intensity achieved during three different ORE training conditions in a non-ambulatory adult with chronic, motor-complete tetraplegia.

Methods: A 29-year-old male (BMI 11.2 kg/m²) with a 13-year history of traumatic spinal cord injury (AIS A, C5-C6) resulting in motor-complete tetraplegia, completed ORE training consisting of three conditions performed consecutively in a single treatment session. Intensity of each condition was assessed using direct breath-by-breath expired gas analysis and the participant was asked to identify which conditions were most challenging. Prior to training, a five-minute ORE warm-up was completed with device software settings individualized to promote a more typical gait pattern and allow for acclimation to the device and being in an upright position. In Condition 1, the participant was instructed to walk in the device “as quickly as possible”. In Condition 2, the participant was instructed to walk with an active arm swing with 2-lb cuff weights placed on each wrist. In Condition 3, the participant was instructed to focus on making complete steps as the device software was adjusted to minimize device assistance.

Results: The participant completed 320 steps in approximately two minutes during warm-up and each condition. METs were 3.10 ± 0.61 during warm-up, 3.05 ± 0.53 Condition 1, 4.76 ± 0.58 Condition 2, and 3.16 ± 0.38 Condition 3. All conditions allowed the participant to achieve moderate intensity for part of the ORE training session, but MVI was sustained throughout during Conditions 2 and 3 with minimum METs of 3.6 and 3.1, respectively. The participant’s subjective report of intensity indicated Condition 2 was as the most challenging.

Conclusions: ORE training elicited MVI in the non-ambulatory adult with chronic, motor-complete tetraplegia. The ability to modulate intensity demand through additional conditions, such as the use of bilateral upper-extremity weights, may allow for development of a progressive ORE exercise prescription. Author Disclosure Information:

Title: Overground Robotic Exoskeleton Gait Training Intensity in Patients with Spinal Cord Injury During Inpatient Rehabilitation

Presenter: Katelyn D. Brown

Authors: Katelyn D. Brown, Chad Elliott, Megan McCorkle, Lindsey Wynne, Jamie Gillespie, Danna Arnold, Seema Sikka, Simon Driver, Chad Swank. (Sponsor: Jakob Vingren, PhD, FACSM)

Abstract: High intensity gait training during inpatient rehabilitation (IPR) promotes functional recovery following spinal cord injury (SCI) and may be achieved with overground robotic exoskeleton gait training (OEGT). Due to neuromuscular and autonomic impairments associated with SCI, assessing intensity through heart rate response and perceived exertion during gait training may be inaccurate. Wearable metabolic systems (WMS) have been used to directly measure intensity using oxygen consumption (VO₂) with SCI. However, the use of WMS to assess OEGT intensity during OEGT in IPR is unexplored.

Purpose: To describe the use of WMS to measure physiological intensity of OEGT in patients with motor incomplete SCI during IPR.

Methods: This observational study included adults aged 18 to 85 admitted to IPR with diagnosis of motor incomplete SCI who were eligible to initiate OEGT. OEGT intensity, duration, and step count were assessed during 1 OEGT session performed within 1 week of gait training initiation following IPR admission. Intensity was assessed by rate of perceived exertion (RPE) and VO₂. VO₂ was measured using a WMS worn during OEGT and expressed in metabolic equivalents (METs). Moderate and high intensity were defined as ≥ 3 and ≥ 6 METs, respectively, with 2.7 mL/min/kg of VO₂ = 1 MET.

Results: 4 participants [3 males; 1 non-Hispanic white, 2 Hispanic white, 1 Black] were aged 52 $\pm$ 8.4 years with a body mass index of 28.4 $\pm$ 3.2. Participants' SCI characteristics were 3 diagnosed ASIA Impairment Scale (AIS) C, 1 AIS D; 2 tetraplegia and 2 paraplegia admitted within 30.5 [range=8-56] days after SCI. Duration of OEGT sessions (n=4) was 15:57 [range=10:23-19:43] minutes and participants completed 512 [287-761] steps. RPE was 4 [2-6], VO₂ was 7.3 [3.05-15.6], and METs were 2.72 [1.1-5.8]. Three participants achieved ≥ 3 METs and ≥ 6 METs for 79-89.6% and 4.2-54.8% of the OEGT session, respectively. VO₂ was highest in the AIS D participant.

Conclusions: WMS use was demonstrated to feasibly obtain intensity data of OEGT in adults with SCI during IPR. Future research should consider the utility of WMS to assess the capacity of OEGT to promote high-intensity gait training in this population during IPR.

RESNA 2023 Annual Conference, presented July 2023

Title: Is there a place for robotic exoskeletons to improve health and function of persons with SCI undergoing rehabilitation?

Presenter: Danna Arnold

Authors: Danna Arnold, Jaime Gillspie, Hui-Ting Shih and Chad Swank

Abstract: With advancing technology, the use of overground robotic exoskeletons (ORE) is becoming more prevalent to address mobility deficits in people with spinal cord injury (SCI). Our previous work has shown that integrating ORE into clinical practice is 1) safe and feasible in the inpatient rehabilitation setting, 2) progressively tolerated, and 3) able to be initiated during inpatient rehabilitation and continue with outpatient therapy. Reported benefits of an ORE intervention include improved mobility, emotional well-being, and bowel and bladder function, and reduced pain and spasticity. This session will highlight the safety, feasibility, tolerability, and benefits of ORE training, share perceptions of persons with lived experience, and suggest future research directions to optimize the use of ORE for persons with SCI across different phases of recovery.

Learning Objectives: (1) Participants will identify common barriers to implementation of ORE use in inpatient rehabilitation. (2) Participants will describe adjustments to device settings that can be made to progress ORE training. (3) Participants will identify health benefits persons with SCI may experience after using ORE during rehabilitation.

ASCIP 2023 Conference, presented September 2023

Title: Clinical reasoning and user experience of overground robotic exoskeleton training during inpatient rehabilitation

Authors: Danna Arnold, DPT, ATP^{1,2}; Hui-Ting Shih, PT, PhD¹; Jaime Gillespie, DPT^{1,2}; Lindsey Wynne, DPT, NCS^{1,2}; Chad Swank, PT, PhD^{1,2}

Affiliation: ¹Baylor Scott and White Research Institute, Dallas, Texas, ²Baylor Scott and White Institute for Rehabilitation

Purpose: This presentation examines clinical reasoning principles to provide overground robotic exoskeleton (ORE) training following spinal cord injury (SCI), and associated patient and therapist perspectives on use during inpatient rehabilitation.

Background: Despite an increasing prevalence in ORE use during rehabilitation after SCI, no evidence-based guidelines exist to inform clinical reasoning. Over the past 6 years our inpatient rehabilitation hospital integrated use of ORE resulting in 18 ORE-trained therapists with 500+ patients over 2,700+ sessions completed including 142 patients and 1,167 sessions with SCI. Concurrent with our clinical experiences, our team has conducted three surveys to ascertain stakeholder perceptions of ORE use during inpatient rehabilitation.

Content: The first survey aimed to inform clinical reasoning regarding initiation, progression, and termination of ORE and was completed by ORE-trained therapists (n=7) averaging 8.9 years of clinical experience and 4.5 years with ORE. ORE-trained SCI therapists reported goals varied across patients with incomplete (recovery of walking function and strengthening) versus complete SCI (upright tolerance and psychosocial benefits). Therapists cited medical stability and ability to tolerate a standing program as key determinants for ORE initiation. Indicators of progression included increased walk time, step count, and decreased swing assist. Reasons for termination of ORE were progression to gait without robotics, prioritizing discharge preparation, and insufficient training intensity. In a second survey, patients with SCI (n=35) were asked to provide their perceived benefits and drawbacks of ORE training. Patients with SCI reported with 80% agreement that their time was well spent in ORE training with perceived improvements in overall health, strength, endurance, and sense of well-being. Patients did not perceive change in spasticity, sleep, or bowel function. Perceived drawbacks were related to the programmed robotic gait pattern (27%) and incommensurate intensity level (17%). SCI team therapists (n=10) completed a third survey to capture the therapist perceived benefits and detriments of ORE training. Results are pending analysis and will be discussed in this presentation.

Conclusion: Given the lack of ORE evidence-based guidelines, user perceptions provide valuable insight to inform clinical practice for individuals with SCI during inpatient rehabilitation. Clinicians utilized ORE to achieve physical and psychosocial effects. The unnatural robotic movements of ORE invoked the greatest proportion of unfavorable experiences.

Source of Funding: “The contents of this presentation were developed under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90IRFE0043) and by the Office of the Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense through the Spinal Cord Injury Research Program under Award No. W81XWH2110922. NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this presentation do not necessarily represent the policy of NIDILRR, ACL, HHS, or the Department of Defense and you should not assume endorsement by the Federal Government.”

Keywords: Neurological Rehabilitation; Exoskeleton Device; Spinal Cord Injury; Physical Therapy; Walking.

Learning Objectives: (1) Discuss clinical goals for utilizing exoskeletons with patients with SCI in inpatient rehabilitation. (2) Describe the patient perceived effects, benefits, and drawbacks of using exoskeletons during rehabilitation. (3) Compare therapist and patient experiences and analyze any discrepancies between treatment goals and perceived outcomes.

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Title: Is there a place for Overground Robotic Exoskeletons in Rehabilitation?

Authors: Karen J. Nolan, PhD¹, Chad Swank, PT, PhD², Candy Tefertiller, PT, PhD³

Affiliation: ¹Kessler Foundation, West Orange, NJ; ²Baylor Scott & White Research Institute, Dallas, TX; ³Craig Hospital, Denver, CO

Session Description: The ability to regain walking function is a highly prioritized goal of individuals following spinal cord injury/disorder (SCI/D). Advances in technology over the past 10 years have allowed for proliferation of overground robotic exoskeleton use as a tool for therapeutic intervention in clinical settings. However, overground robotic exoskeletons have not achieved ecologic validity as independent walking devices in the community for individuals with SCI/D and recent clinical practice guidelines suggest their use as a therapeutic intervention is premature. Nonetheless, the devices are being deployed in a variety of clinical settings across the continuum of care resulting in many questions about how and when these technologies can benefit individuals with SCI/D. The goal of the proposed educational session is to facilitate a conversation regarding the clinical application of robotic exoskeleton technology to advance the care of individuals recovering from SCI/D as well as to discuss the current limitations and challenges associated with implementing these technologies. To achieve this goal, we will (1) provide an updated literature review of overground robotic exoskeleton use and technology, (2) share experiences and lessons learned from three SCI Model Systems centers concerning the use of robotic exoskeletons in clinical settings across a continuum of care, (3) highlight opportunities for further research, (4) suggest collaborative opportunities between clinicians and industry with the goal of advancing technological development of overground robotic exoskeletons, and (5) discuss potential areas of return on investment of overground robotic exoskeleton use after SCI/D.

Session Learning Objectives: Upon completion of this educational session, the learner will be able to (1) Discuss the current status of the literature regarding overground robotic exoskeleton use. (2) Describe experiences and lessons learned from three rehabilitation centers concerning the use of overground robotic exoskeletons in clinical settings across a continuum of care. (3) Identify opportunities for further research, technology development, and return on investment of overground robotic exoskeletons.

Keywords: Neurologic Rehabilitation; Robotic Exoskeleton; Physical Therapy; Physical Medicine and Rehabilitation; Walking.

Teaching and learning assessment methods: Lecture, Question and Answer

Recommended content level: Intermediate

Conflict of interest disclosure:

Karen J. Nolan currently receives funding from NIH (1R01HD099200-01), NIDILRR (90RE5021), and DOD to examine the use of robotic exoskeletons for individuals post stroke.

Chad Swank currently receives funding from NIDILRR (90IFRE0043) and DOD/CDMRP (W81XWH-20-SCIIRP-CTA) to examine the use of robotic exoskeletons with persons with SCI.

Candy Tefertiller: No disclosures as I do not currently have funding to examine exoskeleton use.

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APPENDIX II.

PUBLISHED MANUSCRIPTS

RESEARCH

Open Access



Utilization of overground exoskeleton gait training during inpatient rehabilitation: a descriptive analysis

Jaime Gillespie^{1*}, Danna Arnold¹, Molly Trammell¹, Monica Bennett², Christa Ochoa³, Simon Driver², Librada Callender³, Seema Sikka¹, Rosemary Dubiel¹ and Chad Swank⁴

Abstract

Background Overground exoskeleton gait training (OEGT) after neurological injury is safe, feasible, and may yield positive outcomes. However, no recommendations exist for initiation, progression, or termination of OEGT. This retrospective study highlights the clinical use and decision-making of OEGT within the physical therapy plan of care for patients after neurological injury during inpatient rehabilitation.

Methods The records of patients admitted to inpatient rehabilitation after stroke, spinal cord injury, or traumatic brain injury who participated in at least one OEGT session were retrospectively reviewed. Session details were analyzed to illustrate progress and included: “up” time, “walk” time, step count, device assistance required for limb swing, and therapist-determined settings. Surveys were completed by therapists responsible for OEGT sessions to illuminate clinical decision-making.

Results On average, patients demonstrated progressive tolerance for OEGT over successive sessions as shown by increasing time upright and walking, step count, and decreased assistance required by the exoskeleton. Therapists place preference on using OEGT with patients with more functional dependency and assess feedback from the patient and device to determine when to change settings. OEGT is terminated when other gait methods yield higher step repetitions or intensities, or to prepare for discharge.

Conclusion Our descriptive retrospective data suggests that patients after neurological injury may benefit from OEGT during inpatient rehabilitation. As no guidelines exist, therapists’ clinical decisions are currently based on a combination of knowledge of motor recovery and experience. Future efforts should aim to develop evidence-based recommendations to facilitate functional recovery after neurological injury by leveraging OEGT.

Keywords Walking, Robotic exoskeleton, Neurological rehabilitation, Stroke, Spinal cord injuries, Traumatic brain injury, Rehabilitation hospital, Physical therapy, Recovery of function

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Background

The ability to regain walking function is a highly prioritized goal for individuals after neurological injury [1, 2] as well as rehabilitation clinicians.[3] Despite the emphasis placed on gait training during rehabilitation, recovery of independent community-level walking function is attained in only 37 to 60% post-stroke[4], and 73.3% post-traumatic brain injury (TBI) [5]. For those with spinal cord injury (SCI), recovery of independent community ambulation varies significantly with age and severity of injury resulting in 0–75% post-motor complete SCI, and 25 to 100% post-motor incomplete SCI [6]. Most often, individuals after neurologic injury live with disability due to residual deficits including imbalance, muscle weakness, increased fall risk, and greater energy expenditure [7] leading to barriers in resuming previous life roles [8, 9]. Even when these individuals regain some ability to walk, limitations in recovery often make walking as a primary method of mobility inefficient and impractical [10].

Consequently, new approaches to gait training are necessary following neurologic injury [11]. Due to advancing technology, overground exoskeleton gait training (OEGT) [7], is emerging as a feasible [12], safe [13], and potentially beneficial [14–16] intervention during inpatient rehabilitation. After stroke, current evidence suggests clinically significant improvements in gait outcomes with use of OEGT[17], with particular potential for improvement in the subacute phase [15]. Notably, patients with subacute stroke perceive walking in an exoskeleton as “enjoyable” and “comfortable” [17]. Similarly, gait deficits in those with TBI may resemble that of an individual who has experienced a stroke [18, 19] leading to the conclusion that OEGT may have a similar impact despite a different etiology of the acquired brain injury [19]. After SCI, findings report both physical (e.g., pain and spasticity reduction, improved strength, functional improvements) and psychological benefits with OEGT [20, 21].

Despite the potential benefits of OEGT for patients after neurological injury, there remain no established recommendations for initiation, progression, or termination of OEGT use during inpatient rehabilitation. Previous work has highlighted the need for strong clinical decision making skills by therapists to use OEGT [13]. For example, of four SCI Model Systems, only one center utilized OEGT during inpatient rehabilitation, and limited use to six sessions during the length of stay to allow adequate time for other rehabilitation interventions deemed necessary [20]. A recent protocol paper for a multi-site randomized controlled trial described detailed plans for progressing patients with subacute stroke with OEGT during inpatient rehabilitation [22]. While the subsequent study reported no differences between traditional

therapy and an exoskeleton-based approach, the authors report providing “suggested training targets but allowed therapists to make their own clinical decisions” [23]. Importantly, the findings were determined to be partly attributable to the variability of the delivered OEGT intervention. As such, there is a pressing need for evidence-based recommendations to guide clinical practice for initiation, progression, and termination of OEGT [20].

This retrospective study highlights the clinical use and decision-making of OEGT within the physical therapy plan of care for patients after neurological injury during inpatient rehabilitation. Therapist commentary was obtained to supplement OEGT session data to underscore clinical decision making specific to patients with stroke, SCI, and TBI on the initiation, progression, and termination of OEGT during inpatient rehabilitation.

Methods

Participants

Patients were eligible if they completed a minimum of one OEGT session during inpatient rehabilitation following stroke, SCI, or TBI and were included in the medical record review. OEGT was completed with either the EksoGT [24] (original device) or EksoNR [25] robotic devices, which are wearable exoskeletons that allow full weight-bearing walking overground with the motor adaptability to allow the patient to move under their own control as much as possible [26, 27]. Whereas both devices have FDA class II approval for use with stroke, SCI, and TBI [28], the EksoNR is upgraded with advanced safety mechanisms, enhanced feedback on patient performance, and expanded options for treatment progression. To have participated in OEGT, patients were required to have met the following clinical and manufacturer criteria: (1) age greater than 18; (2) bowel and bladder program established or Foley catheter in place; (3) involved in standing program; (4) met the robotic exoskeleton frame limitations including weighing 100 kg or less, between 1.5 and 1.9 m tall, standing hip width of 0.45 m or less, near normal range of motion in hips, knees, and ankles, able to attain a neutral ankle dorsiflexion with <12 degrees of knee flexion, no more than 12 degree hip flexion contracture, and no significant upper or lower leg length discrepancy. Patients were excluded from participating in OEGT for spinal instability, untreated deep vein thrombosis (DVT), decreased standing tolerance due to orthostatic hypotension, history of osteoporosis that increased the risk of fracture, uncontrolled spasticity, uncontrolled autonomic dysreflexia (AD), skin integrity issues on contact surfaces of the device, and pregnancy.

OEGT sessions included use of overground robotic exoskeletons only. Prior to the first OEGT session, the

therapist completed measurements of the patient (i.e., limb length, hip width, and ranges of motion) to ensure optimal fit within the device. Subsequently, the first session incorporated familiarization to the device as OEGT was initiated. Other gait training approaches (i.e., over-ground with braces or treadmill walking) were not included in OEGT sessions.

Procedure

Hospital institutional review board approval was obtained prior to initiating data collection. Medical records of patients admitted to an inpatient rehabilitation hospital within the United States between September 2016 and March 2022 were retrospectively reviewed. Within the United States healthcare model, patients are provided a minimum of three hours of therapy daily [29] over their inpatient rehabilitation length of stay (average of 16.9 days for stroke [30], 36 days for SCI [31], and 18.4 days for TBI [32]). At this specific rehabilitation hospital, physical therapy sessions are 45 min in length, and a patient may receive one to two physical therapy sessions daily. Once a list of participants who completed a minimum of one OEGT session was obtained, medical records were reviewed for stroke, SCI and TBI diagnoses by four trained data extractors. Oversight and auditing of data extraction was provided throughout the review process by a data analyst and included verification of the accuracy of each medical record and corresponding data entry form.

Outcomes

Demographic data (age, gender, race, ethnicity, diagnosis, and inpatient rehabilitation length of stay) and diagnosis specific details were extracted for all included patients. For patients with stroke, side of lesion was extracted. For those with SCI, the ASIA Impairment Scale (AIS) was extracted for patients with traumatic injury and an AIS equivalent for non-traumatic injuries [33]. For patients

with TBI, emergence from post-traumatic amnesia [34] was tracked to characterize severity of cognitive deficits.

Individual OEGT session data were extracted as captured by the exoskeleton device and included frequency of use and dose defined as “up” time (i.e., amount of time spent in the exoskeleton upright), “walk” time (i.e., amount of time spent walking in the exoskeleton), and number of steps. Device assistance details were captured to indicate how much the exoskeleton needed to assist each lower extremity during the swing phase of gait. These OEGT session details were analyzed across multiple sessions to illustrate any progress made in tolerability (i.e., longer up time, walk time, or greater number of steps per session) or device dependency (i.e., less assistance required by the device for swing). Additionally, therapist-determined device settings and changes were tracked across sessions to describe clinical decisions made to facilitate individual patient progress. Swing Assist Mode illustrated the amount of assistance provided by the device to complete the step trajectory (i.e., step length, step height, and swing time) during swing phase [25]. Swing Assist Mode was determined by the therapist during each session and options included Max, Adapt, Fixed, and Free [25] (characterized in Table 1). During each session, initial swing assist mode settings were documented and changes made during the session were noted as a “mid-session change”. Of note, swing assistance is only captured by the device in the Adapt and Fixed settings.

Therapist commentary

Following data review, surveys were completed by the therapists responsible for planning and executing the OEGT sessions. Survey items (provided in Additional file 1: Appendix S1) were designed to illuminate the clinical decision-making process involved in the initiation (e.g., patient selection, determining patient readiness), progression (e.g., device setting selection), and

Table 1 Therapist-determined settings available for Swing Assist Mode with descriptors

Swing assist mode	Description
Max	Assistance is at 100% for step trajectory. Less susceptible to patient interaction
Adapt	The device can provide up to 100% assistance for step trajectory, but only provides this assistance if needed. Constantly adjusts to patient power needs
Fixed	The ceiling amount of assistance is set to a fixed number (100–0), as determined by the clinician. The patient may use <i>up to</i> , or <i>less than</i> , the programmed value to complete swing along the trajectory
Free	The limb is <i>not</i> being controlled in a trajectory pattern. Allows the patient more freedom to control the step, but the device can provide powered assistance or resistance through the step, as programmed by the therapist

“Step trajectory” is the path and speed of the step and is a combination of step height, step length, and swing time [25]

termination (e.g., discontinuation in favor of alternative gait interventions) of OEGT during inpatient rehabilitation.

Data analysis

Demographic and injury-related characteristics were summarized using means and standard deviations or medians and interquartile ranges for continuous variables, and counts and percentages for categorical variables. Demographic variables were summarized overall and stratified by diagnosis group. In an effort to avoid skewing data due to low sample size at higher number of sessions, OEGT session metrics were summarized for sessions in which approximately 75 percent of the sample had data for each impairment group, yielding up to 8 sessions for patients with stroke, 9 for SCI, and 12 for TBI. Continuous session metrics were summarized with means and standard deviations, and categorical metrics were summarized with counts and percentages. Bar graphs and line graphs were used to visualize the trends and change in session metrics over time. All analysis was performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

Demographic and injury characteristics

Of 3,912 (1,546 stroke, 981 SCI, and 1,385 TBI) admissions, there were 228 patients included in this analysis: 104 stroke, 99 SCI, and 25 TBI (Table 2). Patients with stroke were the oldest with an average age of 55.2 years and patients with TBI were the youngest with an average age of 38.3 years. All patient groups were majority male (67%) and identified as white race (67%). Approximately 39% of patients with stroke were right-sided and 37% were left-sided. Over half (56%) of patients with SCI had cervical level injury, and 47% had motor incomplete impairment based on AIS (and equivalent) scores. For patients with TBI, 40% emerged from post-traumatic amnesia by inpatient rehabilitation discharge. Median length of stay was 35 days for those admitted with stroke, 42 days for SCI, and 40 days for TBI.

Session counts

Patients with TBI averaged the highest number of total OEGT sessions (9.1 ± 5.6) and sessions per week during inpatient rehabilitation (1.73 ± 1.44). Patients with stroke and patients with SCI had similar OEGT session counts (6.3 ± 4.1 and 5.8 ± 4.4 , respectively) and average number of sessions per week (1.05 ± 0.65 and 1.17 ± 0.74 , respectively).

Up time, walk time, and step count

OEGT session up time, walk time, and step counts are summarized in Fig. 1 and detailed means and standard

deviations provided in Additional file 2: Appendix S2. The ratio of walk time to up time and number of steps to up time (summarized in Fig. 2 and Additional file 2: Appendix S2) generally increased over multiple sessions for stroke, SCI, and TBI. For all diagnosis groups, the largest single session increase was observed between sessions 1 and 2, with steady improvement continuing over most subsequent sessions. The average walk time and step count for patients with stroke tripled from the first session (walk time=5:48 min; step count=143) to the eighth session (walk time=17:16 min; step count=440). Patients with SCI averaged the most up time (16:34 min), walk time (10:15 min), and step count (303) in the first session and continued to tolerate increases by doubling the walk time to 20:08 min and average step count to 671 by session 9. Patients with TBI had the most variability over time in up time, walk time, and step count across sessions, but still showed overall improvement from session 1 (up time = 13:30 min; walk time = 6:30; steps = 161) to session 12 (up time = 16:42; walk time = 13:10; step count = 466).

Device assistance for swing phase

Mean OEGT session swing assistance values are provided in Fig. 3. In general, device assistance for swing decreased across sessions for patients with stroke, SCI, and TBI. However, swing assistance was observed to increase for the patients with SCI who received more than seven sessions. By contrast, a steady decline of swing assistance to approximately 60% was observed for patients with stroke and TBI.

Swing Assist Mode with mid-session changes

Therapist-determined Swing Assist Modes are displayed in Fig. 4. Adapt was the most selected mode at session initiation for all diagnoses groups. Additionally, mid-session setting changes increased in frequency across sessions for stroke (1.9 to 20%), SCI (6 to 25%) and TBI (15 to 50%).

Therapist commentary

Seven therapists participated in a semi-structured survey to provide insight for OEGT clinical decision-making (see Additional file 1: Appendix S1). All therapists had completed training for use of Ekso Bionics robotic exoskeleton devices. Overall, therapists had 8.9 years of clinical experience and 4.5 years of experience with OEGT. Therapists specialized in stroke ($n=2$), SCI ($n=2$), TBI ($n=2$), and general debility ($n=1$). Responses to multiple choice survey questions are illustrated in Fig. 5 and comments specific to clinical decision making for initiation, progression, or termination of OEGT are presented in Table 3.

Table 2 Demographic and clinical characteristics

	Overall (n = 228)	SCI (n = 99)	Stroke (n = 104)	TBI (n = 25)
Age at injury, years (mean $\pm$ std. dev.)	48.5 $\pm$ 17.5	44 $\pm$ 17.8	55.2 $\pm$ 13.9	38.3 $\pm$ 19.5
Injury to first OEGT, days (mean $\pm$ std. dev.)	62 $\pm$ 169.1	95.3 $\pm$ 219.7	29.6 $\pm$ 111	61.8 $\pm$ 94
Height, centimeters (mean $\pm$ std. dev.)	173 $\pm$ 8.9	173.7 $\pm$ 9.7	171.5 $\pm$ 8.1	175.5 $\pm$ 8.6
Weight, kilograms (mean $\pm$ std. dev.)	75.8 $\pm$ 15.1	74.7 $\pm$ 15.0	76.1 $\pm$ 16.0	69.9 $\pm$ 10.8
BMI (mean $\pm$ std. dev.)	25 $\pm$ 4.4	24.7 $\pm$ 4.3	25.8 $\pm$ 4.5	22.8 $\pm$ 3.7
Male Sex	153 (67.1%)	72 (72.7%)	62 (59.6%)	19 (76%)
Race				
White	152 (66.7%)	66 (66.7%)	67 (64.4%)	19 (76%)
African American/Black	43 (18.9%)	16 (16.2%)	24 (23.1%)	3 (12%)
Hispanic	12 (5.3%)	6 (6.1%)	5 (4.8%)	1 (4%)
Other	21 (9.2%)	11 (11.1%)	8 (7.7%)	2 (8%)
SCI level				
Cervical		55 (55.6%)		
Thoracic		34 (34.3%)		
Lumbar		5 (5.1%)		
Missing/Unknown		3 (3%)		
ASIA impairment scale				
A		12 (12.1%)		
B		14 (14.1%)		
C		23 (23.2%)		
D		24 (24.2%)		
Missing/Unknown		26 (26.3%)		
Stroke type				
Left			38 (36.5%)	
Right			40 (38.5%)	
Bilateral			9 (8.7%)	
Missing/Unknown			17 (16.3%)	
Emerged from PTA				
No				11 (44%)
Yes				10 (40%)
Unknown/Missing				4 (16%)
FIM—motor total	n = 110	n = 41	n = 59	n = 10
Admission	23.7 $\pm$ 10.1	22.2 $\pm$ 11.0	25.6 $\pm$ 9.5	17.7 $\pm$ 6.2
Discharge	49.9 $\pm$ 15.7	51.4 $\pm$ 18.0	49.9 $\pm$ 13.7	43.9 $\pm$ 16.8
Change	26.3 $\pm$ 12.2	29.1 $\pm$ 14.9	24.3 $\pm$ 9.4	26.2 $\pm$ 13.9
CARE—total	n = 113	n = 54	n = 44	n = 15
Admission	10.4 $\pm$ 4.5	11.7 $\pm$ 5.2	9.8 $\pm$ 3.5	7.7 $\pm$ 1.3
Discharge	27 $\pm$ 13.6	30.9 $\pm$ 14.2	23.4 $\pm$ 11.7	20.0 $\pm$ 11.4
Change	16.4 $\pm$ 12.9	19.4 $\pm$ 14.5	13.4 $\pm$ 9.9	12.2 $\pm$ 11.3

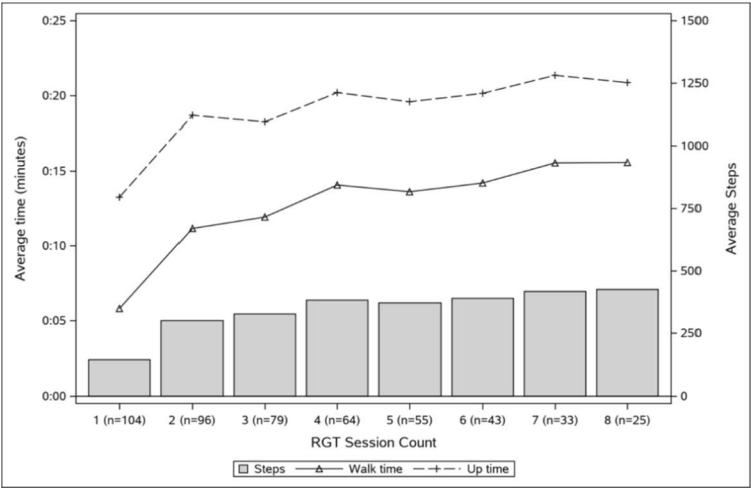
PTA post-traumatic amnesia, std dev standard deviation, BMI body mass index, SCI spinal cord injury, TBI traumatic brain injury, OEGT overground exoskeleton gait training, FIM Functional Independence Measure (used to document functional dependency prior to October 1, 2019); CARE Continuity Assessment Record and Evaluation (used to document functional dependency after October 1, 2019)

Discussion

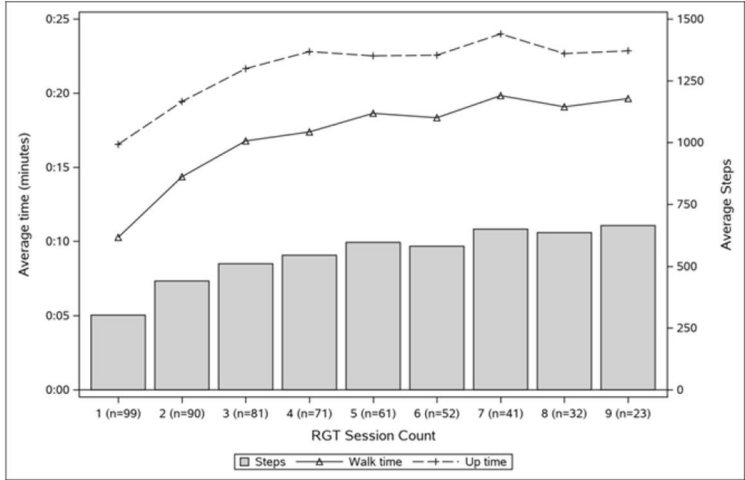
The purpose of this retrospective study was to highlight the clinical use and decision-making of OEGT within the physical therapy plan of care for patients after neurological injury during inpatient rehabilitation. On average,

patients with stroke, SCI, and TBI demonstrated progressive tolerance for OEGT as demonstrated by increasing time upright, time walking, and number of steps over successive sessions. Further, the amount of assistance provided by the robotic exoskeleton generally decreased

a. Stroke



b. SCI



c. TBI

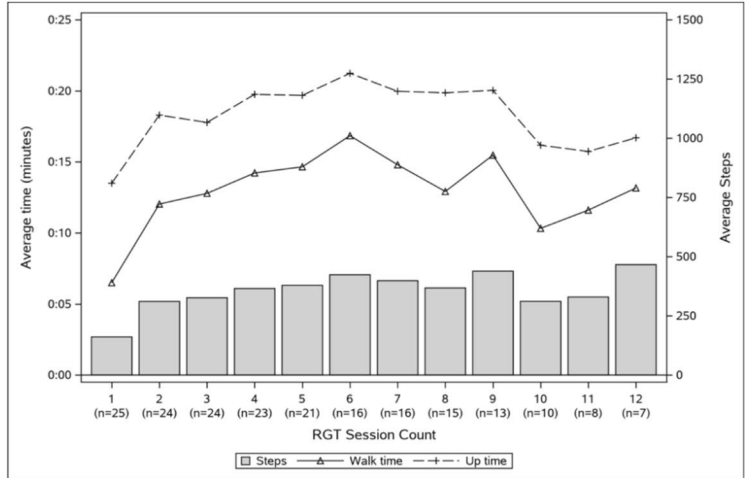
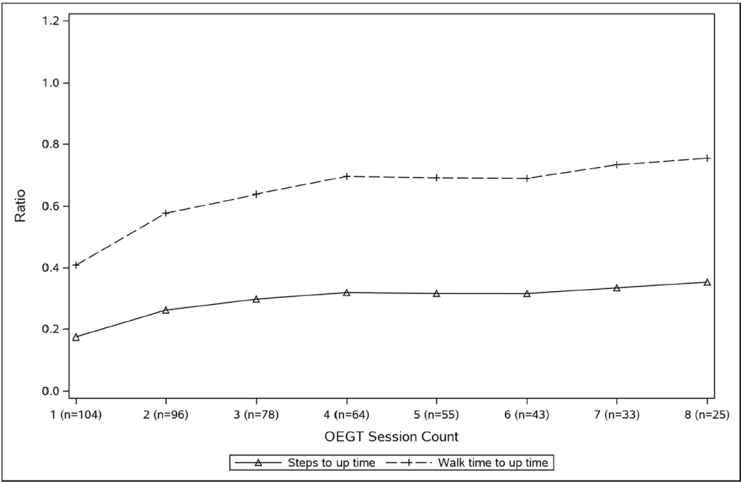
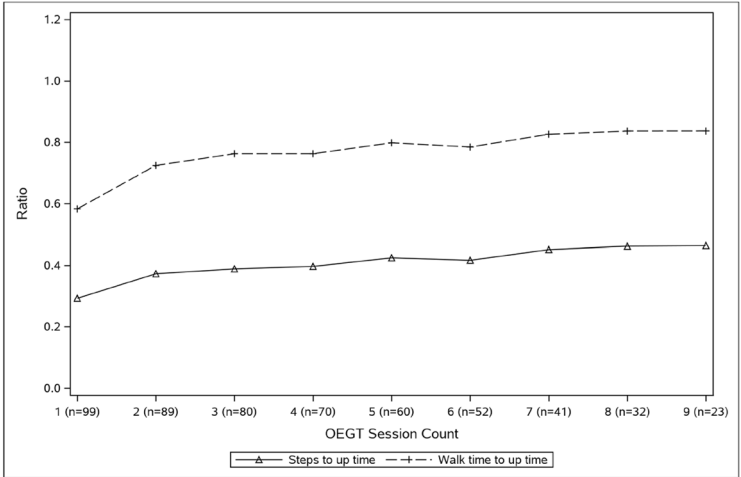


Fig. 1 OEGT session up time, walk time, and step counts over multiple sessions for each diagnosis group. Detailed means and standard deviations provided in Additional file 2: Appendix S2

a. Stroke



b. SCI



c. TBI

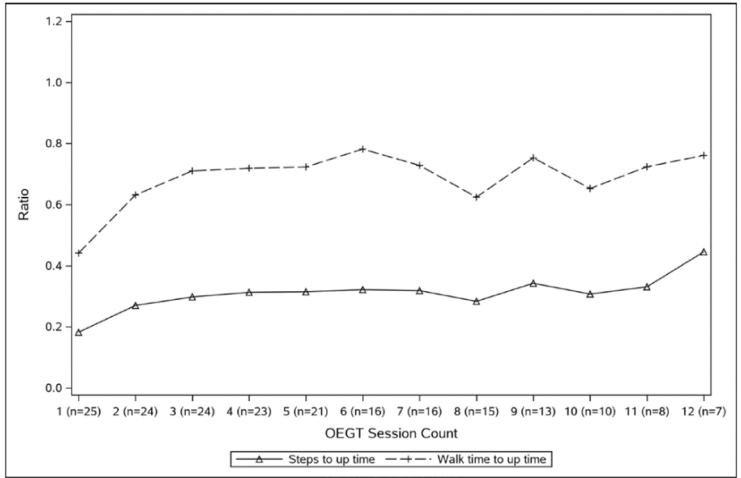


Fig. 2 Ratios of walk time to up time and number of steps to up time for each diagnosis group

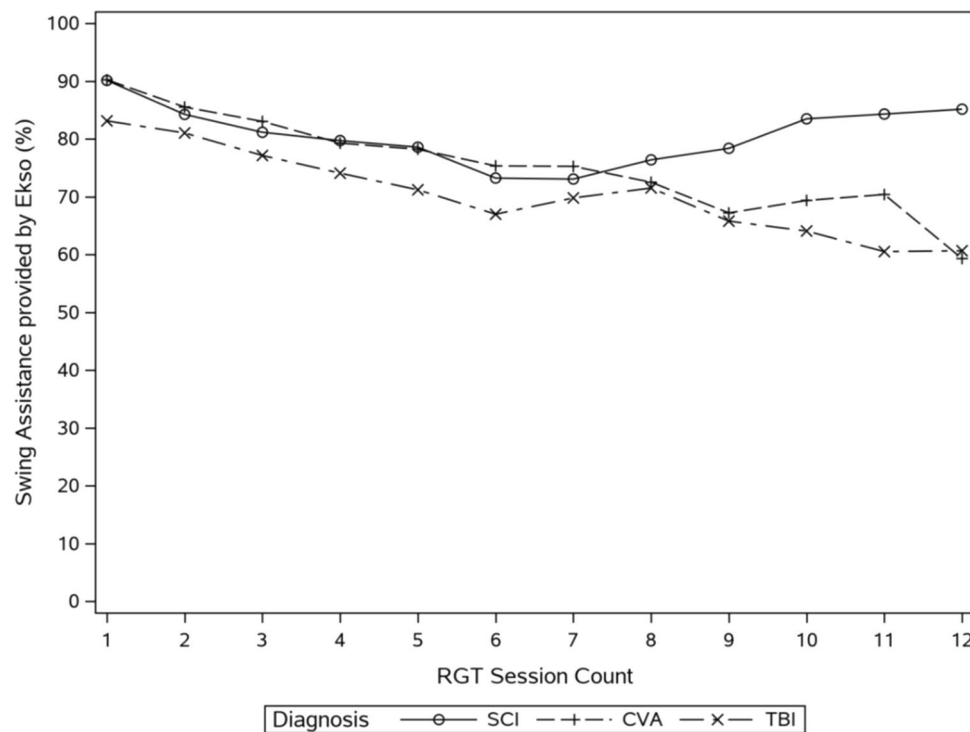


Fig. 3 Mean device assistance required for swing phase of gait across multiple sessions for each diagnosis

across those same sessions. Therapist commentary was used to illuminate clinical decision-making that contributed to the quantitative trends observed in this retrospective analysis. Reflection, evaluation, and making reactive changes are critical to the successful implementation of a new intervention and evolution of clinical practice [35]. As such, the therapists' perspectives are the product of lessons learned over 6 years.

Initiation of OEGT

Prior to initiating OEGT, patients must demonstrate standing tolerance, largely to ensure that orthostatic hypotension [36] is less likely to occur as the patient is walking in an exoskeleton. Perhaps an intuitive observation, nonetheless, manufacturer training guidelines do not specify how to determine standing tolerance. All therapists surveyed indicated "tolerating a standing program" as a primary milestone prior to beginning OEGT. However, the therapists noted an observed greater tolerance for being upright during OEGT compared to a passive standing program in a standing frame. Potentially, the stepping during OEGT allowed for improved venous return in those with neurogenic orthostatic hypotension compared to static standing [37, 38]. Early adoption of OEGT during inpatient rehabilitation could afford patients the opportunity to participate in walking retraining sooner than other gait training methods

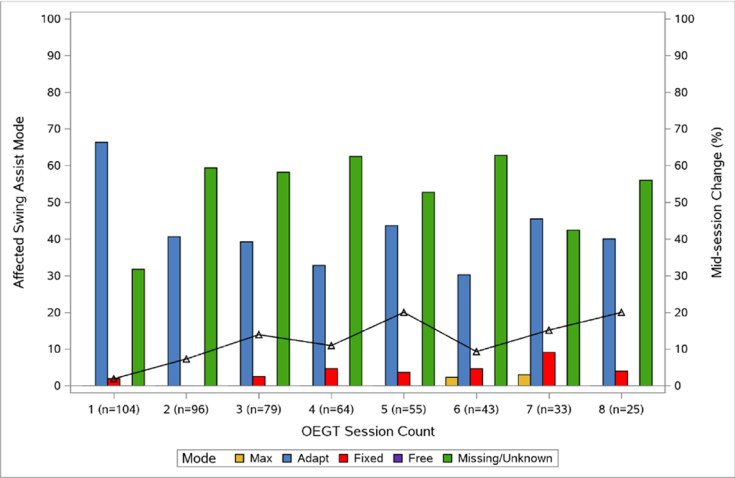
and therefore maximize the limited time available during inpatient rehabilitation [39].

Moreover, our therapists described initiating OEGT prior to other gait training interventions (e.g., body weight supported treadmill or overground walking) for patients who were more severely impaired. Specifically, therapists preferred OEGT for patients "that would be impossible to walk any other way" because of the "supportive" and "controlled" nature of OEGT. Walking interventions using OEGT were described as "less burdensome" (i.e., less physical demand on the therapist or less staff required) and "more successful" (i.e., higher repetition of steps). Contemporary neurorehabilitation recommendations highlight the importance of providing mobility training even for those with severe mobility impairments [40] and OEGT may allow for this opportunity earlier than other gait training methods and with less burden on the therapist [20] due to the supportive but adaptable nature of OEGT compared to more traditional gait training methods.

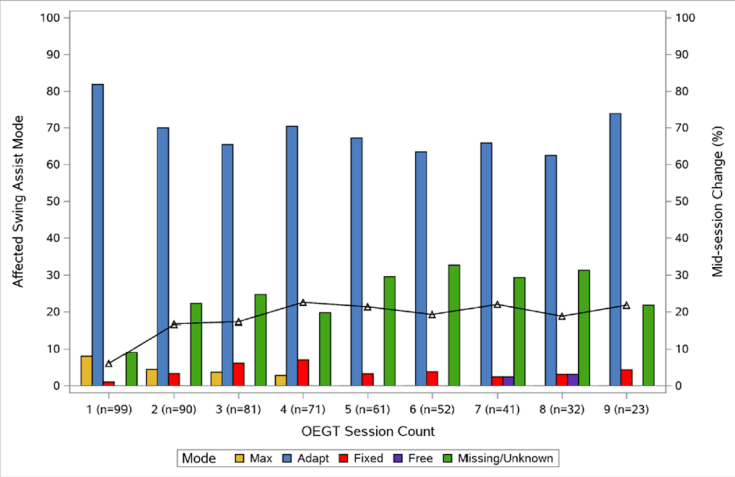
Progression of OEGT

Having initiated OEGT, therapists deliberately sought to progress OEGT to promote recovery of function. Progression of OEGT was achieved by increasing the time walking and step count and reducing device assistance. Further, the ratio of time walking and step count of our

a. Stroke



b. SCI



c. TBI

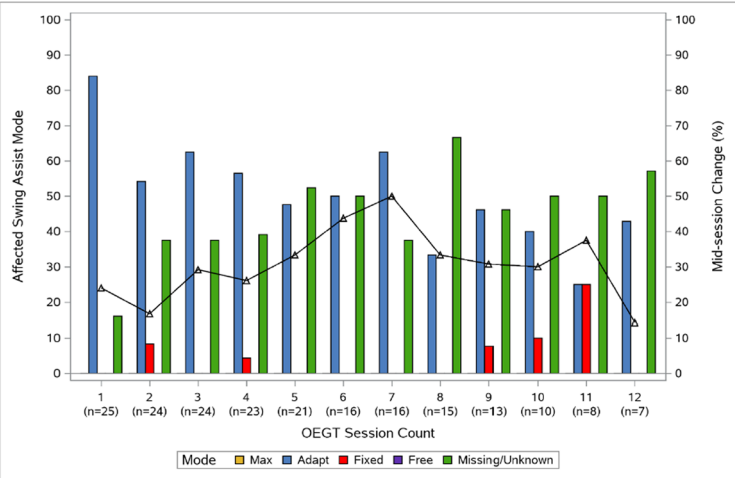


Fig. 4 Therapist-determined Swing Assist Modes for each diagnosis group

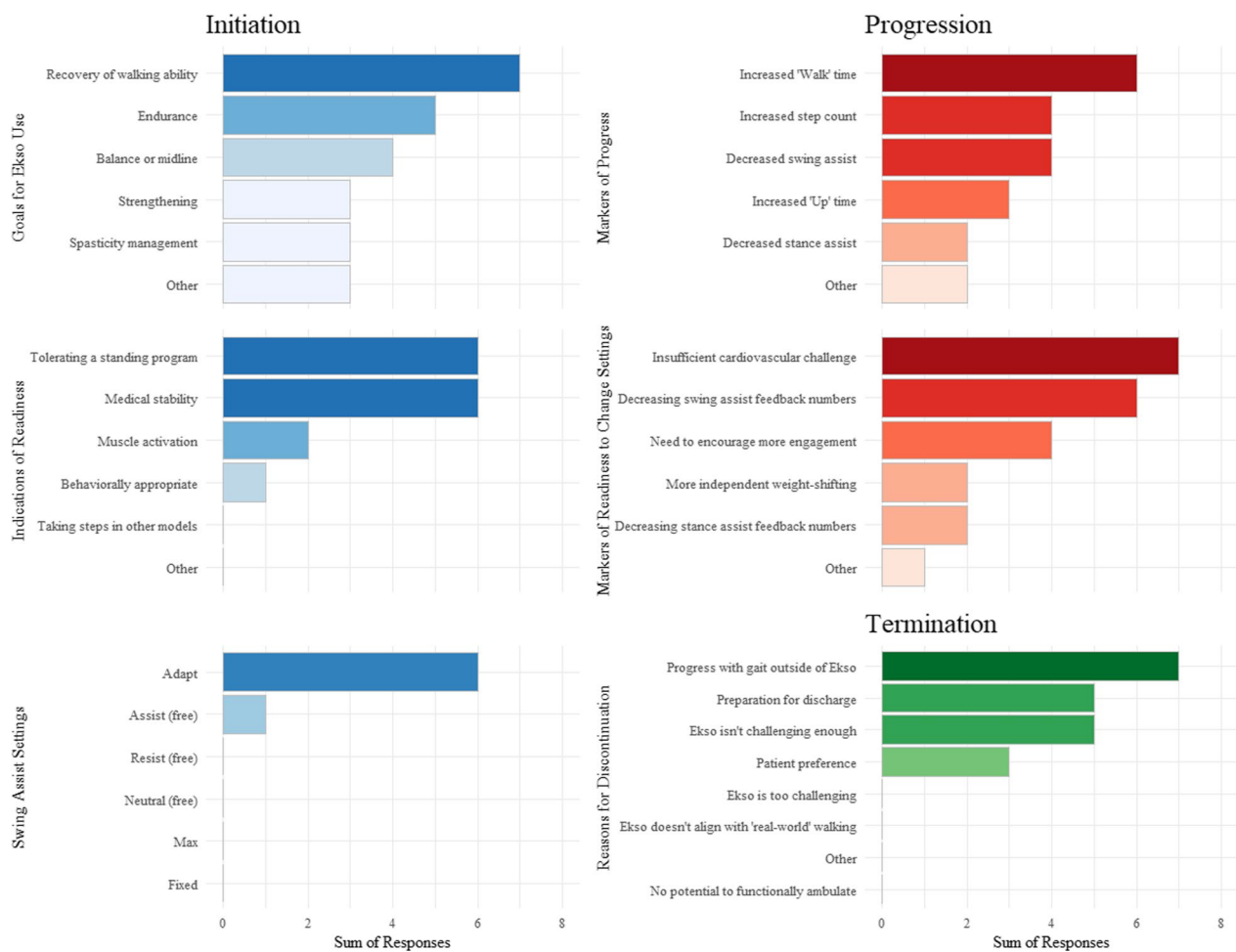


Fig. 5 Physical therapists' responses to multiple choice survey questions designed to describe clinical decisions informing the initiation, progression, and termination of OEGT during inpatient rehabilitation for patients after stroke, SCI, or TBI. See Additional file 1: Appendix S1 for survey questions and response options. Seven therapists were surveyed and were instructed to 'mark all that apply'. Higher number of responses indicate more therapists chose the specific response

Table 3 Physical therapists' comments specific to clinical decisions for OEGT after neurological injury during inpatient rehabilitation

Topic	Therapist commentary
Initiation	"I use it for patients that would be impossible to get up and walking any other way." "To me, Ekso is the most controlled/supportive form of gait training requiring the least amount of stress on both patient and staff. I often have patients ready for this before anything else." "The determination for Ekso to be the primary gait training device is dependent on quality of steps, the amount of intensity, and the repetition of steps as compared to other gait training environments."
Progression	"As soon as I see a decrease in swing assistance or their vitals aren't being challenged I will drive all numbers down in Fixed for less assistance from Ekso as soon as I can because the point of my Ekso treatments is to get them walking over ground." "As heart rate decreases in response to workload, I am clued in that they ready for more load. So, I decrease assist or add resistance and observe quality. If they are constantly corrected by the machine, I increase assist levels back to where they are working hard but successful most of the time."
Termination	"Typically, when a patient gets to Free I move to over ground walking outside of the Ekso so I can incorporate multi-directional walking, stair training, changes in speed, etc." "For CVA or TBI, once they understand the concept of midline, gain some trunk control, and learn the general requirements to produce a reciprocal pattern, I will begin incorporating overground training." "If the patient progresses to the point where gait overground or within another device provides more repetition, intensity, and variability then I will transition them out of the device."

patients to up time trended higher as OEGT sessions progressed with the greatest increase for each diagnosis group between sessions one and two. However, the ratio of walk time to up time plateaued around 0.8 suggesting the necessity of time spent standing but not walking (e.g., checking vital signs, assessing alignment of the device, standing rest breaks) amidst progressing gait training efforts.

Therapists reported patients were ready to progress when individual sessions yielded (1) decreasing assistance needed during the swing phase of gait as indicated by device feedback numbers and (2) therapist-monitored cardiovascular intensity was low despite increased session time and steps. It is human instinct to take advantage of sources for reducing energy expenditure during walking [41] (e.g., the robotic motors) and therapists must be intentional to challenge patients during OEGT sessions. Device feedback monitored by the therapists during OEGT sessions allowed for continuous opportunities to challenge the patient by adopting mid-session changes to reduce swing assistance levels. Specifically, therapists utilized a technique referred to as “submarining” to drop the fixed assist value just below the Swing Assist feedback value. This approach encourages patients to strive to achieve lower fixed assist values for continual challenge. This submarine method continues until the patient approaches relatively low fixed assist values, whereby the therapists consider transition from Fixed to Free mode, to allow the lower limb to not be controlled in the device step trajectory pattern. This method of reducing device assistance has been previously described [22, 42] to provide progressive challenge to the patient during OEGT. However, contemporary robotic exoskeleton devices do not mimic a natural gait pattern in healthy adults [43]. As such, future studies should consider allowing trajectory-free stepping earlier in attempt to promote motor relearning by allowing patients to have more autonomy over their stepping pattern.

Patients in all diagnoses generally demonstrated reduced assistance from the device for swing phase as session count progressed, except for those with SCI who demonstrated an uptick in assistance required from the device after session seven. This observed increase in assistance in later sessions is possibly due to those with more severe injuries (and less potential to participate in swing phase) having longer lengths of stay [44] and therefore more opportunities for higher session counts. Additionally, given that swing assistance was only recorded by the device in Adapt and Fixed settings, it is possible a lack of swing assistance recorded during later OEGT sessions utilizing Free settings influenced our findings. Nonetheless, differences in pathology among patients with stroke, SCI, and TBI will likely yield varying treatment

progressions during OEGT. For example, progression for a patient with hemiparesis after stroke may include unilateral assistance only or a patient with less severe (e.g., AIS D SCI) injuries may incorporate variable stepping [14].

Therapists also noted the need to progress OEGT settings when the cardiovascular intensity elicited by the current settings was low, e.g., less than 60% of heart rate reserve. Recent literature has emphasized the importance of ensuring sufficient cardiovascular intensity to enhance motor recovery after neurological injury [45, 46]. Others have encouraged reflection after each OEGT session to determine appropriate setting changes to meet cardiovascular intensities recommended during gait training [47].

Termination of OEGT

No evidence or manufacturer suggestions currently exist to support clinical decision-making regarding termination of OEGT. Although many patients continued OEGT throughout their entire inpatient rehabilitation stay, termination of OEGT most often occurred to “progress with gait outside of OEGT”. Therapists transitioned away from OEGT to select a gait training modality once they observed a plateau of therapy session intensity and repetition [39, 48]. For patients with stroke or TBI, therapists emphasized the importance of regaining “trunk control” within “midline” prior to transitioning to overground walking. Therapists described gait outside of OEGT as “generalizing more quickly”, possibly because OEGT does not mimic normal gait patterns [43] and walking in variable environments (e.g., stair and obstacle negotiation, multi-directional walking) may more readily adapt patients to walking in real-world settings [49, 50].

Another common reason for termination of OEGT was to allow time for discharge preparation, including training of caregivers. Despite walking being a highly prioritized goal after neurological injury [1, 2], independence with walking is not a requirement prior to discharge from inpatient rehabilitation. Importantly, providing caregiver training is associated with higher satisfaction of care [51] and can improve physical, mental, and emotional outcomes for both the patient and the caregiver [52]. Thus, balancing competing priorities within the constraints of an inpatient rehabilitation stay often requires forgoing task-specific gait training [39, 48] (with the aim of maximizing motor recovery) for caregiver education (with the aim at achieving a safe discharge home).

Some (8 stroke, 10 SCI, and 1 TBI) patients completed only one OEGT session during their inpatient rehabilitation length of stay. Consistent with others, reasons for a single session included therapist prioritization of other interventions to improve functional independence (e.g.,

wheelchair propulsion and transfers) [20], abbreviated inpatient rehabilitation length of stay [13], and periodically reported fearfulness or anxiety during the initial session preventing continue participation [13]. However, most patients were willing and able to participate in a second OEGT session [53].

Next steps

Given our findings, we suggest specific recommendations as next steps to expand the knowledge base guiding clinical use and decision-making of OEGT within the physical therapy plan of care during inpatient rehabilitation.

- A) Initiation: Prospective examination of patients' tolerance for dynamic upright positioning with OEGT compared to passive standing in a standing frame. A favorable outcome may allow for earlier initiation of OEGT and task-specific training.
- B) Initiation: Determination of the physiological burden on therapists during OEGT compared to usual care gait training interventions (e.g., body weight supported treadmill or overground walking). Our therapists perceived OEGT to be less burdensome which influenced their use of exoskeletons for mobility training.
- C) Progression: Incorporation of cardiovascular monitoring during OEGT for patients with neurological injuries. In response to recent literature emphasizing the importance of interventions eliciting sufficient cardiovascular intensity [46], our therapists highlighted the need to adjust OEGT settings when the cardiovascular intensity was low. However, understanding the capacity to elicit cardiovascular intensity through specific OEGT settings may be vital to progressing the intervention [47]. Prior studies suggest OEGT may be capable of eliciting cardiovascular responses into moderate and vigorous ranges during inpatient rehabilitation for patients with stroke, SCI, and TBI [11].
- D) Progression: Modification of manufacturer provided OEGT data collection forms to prompt notation of details of mid-session setting changes. Contemporary exoskeletons offer expanded software options for individualizing settings [54]. However, manufacturer provided documentation templates used by our therapists did not account for the potential of mid-session OEGT setting changes. So, while our therapists attempted to record session changes, the documentation template did not prompt such notation. Thus, specific settings of mid-session changes may not have been documented within the medical record or available for retrospective review. Captur-

ing this data will allow for greater characterization of therapy progression and associated outcomes.

- E) Termination: Establishment of functional milestones for termination of OEGT. Reasons provided by our therapists for termination of OEGT appeared to be based primarily upon device limitations and environmental considerations (e.g., timing of discharge).

Study limitations

This retrospective study has several limitations which restrict our ability to generalize findings. First, our review of OEGT sessions was limited to the data in the medical record as documented at the time the patients received care. For example, much of device and session data (i.e., OEGT device settings and mid-session changes) were missing from the medical record, leading to difficulty drawing concrete conclusions. Further, specific device settings and their association with swing assist values were not tracked in the medical record (e.g., stance support required from device, setting differences between affected and less affected lower extremities), limiting the ability to gauge their contribution to our outcomes. Second, a lack of control subjects (or comparable data tracked during traditional gait training such as step count or time spent walking) within this review contributed to the inability to base clinical decisions on this data alone. However, the inclusion of therapist perspective may have added nuance to understanding the data. Limited sample size for patients with TBI further limits generalizability of this specific data. Additionally, policy changes in the United States healthcare system in 2019 lead to a change in required functional outcome measures. Consequently, the medical record reviewed for this study did not have a consistent functional description of patients participating in OEGT limiting the ability to correlate OEGT status with functional metrics. Lastly, all OEGT sessions were completed using devices from a single manufacturer. Other FDA approved robotic exoskeleton devices may have different device settings and utilization capacities for inpatient rehabilitation populations.

Conclusion

Retrospective data from OEGT sessions for patients after neurological injury during inpatient rehabilitation indicates progressive tolerance for session duration with less device assistance required. Therapists articulated clinical benchmarks to initiate, progress, and terminate OEGT sessions for patients with stroke, SCI, and TBI. Specifically, clinical benchmarks supported early adoption and tailored progression of OEGT and deliberate transition to real-world walking approaches. Although additional clarity is needed to define optimal

clinical practice of OEGT, particularly around progression of OEGT sessions, this descriptive retrospective analysis provides recommendations on clinical application of OEGT during inpatient rehabilitation.

Abbreviations

OEGT	Overground exoskeleton gait training
SCI	Spinal cord injury
TBI	Traumatic brain injury
ASIS	ASIA impairment scale

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12984-023-01220-w>.

Additional file 1. Appendix S1. Clinical decision-making survey completed by the therapists responsible for planning and executing the OEGT sessions.

Additional file 2. Appendix S2. Means and standard deviations to supplement Fig. 1 (OEGT session up time, walk time, and step counts over multiple sessions for each diagnosis group) and Fig. 2 (ratios of walk time to up time and number of steps to up time for each diagnosis group)

Acknowledgements

The authors wish to thank Radha Morar, Holly Bednarz, Maddie Melton, Bridget Denicola, Lindsey Wynne, Faith Meza, Sara Baltz, and Ko-Lin Wu for their contributions in this study.

Author contributions

Study design and planning was led by JG and CS. Retrospective data acquisition was conducted by MB and CO. Data analysis and interpretation were conducted by JG, CS, DA, MT, CO, SD, SS, and RD. Final manuscript preparation was conducted by JG and CS with review by DA, MT, SD, LC, SS, and RD. All authors read and approved the final manuscript.

Funding

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense through the Spinal Cord Injury Research Program under Award number W81XWH2110922 and a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90IRFE0043). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). Opinions, interpretations, conclusions, and recommendations are those of the authors and may not represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Department of Defense or Federal Government.

Availability of data and materials

The data set used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Research activities were performed in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 7 March 2023 Accepted: 16 July 2023

Published online: 04 August 2023

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CASE REPORT



Intensity of overground robotic exoskeleton training in two persons with motor-complete tetraplegia: a case series

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INTRODUCTION: Participation in moderate-to-vigorous intensity physical activity (MVPA) is recommended to reduce chronic disease risk in individuals with tetraplegia. Assessing exercise intensity using traditional methods, such as heart rate, may be inaccurate in patients with motor-complete tetraplegia due to autonomic and neuromuscular dysfunction. Direct gas analysis may be more accurate. Overground robotic exoskeleton (ORE) training can be physiologically demanding. Yet, its utility as an aerobic exercise modality to facilitate MVPA in patients with chronic and acute motor-complete tetraplegia has not been explored.

CASE PRESENTATION: We present the results of two male participants with motor-complete tetraplegia who completed one ORE exercise session while intensity was assessed using a portable metabolic system and expressed in metabolic equivalents (METs). METs were calculated using a rolling 30-s average with 1 MET defined as 2.7 mL/kg/min and MVPA defined as MET $\geq$ 3.0. Participant A (28-year-old) with a chronic (12 yrs) spinal cord injury (C5, AIS A) completed 37.4 min of ORE exercise (28.9 min walking) achieving 1047 steps. Peak METs were 3.4 (average 2.3) with 3% of walk time spent in MVPA. Participant B (21-year-old) with an acute (2 months) spinal cord injury (C4, AIS A) completed 42.3 min of ORE exercise (40.5 min walking) achieving 1023 steps. Peak METs were 3.2 (average 2.6) with 12% of walk time spent in MVPA. Both participants tolerated activity well without observed adverse responses to activity.

DISCUSSION: ORE exercise may be an effective aerobic exercise modality that may increase participation in physical activity in patients with motor-complete tetraplegia.

Spinal Cord Series and Cases (2023)9:24; <https://doi.org/10.1038/s41394-023-00584-4>

INTRODUCTION

Individuals with motor-complete tetraplegia experience functional and physiological challenges that can limit both assessment of and participation in moderate-to-vigorous physical activity (MVPA) [1]. Nonetheless, individuals with motor-complete tetraplegia are encouraged to participate in adequate levels of MVPA to improve cardiorespiratory fitness which can help mitigate the increased risk of developing secondary chronic diseases [2, 3]. Immediate and chronic physiological alterations in cardiovascular and neuromuscular function resulting from disruption of the descending autonomic tracts in individuals with motor-complete tetraplegia [4] limit the utility of traditional non-invasive measures of exercise intensity, such as heart rate (HR), as well as the standardized ranges for intensity categories (e.g., % max HR, % oxygen uptake) that describe MVPA in the general population [5]. Specifically, individuals with motor-complete tetraplegia often demonstrate a non-linear association between HR and workload as well as a blunted peak HR, making it a poor predictor of intensity [6]. Accurate assessment of intensity is integral to the prescription of MVPA; therefore, other non-invasive measures of intensity would be ideal in this patient population. Strong correlations have been described between direct oxygen uptake (VO_2), measured using a metabolic system, and absolute measures

of exercise intensity (e.g., workload) in individuals with tetraplegia during seated exercise [6] and may therefore be a more accurate alternative.

Overground robotic exoskeletons (ORE), like the Ekso GT (Ekso Bionics, Richmond, CA, USA) are a feasible and safe modality that allows individuals with tetraplegia to stand and participate in overground walking exercise [7–15]. However, in a recent systematic review, only one case series described the use of Ekso ORE in an individual ($n = 1$) with motor-complete tetraplegia above C6 [16]. ORE exercise has been shown to be an effective modality to achieve MVPA in patients with spinal cord injuries across the continuum of care [17–20]; however, the utility of OREs to be used as an aerobic exercise modality to facilitate participation in MVPA in individuals with acute or chronic motor-complete tetraplegia is unknown. This case series describes the exercise intensity, measured by VO_2 and HR, attained by two individuals with motor-complete tetraplegia (one acute and one chronic) exercising in an ORE.

CASE PRESENTATION

One individual (Participant A) with chronic motor-complete tetraplegia [ASIA/ISCoS International Standards for Neurological

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Received: 8 June 2022 Revised: 13 June 2023 Accepted: 21 June 2023

Published online: 01 July 2023



Fig. 1 Utilization of a portable metabolic system to assess exercise intensity during overground robotic exoskeleton training in a patient with chronic motor-complete tetraplegia.

Classification of Spinal Cord Injury (AIS) A, C5] [21] that occurred 12 years prior and one individual (Participant B) with acute motor-complete tetraplegia (AIS A, C4) occurring 60 days prior completed an ORE exercise session in a rehabilitation hospital setting. VO_2 and HR were continually recorded throughout the session using a wearable metabolic system (K5, COSMED, Rome, Italy) and a wrist-worn HR monitor (A370 Fitness, ©Polar Electro, Kempele, Finland) (Fig. 1). Both participants underwent pre evaluation and were found to meet safety requirements for participation in ORE. These included criteria for age, weight, height, hip width, upper leg length, range of motion, bowel and bladder programming, standing frame tolerance, ankle dorsiflexion, and degree of hip flexion contracture. Neither participant had spinal instability, a deep vein thrombosis, orthostatic hypotension, osteoporosis, uncontrolled spasticity, uncontrolled autonomic dysreflexia, or skin breakdown. Additionally, both participants had completed a familiarization session in the ORE to reduce variability prior to the day of testing.

The ORE was set to ProStep+ mode with variable assistance provided by the device and actual, real-time assistance level provided by the device during exercise was recorded. Contact guard assistance was provided by a physical therapist to maintain standing balance. Breath-by-breath VO_2 data were collected and expressed using a 30-s rolling average. Intensity was estimated from VO_2 using metabolic equivalents (METs) where 1 MET was equal to 2.7 mL/min/kg of VO_2 , based on previous literature

Table 1. Participant characteristics and ORE session outcomes.

Parameter	Participant A	Participant B
Characteristics		
Age (years)	28	21
Height (cm)	180.34	172.70
Weight (kg)	54.43	51.71
Body Mass Index (kg/m^2)	16.7	17.3
AIS Category	A	A
Level of Injury	C5	C4
Time Since Injury (months)	144	2
ORE Session Outcomes		
Device Assist (Left/Right)	69/77	50/55
Up Time (min)	37.65	42.33
Walk Time (min)	28.90	40.50
Total Steps (#)	1,047	1,023
Average HR (bpm) and age predicted max (%)	112 (60)	76 (38)
Peak HR (bpm) and age predicted max (%)	133 (70)	106 (53)
Absolute VO_2 (mL/min)	339.3 ± 58.3	361.0 ± 51.0
Absolute VO_2 during MVPA (mL/min)	498.5 ± 6.1	446.6 ± 37.6
Relative VO_2 (mL/min/kg)	6.2 ± 1.1	7.0 ± 1.0
Relative VO_2 during MVPA (mL/min/kg)	9.2 ± 0.1	8.6 ± 0.7
Average METs	2.3 ± 0.4	2.6 ± 0.4
Average METs during MVPA	3.4 ± 0.0	3.2 ± 0.3
Duration of MVPA (min)	1	5
% of ORE session in MVPA (%)	3	12

Continuous data presented as mean $\pm$ standard deviation.

MVPA moderate to vigorous physical activity, ORE overground robotic exoskeleton, AIS American Spinal Injury Association Impairment Scale, HR heart rate, VO_2 oxygen uptake, METs metabolic equivalents.

describing resting energy expenditure in individuals with SCI and MVPA was defined as ≥ 3 METs [22].

Participant characteristics and ORE session outcomes are detailed in Table 1. Participant A averaged 2.3 ± 0.4 METs overall, 3.4 ± 0.0 METs during MVPA, and an average and peak HR (% age-predicted-max) of 112 bpm (60%) and 133 bpm (70%), respectively. Participant B averaged 2.6 ± 0.4 METs overall, 3.2 ± 0.3 METs during MVPA, and an average and peak HR (% age predicted max) of 76 bpm (38%) and 106 bpm (53%), respectively. Both participants tolerated the ORE session without adverse responses. MVPA was sustained for 3% and 12% of the total ORE exercise session for Participant A and Participant B, respectively.

DISCUSSION

In this case series, the use of OREs as an aerobic exercise modality, and the exercise intensity attained during ORE exercise, in two individuals with motor-complete tetraplegia of varying chronicity is described. The majority of the ORE session duration was categorized as light intensity (<3 METs), though MET levels consistent with MVPA were observed in both participants. Specifically, Participant A achieved MVPA for only 3% of the ORE session and Participant B achieved MVPA for 12% of the session. However, Participant B demonstrated HR responses consistent with low-intensity physical activity despite having higher average METs and spending more of the ORE session at MET levels

consistent with MVPA. Conversely, Participant A demonstrated HR responses consistent with MVPA despite having lower average VO_2 and spending less of the ORE session at MET levels consistent with MVPA. These results, along with the blunted peak HR observed in both participants, are consistent with the literature describing HR as a poor predictor of exercise intensity in individuals with tetraplegia [6, 17] and supports the use of direct measures of intensity, such as VO_2 as described in this case series.

The discrepancy in exercise intensity achieved using VO_2 between the two participants may be partially explained by chronicity of injury and the ORE settings used during this single session. Individuals with motor-complete tetraplegia often experience hemodynamic, autonomic, and neuromuscular dysfunction resulting in an abnormal response to exercise and impaired oxygen extraction in the paralyzed muscle [23]. Following injury, significant muscular atrophy occurs further reducing contributory muscle mass with significant atrophic changes observed within the first few weeks to a year following SCI [24–26]. It is possible that with 12 years elapsed since his injury despite similarities in height and weight, Participant A may have experienced a higher degree of muscular atrophy and lower fat free mass than Participant B, contributing to the lower VO_2 outcomes.

The variability of fat-free mass loss following injury highlights an important limitation to consider in this case series. Intensity was estimated from VO_2 using MET values derived from research involving individuals with spinal cord injuries of varying chronicity, level, and completeness [22] and does not account for individual variations in fat-free mass [26]. The use of a standardized estimate for 1 MET is a universally accepted concept and, since the literature supports the use of 2.7 mL/kg/min as an estimate for 1 MET in individuals with tetraplegia [22], this value was used for both participants to estimate intensity. Future research could implement testing of resting energy expenditures to individualize the value for one MET when comparing two persons with potential differences in fat-free mass related to chronicity of injury. However, this method may not be feasible in the rehabilitation setting, as was in the present case series, due to scheduling (e.g., unable to access patient while fasting) and resource barriers (e.g., time required for testing, specialized equipment). Additionally, the significant loss of fat-free mass over time in individuals with motor-complete tetraplegia may be an important consideration when choosing the program settings on the Ekso when performing ORE exercise. In this case, Participant A was receiving more assistance from the device than Participant B, which could have implications for intensity. However, the assistance level chosen was individualized to be the lowest assistance level on each side that would still allow for initiation of gait.

Other modalities that directly recruit more active muscle mass in the upper body (e.g., arm ergometry) or that provide neuromuscular stimulation (e.g., FES) may be more effective in facilitating adequate levels of MVPA in individuals with motor-complete tetraplegia [27]. However, ORE exercise allows for these individuals to stand upright, which is associated with multiple health benefits for individuals with spinal cord injuries [7, 28], and allows for continuous exercise bouts while preserving the health of the shoulders which are at risk for overuse injury in this population [29]. Of note, a potential solution to increase the intensity of ORE exercise surrounds the use of peripheral or spinal cord transcutaneous stimulation to enhance the metabolic contribution of the lower limbs during overground walking [30, 31]. If this proves to be safe and effective, it could allow individuals with motor-complete tetraplegia to reap the benefits of upright activity performed during ORE exercise while increasing the metabolic contribution and ideally, exercise intensity. That said, the current state of ORE technology as applied to our two participants appears to have limited potential to elicit consistent MVPA in individuals with motor-complete tetraplegia. Larger investigations into the safety, tolerability, and efficacy of OREs

with and without neuromodulation, to allow individuals with motor-complete tetraplegia to participate in sufficient levels of MVPA to improve health outcomes are warranted.

Last, the intervention described herein (ORE exercise) with concurrent direct measures of intensity (portable metabolic testing) may not be generalizable to all rehabilitation facilities due to the cost of the equipment as well as the specialized staff needed to operate them [28]. However, the discrepancy that exists between other non-invasive measures of intensity (e.g., HR, rate of perceived exertion) and work being performed emphasizes the need for more direct measures of intensity. Furthermore, many rehabilitation hospitals are working to implement technology, which becomes increasingly available and affordable with the passing years, to support the health and function of individuals with motor-complete tetraplegia and other neurological injuries, which could include OREs and metabolic equipment.

Nonetheless, the results of this case series highlight that two young males with motor-complete tetraplegia of varying chronicity were able to safely complete over 1000 steps during an ORE exercise session, mostly spent in light levels of intensity, with no adverse events or responses. These results support the exploration into utilizing OREs as a modality to perform aerobic exercise in an upright position in individuals with motor-complete tetraplegia who experience functional and physiological barriers to participating in adequate levels of physical activity. Investigating the utility of OREs to function as an aerobic exercise modality as well as a gait training modality has significant implications for individuals with spinal cord injuries or other neurological conditions, particularly those who are non-ambulatory or may otherwise be unable to participate in overground walking exercise. This information will help clinicians and fitness professionals develop exercise prescriptions that can allow for individuals with motor-complete tetraplegia, whether acute or chronic, to participate in recommended levels of physical activity needed to improve cardiorespiratory fitness and other health parameters.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, KDB, upon reasonable request.

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ACKNOWLEDGEMENTS

The authors would like to acknowledge the Baylor Scott & White Foundation for support of this project.

AUTHOR CONTRIBUTIONS

All authors contributed equally and have read and approved the submission of this case series.

COMPETING INTERESTS

This work was supported by the Baylor Scott & White Research Institute Operations. The authors report there are no competing interests to declare.

ETHICAL APPROVAL

Need for formal ethical approval was waived, however, the individuals described herein have given permission for their information to be used in this submission.

ADDITIONAL INFORMATION

Supplementary information The online version contains supplementary material available at <https://doi.org/10.1038/s41394-023-00584-4>.

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Clinical Delivery of Overground Exoskeleton Gait Training in Persons With Spinal Cord Injury Across the Continuum of Care: A Retrospective Analysis

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Background: After spinal cord injury (SCI), inpatient rehabilitation begins and continues through outpatient therapy. Overground exoskeleton gait training (OEGT) has been shown to be feasible in both settings, yet its use as an intervention across the continuum has not yet been reported. **Objectives:** This study describes OEGT for patients with SCI across the continuum and its effects on clinical outcomes. **Methods:** Medical records of patients with SCI who completed at least one OEGT session during inpatient and outpatient rehabilitation from 2018 to 2021 were retrospectively reviewed. Demographic data, Walking Index for Spinal Cord Injury-II (WISCI-II) scores, and OEGT session details (frequency, “walk” time, “up” time, and step count) were extracted. **Results:** Eighteen patients [male (83%), White (61%), aged 37.4 ± 15 years, with tetraplegia (50%), American Spinal Injury Association Impairment Scale A (28%), B (22%), C (39%), D (11%)] completed OEGT sessions (motor complete, 18.2 ± 10.3 ; motor incomplete, 16.7 ± 7.7) over approximately 18 weeks (motor complete, 15.1 ± 6.4 ; motor incomplete, 19.0 ± 8.2). Patients demonstrated improved OEGT session tolerance on device metrics including “walk” time (motor complete, $7:51 \pm 4:42$ to $24:50 \pm 9:35$ minutes; motor incomplete, $12:16 \pm 6:01$ to $20:01 \pm 08:05$ minutes), “up” time (motor complete, $16:03 \pm 7:41$ to $29:49 \pm 12:44$ minutes; motor incomplete, $16:38 \pm 4:51$ to $23:06 \pm 08:50$ minutes), and step count (motor complete, 340 ± 295.9 to 840.2 ± 379.4 ; motor incomplete, 372.3 ± 225.2 to 713.2 ± 272). Across therapy settings, patients with motor complete SCI experienced improvement in WISCI-II scores from 0 ± 0 at inpatient admission to 3 ± 4.6 by outpatient discharge, whereas the motor incomplete group demonstrated a change of 0.2 ± 0.4 to 9.0 ± 6.4 . **Conclusion:** Patients completed OEGT across the therapy continuum. Patients with motor incomplete SCI experienced clinically meaningful improvements in walking function. **Key words:** exoskeleton device, locomotor training, neurological rehabilitation, physical therapy, spinal cord injury

Introduction

Following spinal cord injury (SCI), intensive rehabilitative efforts begin in the inpatient rehabilitation setting and often continue with outpatient therapy services. During the first year following SCI, 44% of total therapy hours occur in inpatient rehabilitation,¹ with an average length of stay of 32 days.² The remaining 56% of therapy hours over the first year are completed in the outpatient setting¹ with goals to promote neurologic recovery and improved function through continued activity-based therapy.³ As walking and mobility-related

goals are a high priority to patients with SCI,⁴⁻⁶ gait training is a common activity-based intervention for persons with SCI during both inpatient rehabilitation and outpatient therapy settings.^{3,7}

Contemporary usual care gait training efforts vary for people with SCI, with a lack of clear recommendations to guide best practice.⁸ The use of body weight-supported treadmill training and conventional overground gait training using assistive devices have demonstrated limited and equivocal effectiveness to improve walking ability following SCI.^{3,7,8} However, advancing technology

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Top Spinal Cord Inj Rehabil
Advance online publication
www.asia-spinalinjury.org
doi: 10.46292/sci23-00001

has developed wearable powered robotic exoskeleton devices capable of walking overground.⁹ These devices are becoming increasingly prevalent and may provide an alternative to usual care gait training approaches.^{9,10} Overground exoskeleton gait training (OEGT) has been shown to be safe and feasible with both the subacute^{11,12} and chronic⁶ SCI populations and across varying injury levels and severity of SCI.^{6,7,10,13-15} Existing literature suggests a variety of potential benefits including psychological benefits; improved posture, strength, and bowel and bladder sensation and function; decreased pain and spasticity; and reduced complications affecting cardiovascular and respiratory systems, in addition to functional and gait improvements.^{7,16,17}

Despite documented feasibility and tolerability of OEGT in both inpatient and outpatient settings,^{6,11,12} the impact of OEGT on clinical outcomes as a therapeutic intervention carried out across the therapy continuum has yet to be illustrated. With the dramatic decrease in inpatient rehabilitation length of stay after SCI,¹⁸ the risk of postrehabilitation health and functional decline after SCI has increased.¹⁹ Recent findings suggest that higher function²⁰ and a protracted gait intervention after SCI²¹ can reduce health care utilization and maximize outcomes for people with SCI. The purpose of this retrospective study is to describe the use of OEGT beginning early in inpatient rehabilitation, a critical window for neurological recovery,^{22,23} and continuing into outpatient therapy settings and its effects on clinical outcomes in persons with motor complete versus motor incomplete SCI. Specifically, we anticipated patients with motor complete and motor incomplete SCI would experience improvements in device metrics, illustrating the ability to be progressively challenged across the therapy continuum using OEGT. Additionally, we hypothesized that patients with motor incomplete SCI, in contrast to motor complete, would demonstrate improvements in walking function over time.

Methods

Participants

Based on review of the medical record, patients were eligible and included if they completed a minimum of one OEGT session during both inpatient and outpatient therapy at our facility following SCI.

Eligibility aligned with clinical and exoskeleton manufacturer inclusion criteria and frame limitations: age greater than 18 years; bowel and bladder continence or Foley catheter in place; involved in standing program; having weight of 100 kilograms or less, height between 1.5 and 1.9 meters tall, and standing hip width of 0.45 meters or less; having near normal range of motion in hips, knees, and ankles (able to attain a neutral ankle dorsiflexion with <12 degrees of knee flexion, no more than 12 degrees of knee flexion contracture, and no more than 17 degrees of hip flexion contracture); and having no upper leg length discrepancy greater than 1.3 cm or lower leg discrepancy greater than 1.9 cm. Patients were excluded from OEGT for spinal instability, untreated deep vein thrombosis (DVT), decreased standing tolerance due to orthostatic hypotension, known history of osteoporosis that prevented safe standing or increased the risk of fracture caused by standing or walking, uncontrolled spasticity, uncontrolled autonomic dysreflexia (AD), skin integrity issues on contact surfaces of the device or on surfaces that would prohibit sitting, and pregnancy.¹⁵

Device

The exoskeleton device used was the Ekso GT²⁴ (Ekso Bionics, San Rafael, CA), which is a wearable, battery-operated exoskeleton that is powered by motors at the hip and knee joints. The device allows stepping motion to be initiated by specific patient weight shift; the amount of motor assistance provided by the device can be varied as the patient progresses across therapy sessions. The Ekso GT provides bilateral assistance to the lower extremities and allows for programmatic settings to be adjusted throughout the session to provide maximal, adaptive, fixed, or no assistance (free mode) throughout the gait cycle.²⁴ This device has class II FDA approval for use with people with SCI.²⁵

A typical OEGT session in both inpatient rehabilitation and outpatient therapy settings was 45 minutes during which the participant completed standing and walking tasks in the exoskeleton device. Device parameters and treatment progression were selected by the treating physical therapist and individualized for each patient according to their tolerance and treatment goals.

Procedure

Hospital institutional review board approval and waiver of consent due to retrospective analysis were obtained prior to initiating data collection procedures. Based on eligibility criteria, medical records were retrospectively reviewed at one rehabilitation hospital comprised of inpatient and outpatient departments from December 2018 to December 2021 to identify patients who participated in OEGT for a minimum of one therapy session in each setting. Research staff were trained to review the demographic and clinical variables extracted from the medical record, and extracted data were audited by the research team for accuracy.

OEGT session data were first recorded onto paper case report forms by the treating therapist and then entered into the electronic medical record. A member of the research team then retrieved OEGT session data from the medical record and cross-referenced data with the case report forms for confirmation. Clinical outcome measures were captured at admission and discharge from inpatient and outpatient rehabilitation by the primary therapist.

Outcomes

Demographic data included age, gender, race, ethnicity, diagnosis, mechanism of injury, time since injury, and inpatient rehabilitation and outpatient therapy lengths of stay. Severity of injury was obtained using the American Spinal Injury Association Impairment Scale (AIS) for patients with traumatic injury and an AIS equivalent for nontraumatic injuries.²⁶ The primary clinical outcome collected during both inpatient and outpatient admissions was the Walking Index for Spinal Cord Injury-II (WISCI-II).^{27,28} The WISCI-II defines the physical limitation for walking secondary to impairment at the person level and is indicative of the ability of a person to walk after SCI.²⁷ A change of one WISCI level can be considered clinically meaningful.²⁸ OEGT session data included frequency of robotic exoskeleton use, up time (i.e., amount of time spent in the device in upright standing), walk time (i.e., amount of time spent walking in the device), and number of steps.

Data analysis

Demographic and injury-related characteristics were summarized using means and standard deviations for continuous variables and counts and percentages for categorical variables. Demographic variables were summarized overall and stratified by injury impairment (motor complete vs. motor incomplete). OEGT session metrics were summarized by impairment and across both inpatient and outpatient settings. Graphs were used to visualize the trends and change in session metrics over time. Analysis was performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

Demographic and injury characteristics

Overall, 569 patients with a spinal cord injury/disorder (SCI/D) diagnosis were admitted to our inpatient rehabilitation hospital during the 3-year study period. Of these, 74 participated in OEGT during inpatient rehabilitation and 18 continued the intervention into outpatient therapy. These 18 patients met eligibility criteria and were included in this analysis (**Table 1**). AIS scores indicated that nine patients experienced motor complete injuries (AIS A and B) and nine experienced motor incomplete injuries (AIS C and D). Patients were 37.4 ± 15 years of age, and were majority male (83%), and White (61%). Injuries were primarily due to a traumatic event, with motor vehicle incident (39%) and gunshot wound (17%) being the most common mechanisms. Over half (56%) of the patients had a cervical level injury, and there were no lumbar injuries.

OEGT session frequency

The average number of OEGT sessions across inpatient and outpatient settings was approximately 19 for both motor complete and motor incomplete SCI groups spanning over an average of 17 to 18 weeks. **Figure 1** illustrates the number of patients at each session count stratified by impairment group. Both groups completed a greater number of sessions in outpatient therapy than in inpatient rehabilitation (**Table 2**). Interestingly, following inpatient discharge, 22.6 ± 20.2 days (motor complete) and 52.1 ± 40.2 days (motor incomplete) elapsed before the first outpatient OEGT session.

Table 1. Summary of demographic data

	All (N = 18)	Motor complete (n = 9)	Motor incomplete (n = 9)
Age at injury	37.4 ± 15	30.1 ± 11.3	44.7 ± 15.1
Sex, male	15 (83.3%)	8 (88.9%)	7 (77.8%)
Race			
White	11 (61.1%)	6 (66.7%)	5 (55.6%)
Asian	3 (16.7%)	1 (11.1%)	2 (22.2%)
African American/Black	2 (11.1%)	1 (11.1%)	1 (11.1%)
Unknown	2 (11.1%)	1 (11.1%)	1 (11.1%)
Insurance - Inpatient			
Self-pay or uninsured	2 (11.1%)	0 (0%)	2 (22.2%)
Unknown/missing	16 (88.9%)	9 (100%)	7 (77.8%)
Insurance - Outpatient			
Private	13 (72.2%)	7 (77.8%)	6 (66.7%)
Self-pay or uninsured	2 (11.1%)	2 (22.2%)	0 (0%)
Medicare	1 (5.6%)	0 (0%)	1 (11.1%)
Unknown/missing	2 (11.1%)	0 (0%)	2 (22.2%)
Mechanism of injury			
Motor vehicle	7 (38.9%)	3 (33.3%)	4 (44.4%)
Motorcycle	1 (5.6%)	1 (11.1%)	0 (0%)
Gunshot wound	3 (16.7%)	2 (22.2%)	1 (11.1%)
Water sports	2 (11.1%)	1 (11.1%)	1 (11.1%)
Air sports	1 (5.6%)	1 (11.1%)	0 (0%)
Other unclassified	1 (5.6%)	0 (0%)	1 (11.1%)
N/A, nontraumatic	3 (16.7%)	1 (11.1%)	2 (22.2%)
Paraplegia or tetraplegia			
Paraplegia	9 (50.0%)	5 (55.6%)	4 (44.4%)
Tetraplegia	9 (50.0%)	4 (44.4%)	5 (55.6%)
SCI level			
Cervical	10 (55.6%)	4 (44.4%)	6 (66.7%)
Thoracic	7 (38.9%)	4 (44.4%)	3 (33.3%)
Lumbar	0 (0%)	0 (0%)	0 (0%)
Missing/unknown	1 (5.6%)	1 (11.1%)	0 (0%)

(continues)

Table 1. Summary of demographic data (*cont.*)

	All (<i>N</i> = 18)	Motor complete (<i>n</i> = 9)	Motor incomplete (<i>n</i> = 9)
ASIA Impairment Scale			
A	5 (27.8%)		
B	4 (22.2%)		
C	7 (38.9%)		
D	2 (11.1%)		

Note: Values are given as *n* (%) except for age, which is given as mean $\pm$ SD. Motor complete = ASIA Impairment Scale A and B; motor incomplete = ASIA Impairment Scale C and D; SCI = spinal cord injury; WISCI-II = Walking Index for Spinal Cord Injury-II.

Table 2. WISCI-II scores across inpatient and outpatient therapy

	<i>n</i>	Time since injury, weeks	LOS, weeks	No. of OEGT sessions	Admit WISCI-II	Discharge WISCI-II	Gain WISCI-II	Effect size (<i>d</i>) for gain
Inpatient								
Complete	9	9.6 $\pm$ 20.2	6.8 $\pm$ 3.6	8.3 $\pm$ 5.2	0 $\pm$ 0	0.3 $\pm$ 1.0	0.3 $\pm$ 1.0	0.30
Incomplete	9	9.5 $\pm$ 10.2	6.3 $\pm$ 3.2	5.8 $\pm$ 3.4	0.2 $\pm$ 0.4	1.9 $\pm$ 3	1.7 $\pm$ 3.1	0.55
Outpatient								
Complete	6	13.0 $\pm$ 7.5	9.9 $\pm$ 6.0	12.2 $\pm$ 9.3	0 $\pm$ 0	3.0 $\pm$ 4.6	3.0 $\pm$ 4.6	0.65
Incomplete	7	18.8 $\pm$ 10.8	13.0 $\pm$ 8.6	12.7 $\pm$ 7.3	4.0 $\pm$ 2.8	9.0 $\pm$ 6.4	5.0 $\pm$ 6.0	0.83

Note: Values are given as mean $\pm$ SD. Complete = motor complete injuries (ASIA Impairment Scale A and B); Incomplete = motor incomplete injuries (ASIA Impairment Scale C and D); LOS = length of stay; OEGT = overground exoskeleton gait training; WISCI-II = Walking Index for Spinal Cord Injury-II.

Up time, walk time, and step count

OEGT session walk time, up time, and step counts are summarized in **Figure 2A** for patients with motor complete SCI and **Figure 2B** for patients with motor incomplete SCI. Patients averaged 16:03 $\pm$ 7:41 minutes (motor complete) and 16:38 $\pm$ 4:51 minutes (motor incomplete) of up time and 7:51 $\pm$ 4:42 minutes (motor complete) and 12:16 $\pm$ 6:01 minutes (motor incomplete) of walk time during the first OEGT session. Walk time increased steadily through session 13 for both groups (motor complete, up time 29:49 $\pm$ 12:44 minutes, walk time 24:50 $\pm$ 9:35 minutes; motor incomplete, up time 23:06 $\pm$ 08:50, walk time 20:01 $\pm$ 08:05 minutes). Few patients had more than

19 sessions, resulting in highly variable estimates at higher session counts.

Walking function

WISCI-II scores were available for nine patients with motor complete SCI and nine patients with motor incomplete SCI at inpatient admission and discharge, and six patients with motor complete SCI and seven patients with motor incomplete SCI at outpatient admission and discharge (**Table 2**). At inpatient admission, patients were unable to stand or walk, scoring an average of 0 $\pm$ 0 (motor complete) and 0.2 $\pm$ 0.4 (motor incomplete). Discharge scores represent limited gains in walking function by the end of inpatient rehabilitation. Following outpatient

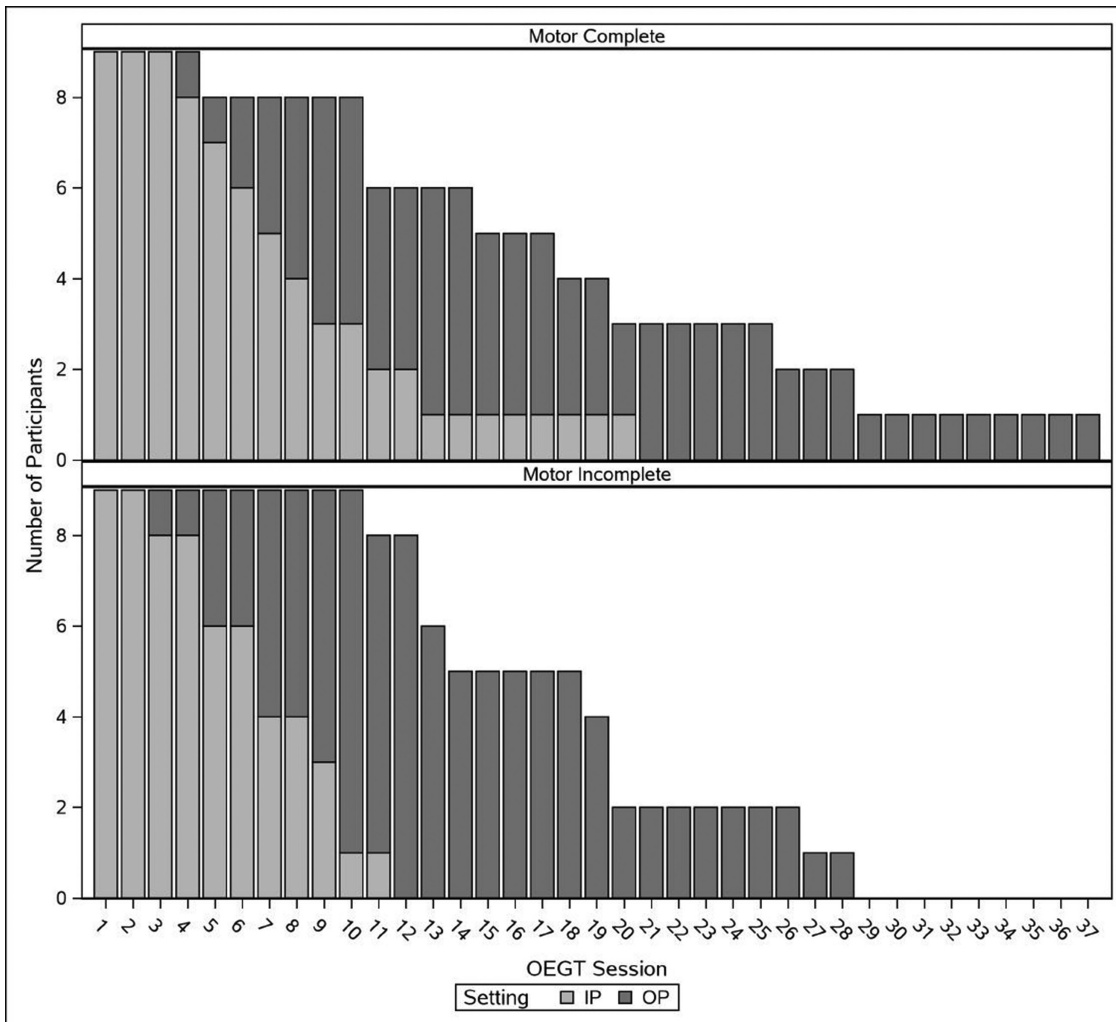


Figure 1. Overground exoskeleton gait training (OEGT) session count by setting and stratified by motor complete and motor incomplete spinal cord injury (SCI). For both SCI groups, a greater number of sessions were completed in the outpatient (OP) therapy setting than while in inpatient (IP) rehabilitation.

therapy, patients with motor complete SCI were able to walk in parallel bars with bracing and assistance of one person (WISCI-II level 3), and patients with motor incomplete SCI were able to walk with a walker and braces with no physical assistance (WISCI-II level 9). Cohen's *d* effect sizes for gain in WISCI-II scores during inpatient rehabilitation shows a small effect for complete and medium effect for incomplete injuries. During outpatient therapy, medium and large effects were seen for complete and incomplete injuries, respectively. **Figures 3A** and **3B** highlight the walking function over time

as expressed by the WISCI-II scores for motor complete (A) and motor incomplete (B) SCI.

Close inspection of the motor complete SCI group revealed that improvement in walking function occurred in only three individuals. One patient was diagnosed as T12 AIS A with a zone of partial preservation to L1 upon admission to inpatient rehabilitation. This individual was able to walk with bracing and therapist assistance at discharge from inpatient rehabilitation but did not progress beyond requiring this level of assistance during outpatient therapy. Two patients diagnosed

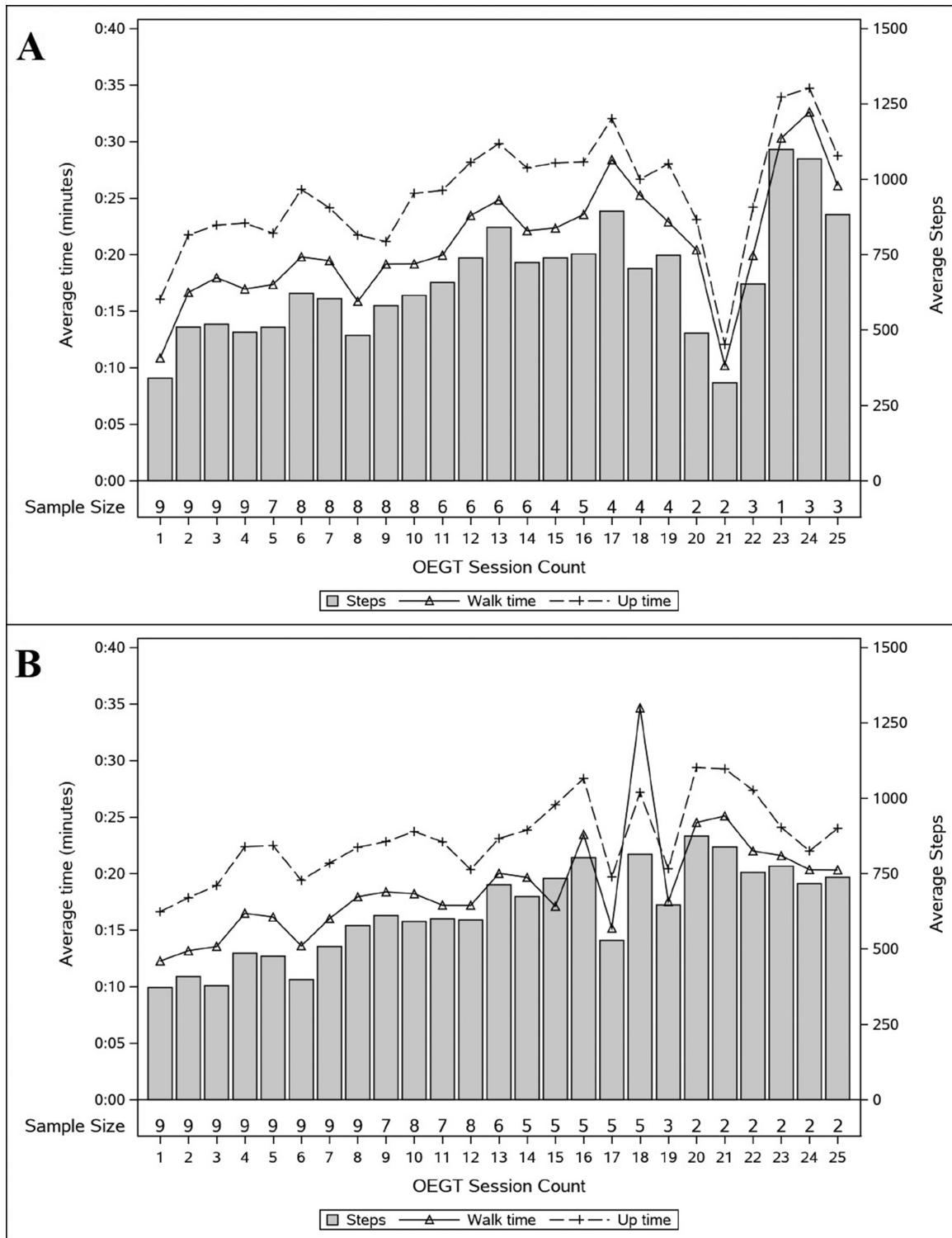


Figure 2. Overground exoskeleton gait training (OEGT) session metrics for patients with (A) motor complete and (B) motor incomplete SCI. Across sessions, patients with spinal cord injury demonstrate upward trends in number of steps, walk time, and up time irrespective of severity of injury.

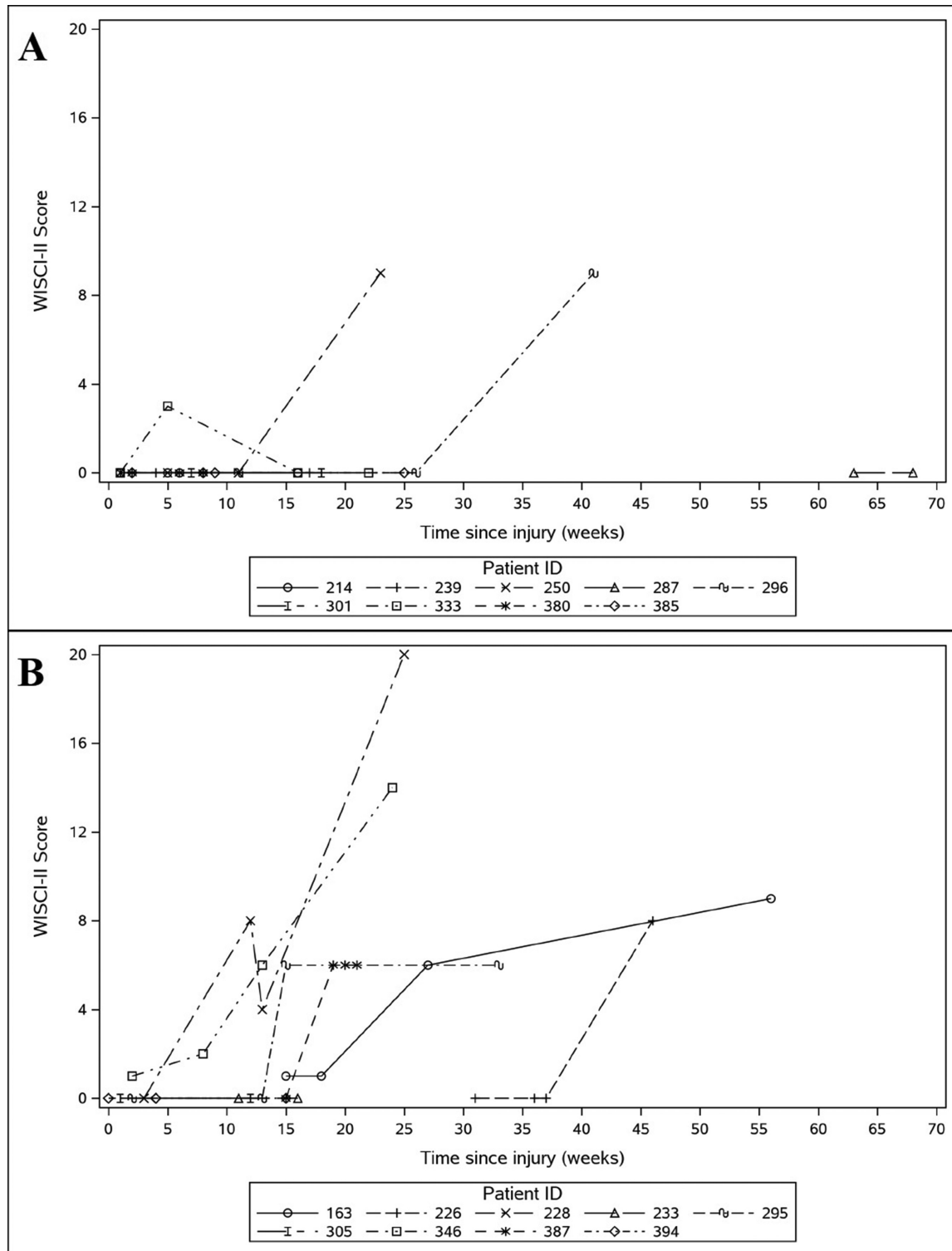


Figure 3. Trajectory of individual Walking Index for Spinal Cord Injury-II (WISCI-II) scores by patient from time since injury at four timepoints: admission/discharge from inpatient rehabilitation and admission/discharge from outpatient therapy. (S) Patients with motor complete spinal cord injury (SCI) ($n = 9$) remained at a WISCI-II = 0 throughout. Exceptions were observed in two patients who experienced a conversion from motor complete to motor incomplete by outpatient discharge. (B) Patients with motor incomplete SCI ($n = 9$) demonstrate varying gains in WISCI-II scores across the inpatient to outpatient continuum.

as motor complete at inpatient rehabilitation admission (T11 AIS B and C7 AIS B) converted to motor incomplete (AIS C) as they transitioned to the outpatient therapy setting.

Discussion

This retrospective study describes OEGT initiated in inpatient rehabilitation and continued into outpatient therapy settings following SCI and its impact on clinical outcomes. Importantly, we are interested in the delivery of OEGT initiated early in the rehabilitation process, a critical window for recovery,^{22,23} and continued as a single intervention into outpatient therapy. Given the brevity of inpatient rehabilitation lengths of stay,² identifying interventions delivered across the continuum may be necessary to maximize dosage and neuroplastic potential following SCI.^{22,29} Our findings suggest OEGT can be completed across the continuum of care for patients with SCI. However, our retrospective review identified several factors that appear to impact the delivery of OEGT during inpatient and outpatient settings. In general, patients completed a greater number of OEGT sessions in the outpatient therapy setting than during inpatient rehabilitation. This finding is consistent with others indicating patients receive a greater number of hours of postdischarge therapy than in inpatient rehabilitation.¹ More specifically, as it relates to OEGT, fewer sessions logged during inpatient stay may be due to medical concerns limiting patient readiness to participate in OEGT acutely following SCI.¹⁵ In this study, the average time from inpatient admission to the first OEGT session ranged from 21 to 32 days for motor incomplete and motor complete SCI, respectively, suggesting those with motor incomplete injuries may experience fewer medical concerns limiting readiness to initiate OEGT.

Furthermore, the transition from inpatient rehabilitation to outpatient therapy services requires a coordinated effort to deliver a uniform OEGT intervention. Despite the OEGT intervention delivered within the same building, the unique settings (inpatient vs. outpatient) within our rehabilitation hospital have differing hospital leadership, electronic medical records, billing and insurance demands, and therapy

staff delivering OEGT. At our facility, a clinical liaison communicates between the patient and the inpatient and outpatient clinical teams to promote a seamless transition of care across settings. Additionally, inpatient therapists communicate directly with outpatient therapists concerning patient measurements, device settings, and OEGT status at the outset of outpatient therapy.

Although these processes were in place, we observed a delay between inpatient rehabilitation discharge and the first outpatient OEGT session of about 7 weeks. While inpatient to outpatient transition timelines have not been published, van den Berg-Emons et al. found that persons with traumatic SCI experienced a significant decline in physical activity level 2 months after discharge from inpatient rehabilitation.³⁰ The availability of individual postdischarge resources such as transportation and insurance likely affects the timing of the inpatient-to-outpatient transition.¹ Others may experience a delay in therapy services due to poor adjustment to injury and/or a lack of social support as they transition home.³¹ Although determination of whether or not the patient received therapy services during this 7-week transition period was not possible within the review of the medical record, some patients may have received other therapy services excluding OEGT (e.g., home health services, traditional outpatient therapy). Nonetheless, we observed a continued progression of OEGT session walk time, up time, and step counts from inpatient rehabilitation to outpatient therapy settings. Importantly, the continued progression of OEGT session characteristics demonstrates the capability of delivering a uniform intervention across continuum settings even with a gap in therapy service.

Despite inclusion of patients with a range of neurological levels and severity of injury, none of the current overground robotic exoskeleton literature describe OEGT use and clinical outcomes between motor complete and motor incomplete SCI.^{6,14} Though recovery of walking is a priority among persons with SCI irrespective of severity of injury, time since injury, and age at time of injury,⁵ recovery of walking is less likely if the injury is complete.³² Thus, we anticipated there would be observed variations in OEGT session characteristics

and walking function outcomes between motor complete and motor incomplete injuries. Indeed, we observed those with motor incomplete SCI to have greater up time, walk time, and step count during the first session than those with complete SCI, though both groups demonstrated a slow progression in subsequent OEGT sessions. Others have suggested those with motor complete SCI experience higher medical acuity and may account for some of the variance in OEGT session tolerance.¹⁵

As expected, we also observed a greater recovery of walking function for those with motor incomplete SCI compared to those with motor complete SCI. Given that a change of one WISCI-II level can be considered clinically meaningful,²⁸ our findings suggest patients with motor incomplete SCI achieved a meaningful improvement in walking function in both inpatient rehabilitation and outpatient therapy settings, with the greatest gain occurring in the outpatient setting. Specifically, our average patient with motor incomplete SCI was unable to walk at inpatient rehabilitation admission and progressed to walking in the parallel bars with bracing and the assistance of two therapists at inpatient rehabilitation discharge. By the time they discharged from outpatient therapy at approximately 9 months post-SCI, the patient could ambulate with bracing, using a walker, and without physical assistance from another person. Our findings are consistent with others who report motor incomplete patients with AIS C (and less than 50 years of age) to have a 75% rate of recovery of walking function in 1 year^{33,34} and an excellent walking prognosis at 1 year postinjury for those with AIS D.³⁵ Furthermore, we observed improvement in walking function for those with motor complete SCI who converted to motor incomplete SCI over time. This finding is consistent with others who reported that some patients with motor complete SCI will convert to incomplete status within 1 year of injury.^{33,36-38} For our study, two of eight patients (25%) with motor complete SCI converted to motor incomplete status by outpatient discharge at 23 weeks postinjury. Both patients were able to walk with a walker, with bracing, and with no assistance, which can be considered clinically and functionally meaningful.

Study Limitations

This study has several limitations. Notably, the retrospective observational design of this study reduces our ability to generalize our findings. Further, our review of OEGT sessions and outcomes was limited to the information found in the medical record. Aside from the WISCI-II, other outcomes of potential interest for recovery of mobility and function after SCI, including the 10-meter walk test (10MWT),³⁹ 6-minute walk test,^{40,41} and Berg Balance Scale,⁴² were not consistently completed across inpatient rehabilitation and outpatient therapy settings, limiting the overall clarity in motor recovery after SCI. Others have suggested that a combination of the 10MWT and the WISCI-II provides the most valid measure of improvement in walking following SCI,⁴⁰ while consistent use of standardized outcomes across the continuum of care is recommended.³⁹⁻⁴³ Also, the medical record did not contain information regarding the level of robotic assistance provided to the patients across sessions. Likewise, we did not have access to feedback provided to the patient regarding their performance or therapists' decisions regarding level of robotic assistance. As there may be an association between device-provided assistance, patient feedback, and level of recovery,⁴⁴ we recommend inclusion of these data in prospective research efforts. One constant across our rehabilitation hospital settings was the 45-minute duration for therapy sessions. As a result, there may be an artificially imposed ceiling effect in OEGT session metrics due to the therapy session time constraint.

Additionally, the small sample size and absence of a control group limit our ability to compare the effect of OEGT with other gait training interventions provided as usual care following SCI. Our aim was to generate a hypothesis regarding the capability of a large urban rehabilitation hospital to initiate OEGT early in rehabilitation and deliver a uniform intervention across a continuum of care. Nonetheless, our small sample size may limit our ability to draw firm conclusions concerning estimations of time since injury to the initiation of inpatient or outpatient therapy, incidence of patients participating in OEGT converting from complete to

incomplete SCI, and the inability to capture reasons why others who completed OEGT in inpatient were unable to continue into outpatient. Lastly, our 3-year time period for data abstraction was December 2018 through December 2021. The timelines for admission, length of stay, and transition time from inpatient rehabilitation to outpatient therapy may have been impacted by the COVID-19 pandemic and related access to care issues.⁴⁵

Conclusion

The use of OEGT across the continuum of care was described at our large urban rehabilitation hospital. We observed our patients to demonstrate progressive tolerance for OEGT across rehabilitation settings despite anticipated differences in walking function outcomes between motor complete and motor incomplete SCI. Regardless of a time lapse between inpatient discharge and outpatient therapy, OEGT sessions progressively challenged patients across settings. Further, patients with motor incomplete

SCI experienced clinically meaningful improvements in walking function over time with the greatest gains occurring in the outpatient setting. Future research may consider examining dosage parameters of an OEGT intervention beginning in inpatient rehabilitation and continuing in the outpatient therapy setting to drive optimal walking outcomes for persons with SCI.

Conflicts of Interest

The authors report no conflicts of interest. No financial support was received for this study. The device used in this study, the Ekso GT (Ekso Bionics, USA), has class II FDA approval for use with the spinal cord injury population.

Acknowledgments

The authors wish to thank Lindsey Wynne, Christi Stevens, Molly Trammell, Austin Wong, Christa Ochoa, Faith Meza, and Ko-Lin Wu for their contributions in this study.

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APPENDIX III.

QUAD CHART

Updated: September 2023