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Experience of Robotic Exoskeleton Use at Four Spinal Cord Injury Model Systems Centers

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Abstract

Background and Purpose: Refinement of robotic exoskeletons for overground walking is progressing rapidly. We describe clinicians' experiences, evaluations, and training strategies using robotic exoskeletons in spinal cord injury rehabilitation and wellness settings and describe clinicians' perceptions of exoskeleton benefits and risks and developments that would enhance utility.

Methods: We convened focus groups at 4 spinal cord injury model system centers. A court reporter took verbatim notes and provided a transcript. Research staff used a thematic coding approach to summarize discussions.

Results: Thirty clinicians participated in focus groups. They reported using exoskeletons primarily in outpatient and wellness settings; 1 center used exoskeletons during inpatient rehabilitation. A typical episode of outpatient exoskeleton therapy comprises 20 to 30 sessions and at least 2 staff members are involved in each session. Treatment focuses on standing, stepping, and gait training; therapists measure progress with standardized assessments. Beyond improved gait, participants attributed physiological, psychological, and social benefits to exoskeleton use. Potential risks included falls, skin irritation, and disappointed expectations. Participants identified enhancements that would be of value including greater durability and adjustability, lighter weight, 1-hand controls, ability to navigate stairs and uneven surfaces, and ability to balance without upper extremity support.

Discussion and Conclusions: Each spinal cord injury model system center had shared and distinct practices in terms of how it integrates robotic exoskeletons into physical therapy services. There is currently little evidence to guide integration of exoskeletons into rehabilitation therapy services and a pressing need to generate evidence to guide practice and to inform patients' expectations as more devices enter the market.

Video Abstract available for more insights from the authors (see Video, Supplemental Digital Content 1, available at: http://links.lww.com/JNPT/A231).

INTRODUCTION

The impairment or loss of the ability to stand and walk following spinal cord injury (SCI) results in significant health consequences, not only limiting mobility and performance of activities of daily living but also limiting functional recovery and increasing the risk for secondary complications. Secondary complications include pressure injuries, increased spasticity, limited joint range of motion, contractures, muscle disuse or reduced use atrophy, reduced bone density, increased pain (both neuropathic and musculoskeletal), depression, and impaired digestive, respiratory, renal, and cardiovascular function. 1 Even for individuals with motor incomplete SCI who are able to walk, walking is generally slow, labored, uncoordinated, and variable. 2 With intensive training, walking function sometimes can be improved, but walking speed may remain slower than that required for community ambulation. 3 Thus, many individuals who have some motor function below their lesion level use a wheelchair as their primary mode of mobility. Thus, there exists a need for better therapeutic and mobility training devices.

Potential Benefits and Limitations of Robotic Exoskeletons

Overground robotic exoskeletons offer potential therapeutic benefits while providing intense overground stepping practice and, compared with some approaches, may require fewer therapists to provide assistance for stepping and stability during training in individuals with very limited stepping function. Other benefits of exoskeleton use reported in the literature include improved posture and reduced spasticity and reduced complications affecting cardiovascular, gastrointestinal, and renal systems. 4,5 Standing may provide psychological benefits as well. 6 Exoskeletons thus may provide an alternative strategy to realize the same benefits associated with other mobility training strategies. 7

Currently, however, most studies have been limited to evaluation of the safety and efficacy of robotic exoskeletons for individuals with SCI using the 3 main commercially available exoskeletons (Ekso, ReWalk, and Indego). Specifically, using the Indego exoskeleton, individuals with paraplegia transitioned to limited community ambulation after five, 1.5-h gait-training sessions. The Indego required less effort than a standard locked knee-ankle-foot orthoses, and participants performed strength and endurance tests 25% to 75% faster. In a small, prospective study involving 8 individuals with SCI at the T1 level and below, the Ekso exoskeleton was used safely for overground walking when monitored by a therapist. In an another case series of 3 individuals with complete SCI, participants achieved walking speeds and distances comparable with persons with motor incomplete injuries, although there were no changes in volitional leg muscle activation or cortical activity and negligible improvement in metabolic efficiency. In Similar safety and efficacy studies exist for the ReWalk exoskeleton. 13-16

Potential Benefits of Robotic Exoskeletons: Health Care Providers and Therapists

Exoskeletons have the potential to decrease burden on therapists during overground walking, while encouraging high intensity and dosage with less fatigue compared with traditional therapy. Thus, they could reduce personnel costs to the health system, while potentially achieving similar functional and health outcomes. In contrast to treadmill, robot-based approaches, exoskeletons enable overground mobility in home and wellness settings for individuals who may not achieve this level of function with conventional therapy. However, these devices are still in their early days of development, lack strong evidence for clinical and cost effectiveness, and providers are exploring optimal ways of tapping the clinical and financial viabilities of these technologies.

Given the rapid development and deployment of exoskeletons and the costs of rehabilitation, it is essential to learn from early adopters of robotic exoskeletons. Thus, this study obtained clinician input on the usability and applications of exoskeletons as part of rehabilitation services for adults with SCI (<u>Tables 1 and 2</u>). The aim of the study was to describe clinicians' experiences, evaluations, and training strategies using exoskeletons in rehabilitation and wellness settings. This study addresses 3 primary questions:

Table 1. Robotic Exoskeletons Marketed for Rehabilitation

Device Manufacturer	FDA Approval	Description	Approximate Purchase
ReWalk (ReWalk Robotics, Inc)	Therapy for personal mobility	Independently controlled bilateral hip and knee joint motors, a rigid pelvic frame that links both lower limbs, ankles comprise double action orthotic joints with limited motion and adjustable spring-assisted dorsiflexion	\$75 000
Indego (Parker Hannifin Corporation)	Therapy for personal mobility	Consists of 3 devices (small, medium, and large) including a hip segment and right and left thigh and shank segments.17 Four motors, 1 at each hip and knee joint, power movement, and built-in ankle-foot-orthoses support the ankles9 Purchase price includes therapy kit, software suite, 3-d clinical training on-site, and storage unit	\$189 670
Ekso (Ekso Bionics)	Therapy	Incorporates hip and knee motors; adjustable, spring-assisted ankles with dorsiflexion/plantarflexion support assistance; variable/adjustable swing assistance; adjustable stance support and free trajectory assist; and femoral and tibial shanks support body weight	\$125 000

Abbreviation: FDA, Food and Drug Administration

Device Manufacturer	FDA Approval	Description	Approximate Purchase Cos
ReWalk (ReWalk Robotics, Inc)	Therapy for personal mobility	Independently controlled bilateral hip and knee joint motors, a rigid pelvic frame that links both lower limbs, ankles comprise double action orthotic joints with limited motion and adjustable spring-assisted dorsiflexion	\$75 000
Indego (Parker Hannifin Corporation)	Therapy for personal mobility	Consists of 3 devices (small, medium, and large) including a hip segment and right and left thigh and shank segments. ¹⁷ Four motors, I at each hip and knee joint, power movement, and built-in ankle-foot-orthoses support the ankles ⁹	\$189670
		Purchase price includes therapy kit, software suite, 3-d clinical training on-site, and storage unit	
Ekso (Ekso Bionics)	Therapy	Incorporates hip and knee motors; adjustable, spring-assisted ankles with dorsiflexion/plantarflexion support assistance; variable/adjustable swing assistance; adjustable stance support and free trajectory assist; and femoral and tibial shanks support body weight	\$125 000

Table 2. Manufacturers' Guidelines for Robotic Exoskeleton Candidate Selection

Manufacturers' Guideline	EKSO	ReWalk	Indego
Physician clearance	Yes	Yes	Yes
required			
Standing program needed	Yes	Yes	Yes
Weight limit	<100 kg	<100 kg	<113 kg
Height limit	152-193 cm	152-193 cm	155-191 cm
Leg length discrepancy	Upper leg: <1.3 cm N/A	Femur range: 36-48.5 cm	Femur length: 35.6-47 cm
	Lower leg: <1.9 cm	Tibia range: 43.5-56 cm	
Standing hip width	≤45.7 cm	29-37 cm	≤42.2 cm seated
ROM	Hip: ≤17°	Sufficient LE ROM to allow	Sufficient shoulder, hip,
	Knee: ≤12°	ambulation	knee, and ankle ROM, with
	Neutral ankle dorsiflexion		functional limits for walking
			with a stability aid

SCI level and	T4-L5	T7-L5 community	T7-L5 community
completeness	C7-T3 ASIA D T4-T6	ambulation	ambulation
therapy ambulation T4-L5		T4-T6 therapy ambulation	T4-L5 therapy ambulation
			,
therapy ambulation Contraindications	 ROM restrictions that would prevent a patient from achieving a normal, reciprocal gait pattern, or would restrict a patient from completing normal sit-to-stand or stand-to-sit transitions Spinal instability (or spinal orthotics unless cleared by a medical doctor) Unresolved DVT Subcutaneous cranial bone flap stored in abdomen Decreased standing tolerance due to orthostatic hypotension Significant osteoporosis that prevents safe standing or may increase the risk of fracture caused by standing or walking Uncontrolled spasticity Uncontrolled autonomic dysreflexia Skin integrity issues on contact surfaces of the device or that would prohibit sitting 	Uncontrolled spasticity or clonus Fractures Infection Pressure injury DVT Severe concurrent medical conditions Psychiatric or cognitive issues Pregnancy Lactation	Severe spasticity (Modified Ashworth 3) Heterotopic ossification Skin integrity issues Upper extremity strength deficits Spinal instability Spinal orthotics Unresolved DVT Diminished standing tolerance due to orthostatic hypotension Osteoporosis ROM restrictions Uncontrolled autonomic dysreflexia Colostomy Lower limb prosthesis Cognitive impairments Pregnancy or planning to be pregnant
	 Pregnancy 		

- 1. What are clinicians' experiences, clinical evaluations, and training strategies using robotic exoskeletons in rehabilitation and wellness settings?
- 2. What benefits and risks of exoskeletons do clinicians perceive?
- 3. What limitations of exoskeletons do clinicians identify, and what changes do they suggest for hardware and software development?

METHODS

Sample

This study used qualitative methods to address the questions by organizing focus groups at 4 SCI model systems (SCIMS): (1) Shirley Ryan AbilityLab (formerly the Rehabilitation Institute of Chicago), (2) Craig Hospital, (3) Shepherd Center, and (4) TIRR Memorial Hermann. These centers chose to participate in the AbilityLab's collaborative module during the current SCIMS funding cycle. The focus groups occurred between February and April 2017, comprising primarily physical therapists with experience using robotic exoskeletons. Clinicians provided informed consent and received a modest honorarium.

Procedures

Collaborators developed a discussion guide, which the moderator used for all focus groups (see the Appendix). The moderator led the AbilityLab focus group in person and used videoconferencing technology to lead focus groups at the other 3 centers. A court reporter took verbatim notes and provided a transcript of the discussion. Research staff members took notes to supplement transcript reviews, which provided the basis for qualitative coding and analysis.

Data Analysis

We adopted a thematic coding approach 18 to summarize clinicians' responses to questions regarding patients' motivations for exoskeleton use and their perceived risks and benefits of exoskeleton use; most questions did not require qualitative coding as they focused on details regarding settings in which exoskeletons are used, eligibility criteria, assessment protocols, and other therapy procedures. For questions requiring qualitative coding, the procedures involved developing a codebook, testing the reliability of codes, summarizing data and identifying initial themes, applying code templates, connecting codes and themes, and corroborating and legitimating coded themes. Center principal investigators and coordinators participated in codebook development and transcript coding. They resolved coding discrepancies by discussing their different perspectives and reaching code consensus. Northwestern University's and Shepherd Center's institutional review boards approved the protocol.

Table 3. Fo	cus Group	Participant	Demographic	Characteristics
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Demographic Characteristic	Craig Hospital (n = 5)	Shepherd Center (n = 10)	Shirley Ryan AbilityLab (n = 4)	TIRR Memorial Hermann (n = 11)	Total (n = 30
Age (median years, range)	42 (33-48)	40 (28-53)	34 (30-40)	33 (29-46)	37 (28-53)
Clinical experience (median years, range)	9 (3-20)	13 (4-30)	5 (3-6)	9 (2-22)	9 (2-30)
Other experience (median years, range)	0	14 (3-25)	0	0	14 (3-25)
Sex					
Female	100%	80%	75%	91%	86%
Race					
White	60%	90%	100%	82%	83%
Asian/Indian	0%	0%	0%	9%	2%
Multiracial	40%	0%	0%	0%	10%
Missing	0%	10%	0%	9%	5%
Hispanic					
Yes	20%	0%	0%	0%	5%
No	80%	90%	100%	91%	90%
Missing	0%	10%	0%	9%	5%
Role					
Physical therapist	100%	60%	100%	100%	90%
Administrative	0%	10%	0%	0%	2%
Other clinical role (exercise therapist, recreational therapist)	0%	30%	0%	0%	8%

Table 3. Focus Group Participant Demographic Characteristics

Demographic Characteristic	Craig Hospital (n = 5)	Shepherd Center (n = 10)	Shirley Ryan AbilityLab (n = 4)	TIRR Memorial Hermann (n = 11)	Total (n = 30)
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Sex					
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Race					
White	60%	90%	100%	82%	83%
Asian/Indian	0%	0%	0%	9%	2%
Multiracial	40%	0%	0%	0%	10%
Missing	0%	10%	0%	9%	5%
Hispanic					
Yes	20%	0%	0%	0%	5%
No	80%	90%	100%	91%	90%
Missing	0%	10%	0%	9%	5%
Role					
Physical therapist	100%	60%	100%	100%	90%
Administrative	0%	10%	0%	0%	2%
Other clinical role (exercise therapist,	0%	30%	0%	0%	8%

RESULTS

Sample Characteristics

<u>Table 3</u> summarizes the characteristics of the 30 focus group participants. The sample represents nearly all therapists trained in exoskeleton use, although a few did not participate because of illness or schedule conflicts. They were predominantly female and white and had an average of 10 years of clinical experience. Most were physical therapists but included other clinical and support staff members with training and experience in the use of robotic exoskeletons.

Focus Group Data

We organize focus group data under 3 topics: (1) exoskeleton experience, clinical evaluations, and training strategies, (2) exoskeleton benefits and risks, and (3) exoskeleton preferences. Two investigators read the transcript from each of the 4 focus groups, highlighted text relevant to patients' motivation for seeking therapy incorporating exoskeletons and clinicians' perceptions of risks and benefits. Thematic code development was straightforward, given the finite range of responses and consistency of responses across centers. Coders achieved consensus by discussing the instances for which they initially assigned discrepant codes. Investigators did not code responses to questions focused on procedural details of therapy involving exoskeletons, given the fact-focused nature of the questions.

Topic 1: Exoskeleton Experience, Clinical Evaluations, and Training Strategies

Topic 1 included several subtopics, perceived benefits and risks of exoskeletons pertaining to therapists' experiences, clinical evaluations, and training strategies. <u>Table 4</u> summarizes the therapists' answers to the discussion questions at each center. The "topic column" represents the questions posed to each of the groups. The table's cells contain bulleted lists summarizing the discussion.

Торіс	Craig Hospital	Shepherd Center	Shirley Ryan AbilityLab (RIC)	TIRR Memorial Herm
In what settings do you provide robotic exoskeleton therapy?	Wellness program (private pay) Research	Outpatient Research (ReWalk, Indego) Wellness Program (private pay)	Outpatient Research	Inpatient Outpatient Home use (private pay) Research
How do you use robotic exoskeletons in your practice?	Basic skills training (includes transfers, manual joint adjustment, don/doff, standing balance, sit to/from stand, communicator use, 10 MWT ≥0.15 m/s, turning R/L 180°, walk through doorway, stopping, graceful collapse, bypass mode, skin check, general equipment knowledge, wall rest) Advanced skills training (includes walkie-talkie, walking in busy environment, reading, door navigation, timed automatic door navigation, bench sit to/from stand, timed walking at crosswalk, ramps, side angle walking, multiple surface such as tile, carpet, asphalt, 10 MWT ≥0.4 m/s, 6MWT ≥100 m, curb cutouts	 Weight bearing Balance Gait training Cardiovascular health 	Mobility Retraining Gait training	As a modality to prome neurorecovery Gait training
What criteria do you use to select patients with SCI for robotic exoskeletons?	Manufacturer's criteria Functional level; use Indego for patients with more function, Ekso for patients with less function Resources to purchase device	Manufacturer's criteria Lower extremity function Recovery Personal use	Manufacturer's criteria Motivation Confidence Cognitive ability Seeking mobility options	Manufacturer's criteria Ability to follow comn Tolerate being upright Secondary health bene No contraindications Patient goals
What goals do patients pursue with a robotic exoskeleton?	Personal use training Health and wellness	Personal use trainingHealth and wellnessGait training	Personal use trainingStanding uprightGait training	 Personal use training Standing and stepping Gait training Self-control Spasticity Neurorecovery
What motivates patients to try a robotic exoskeleton?	Exercise Walking Standing upright Improved bowel and bladder function Reduced spasticity	Exercise Walking Opportunity to try something new Standing Balance Strengthening core and peripheral muscles	Family encouragement Opportunity to try something new Increase strength	Walking Upright standing (eye-contact) Increase strength
What devices are you using?	IndegoEksoReWalk	• Indego • ReWalk	IndegoEksoReWalk	 Indego and Ekso for re Ekso for inpatient ReWalk for outpatient

Craig Hospital	Shepherd Center	Shirley Ryan AbilityLab (RIC)	TIRR Memorial Herma
Outpatient typically 6-8 Personal use up to 16	Variable: Depends on insurance and personal resources		Inpatient: 6 sessions, 1-h duration Outpatient: 15-20 for ReWalk Outpatient: 30 for independent
1 PT and 1 aide/caregiver Varies depending on functional ability of client	1 PT and exercise specialist for initial setup in wellness program 1 exercise specialist and I aide/caregiver for training in wellness program 1 PT and I aide for evaluation and training in outpatient program	1 PT and 1 aide/caregiver	• 1 PT and 1 aide
Standing upright Weight bearing Cardiovascular Reduced pain Bowel/bladder benefits Reduced spasticity Sense of well-being	Increased trunk strength Improved function Reduced pain Reduced spasticity Reduced spasticity Reduced medication use Increased strength Improved ASIA scores Improved confidence Psychosocial benefits More steps Reduced UTIs	Standing upright Weight bearing Improved confidence Psychosocial benefits Improved function More steps	Standing upright Bowel/bladder function Gait Trunk strength Reduced pain Reduced spasticity Increased strength Increased endurance Reduced need for assista Psychosocial benefits
Disappointment of expectations (eg, not able to transport device, still need caregiver)	FallsFracturesSkin breakdownDisappointment of expectations	FallsSkin breakdown	Fracture risksSkin breakdown
10-m walk 6-minute walk test Trunk assessment Berg Balance Scale Document time up and walking Timed Up and Go Don and doff time Step count Rate of Perceived Exertion FIM walking rating Skills inventory for ReWalk	10-m walk test 6-minute walk test Trunk assessment Berg Balance Scale Cardiovascular testing Range of motion Skin assessment Spinal cord assessment tool for spastic reflexes Goals ASIA Impairment Scale Manual muscle testing	10-m walk test 6-minute walk test Berg Balance Scale Function in Sitting Test Functional gait assessment Five Times Sit to Stand Test Metabolic assessment Informal patient report	10-m walk 6-minute walk test Trunk assessment
	Outpatient typically 6-8 Personal use up to 16 1 PT and 1 aide/caregiver Varies depending on functional ability of client Veries depending on functional ability of client Veries depending on functional ability of client Veries depending Cardiovascular Reduced pain Bowel/bladder benefits Reduced spasticity Sense of well-being Disappointment of expectations (eg, not able to transport device, still need caregiver) 10-m walk -6-minute walk test Trunk assessment Berg Balance Scale Document time up and walking Timed Up and Go Don and doff time Step count Rate of Perceived Exertion FIM walking rating	Outpatient typically 6-8 Personal use up to 16 1 PT and 1 aide/caregiver Varies depending on functional ability of client 1 PT and 1 aide/caregiver Varies depending on functional ability of client 1 PT and 2 exercise specialist for initial setup in wellness program 1 exercise specialist and 1 aide/caregiver for training in wellness program 1 PT and 1 aide for evaluation and training in outpatient program 1 PT and 1 aide for evaluation and training in outpatient program 1 PT and 1 aide for evaluation and training in outpatient program 1 Increased trunk strength Improved function Reduced pain Reduced pain Reduced spasticity Sense of well-being 1 Increased strength 1 Improved ASIA scores 1 Improved ASIA scores 1 Improved confidence Psychosocial benefits More steps Reduced offidence Psychosocial benefits More steps Reduced UTIs Disappointment of expectations (eg, not able to transport device, still need caregiver) 10-m walk 6-minute walk test Trunk assessment Berg Balance Scale Document time up and walking Timed Up and Go Don and doff time Step count Rate of Perceived Exertion FIM walking rating Skills inventory for ReWalk ASIA Impairment Scale	• Outpatient typically 6-8 • Personal use up to 16 • 1PT and 1 aide/caregiver • Varies depending on functional ability of client • 1PT and 1 aide/caregiver • Varies depending on functional ability of client • 1PT and 1 aide caregiver for training in wellness program • 1 Par 1 and 1 aide for evaluation and training in unpatient program • Standing upright • Weight bearing • Cardiovascular • Reduced pain • Reduced pain • Reduced pain • Reduced spasticity • Sense of well-being • Disappointment of expectations (eg, not able to transport device, still need caregiver) • Disappointment of expectations (eg, not able to transport device, still need caregiver) • 10-m walk • 6-minute walk test • Trunk assessment • Berg Balance Scale • Document time up and walking • Timed Up and Go • Don and doff time • Skill assessment • Skill anpairment Scale • Metabolic assessment • Metabolic assessm

Горіс	Craig Hospital	Shepherd Center	Shirley Ryan AbilityLab (RIC)	TIRR Memorial Herma
Have patients purchased a robotic exoskeleton? What robotic exoskeleton features would you like to see added?	ReWalk (1) FES integrated in exoskeleton Reduce fall risk Lighter weight Greater durability One hand free Adjustable ankles Therapy flex mode for Indego Capacity to ascend and descend stairs Capacity to navigate uneven surfaces	Indego (2) FES integrated in exoskeleton Self-balancing capacity Dynamic ankle joint Powered ankle joint Capacity to ascend and descend stairs	In process Better fit Adjustable for more body types Lighter weight Accommodation of thoracolumbosacral orthosis or colostomy	ReWalk Personal 6 (1) FES integrated in exoskeleton Better fit Lighter weight More intuitive user inte (battery level, ease, and clarity of changing mod greater modular design, ability to modify param to adapt to the environn Capacity to ascend and descend stairs Capacity to navigate un surfaces Ability to step backware Silent motors Voice recognition feature Dynamic standing optic Improved rehabilitation support of distal lower extremity (similar to a personal unit) Decreased friction of lo extremity Cuffs over fibular head

Table 4. Summary of Robotic Exoskeleton Experience at 4 SCI Model System Centers

Topic	Craig Hospital	Shepherd Center	Shirley Ryan AbilityLab (RIC)	TIRR Memorial Hermann
In what settings do you provide robotic exoskeleton therapy?	Wellness program (private pay)Research	 Outpatient Research (ReWalk, Indego) Wellness Program (private pay) 	OutpatientResearch	 Inpatient Outpatient Home use (private pay) Research
How do you use robotic exoskeleton s in your practice?	 Basic skills training (includes transfers, manual joint adjustment, don/doff, standing balance, sit to/from stand, com icator use, 10 MWT 0.15 m/s, turning R/L18 I collapse, byp edge, wall rest) Advanced skills training (includes walkie-talkie, walking in busy environment, reading, door navigation, timed automatic door navigation, timed automatic door navigation, bench sit to/from stand, timed walking at crosswalk, ramps, side angle walking, multiple surface such as tile, carpet, asphalt, 10 MWT ≥0.4 m/s, 6MWT ≥ utouts 	 Weight bearing Balance Gait training Cardiovascula r health 	Mobility Retraining Gait traini	As a modality to promote neurorecove ry Gait training

What criteria do you use to select patients with SCI for robotic exoskeleton s?	 Manufacturer's criteria Functional level; use Indego for patients with more function, Ekso for patients with less function Resources to purchase device 	 Manufacturer's criteria Lower extremity function Recovery Personal use 	 Manufacturer's criteria Motivation Confidence Cognitive ability Seeking mobility options 	 Manufacturer 's criteria Ability to follow commands Tolerate being upright Secondary health benefits No contraindicati ons Patient goals
What goals do patients pursue with a robotic exoskeleton ?	Personal use training Health and wellness	 Personal use training Health and wellness Gait training 	 Personal use training Standing upright Gait training 	 Personal use training Standing and stepping Gait training Self-control Spasticity Neurorecove ry
What motivates patients to try a robotic exoskeleto n?	 Exercise Walking Standing upright Improved bowel and bladder function Reduced spasticity 	 Exercise Walking Opportunity to try something new Standing Balance Strengthenin g core and peripheral muscles 	 Family encouragement Opportunity to try something new Increase strength 	 Walking Upright standing (eye-to-eye contact) Increase strength
What devices are you using?	Indego Ekso ReWalk	IndegoReWalk	IndegoEksoReWalk	 Indego and Ekso for research Ekso for inpatient ReWalk for outpatient
How many sessions comprise a typical episode of robotic exoskeleto n therapy?	 Outpatient typically 6-8 Personal use up to 16 	 Variable: Depends on insurance and personal resources 		 Inpatient: 6 sessions, 1-h duration Outpatient: 15-20 for ReWalk Outpatient: 30 for independent

How many staff members are involved in a therapy session using a robotic exoskeleto n?	 1 PT and 1 aide/caregiv er Varies depending on functional ability of client 	 1 PT and exercise specialist for initial setup in wellness program 1 exercise specialist and 1 aide/caregiv er for training in wellness program 1 PT and 1 aide for evaluation and training in outpatient program 	1 PT and 1 aide/caregiver	• 1 PT and 1 aide
What benefits do patients experience in using a robotic exoskeleto n?	 Standing upright Weight bearing Cardiovascul ar Reduced pain Bowel/bladd er benefits Reduced spasticity Sense of well-being 	 Increased trunk strength Improved function Reduced pain Reduced spasticity Reduced medication use Increased strength Improved ASIA scores Improved confidence Psychosocial benefits More steps Reduced UTIs 	 Standing upright Weight bearing Improved confidence Psychosocial benefits Improved function More steps 	 Standing upright _ Bowel/bladd er function Gait Trunk strength Reduced pain Reduced spasticity Increased strength Increased endurance Reduced need for assistance Psychosocial benefits
What risks might patients experience in using a robotic	Disappointm ent of expectations (eg, not able to transport device, still	 Falls Fractures Skin breakdown Disappointm ent of expectations 	FallsSkin breakdown	Fracture risksSkin breakdown

exoskeleto	need			
n?	caregiver)			
Do you use any standardize d assessment s to monitor progress in robotic exoskeleto n therapy?	 10-m walk 6-minute walk test Trunk assessment Berg Balance Scale Document time up and walking Timed Up and Go Don and doff time Step count Rate of Perceived Exertion FIM walking rating Skills inventory for ReWalk 	 10-m walk test 6-minute walk test Trunk assessment Berg Balance Scale Cardiovascul ar testing Range of motion Skin assessment Spinal cord assessment tool for spastic reflexes Goals ASIA Impairment Scale Manual muscle testing 	 10-m walk test 6-minute walk test Berg Balance Scale Function in Sitting Test Functional gait assessment Five Times Sit to Stand Test Metabolic assessment Informal patient report 	 10-m walk 6-minute walk test Trunk assessment
Have patients purchased a robotic exoskeleto n?	• ReWalk (1)	• Indego (2)	• In process	ReWalk Personal 6 (1)
What robotic exoskeleto n features would you like to see added?	 FES integrated in exoskeleton Reduce fall risk Lighter weight Greater durability One hand free Adjustable ankles 	 FES integrated in exoskeleton Self-balancing capacity Dynamic ankle joint Powered ankle joint Capacity to ascend and descend stairs 	 Better fit Adjustable for more body types Lighter weight Accommodation of thoracolumbosa cral orthosis or colostomy 	 FES integrated in exoskeleton Better fit Lighter weight More intuitive user interface (battery level, ease, and clarity of changing modes), greater

г		T		
	 Therapy flex 			modular
	mode for			design,
	Indego			ability to
	 Capacity to 			modify
	ascend and			parameters
	descend			to adapt to
	stairs			the
	 Capacity to 			environment
	navigate			 Capacity to
	uneven			ascend and
	surfaces			descend
				stairs
				 Capacity to
				navigate
				uneven
				surfaces
				 Ability to
				step
				backwards
				• Silent
				motors
				Voice
				recognition
				feature
				Dynamic
				standing
				_
				option
				 Improved rehabilitatio
				n unit
				support of
				distal lower
				extremity
				(similar to a
				personal
				unit)
				Decreased
				friction of
				lower
				extremity
				 Cuffs over
				fibular head
Abbreviations:	ASIA D. American Spina	al Injury Association D. F	ES, Functional Electrical Stir	nulation: FIM

Abbreviations: ASIA D, American Spinal Injury Association D; FES, Functional Electrical Stimulation; FIM, Functional Independence Measure; MWT, Meter Walk Test; PT, physical therapist; RIC, Rehabilitation Institute of Chicago; SCI, spinal cord injury; UTIs, Urinary Tract Infection.

Participants reported using exoskeletons for various clinical and research applications. All used exoskeletons in outpatient settings and community wellness facilities, with 1 center (TIRR) reporting selective use during inpatient rehabilitation. All SCIMS centers followed device manufacturers' patient selection criteria faithfully. Clinicians commented on the lack of guidance available regarding the integration of exoskeletons into rehabilitation therapy services. One clinician stated:

When we were going through the training with devices we pulled some folks from inpatient, some of our other programs ... in order for us to get experience, but we are still trying to kind of figure out how, from an outpatient perspective, we are going to be utilizing the devices ... on a more regular basis in our centers. So really the main experience that ... [we had] are just folks who have ... decided to purchase a device, and ... are using their insurance benefits to come ... for training.

Another therapist elaborated on the limited evidence base:

This is a new device for us, and so we are being very systematic about what are we doing with the decision[s] we are making, so that people feel like they have support for the decisions that they may be making as an individual.... We have started in the key area of outpatient because that was a little cleaner, and we also ... had people that were ready to go and willing to get their personal devices.

Clinicians emphasized the importance of screening candidates thoroughly to avoid adverse consequences:

I think out in the community people are going to fall, and they probably will injure themselves, and whether you have 6 pounds on top of you if you are walking in of them versus 26 pounds, I think there is risks for injury, for fracture, for ... bone fractures or skin injury. But I think the key to that in reducing that is proper screening and the training that goes behind it the screening process and the education is really important to reduce those risks.

Another focus group participant emphasized discussing patients' expectations during screening, considering not only physiological and functional characteristics but also psychosocial characteristics. A clinician commented:

...screening for personal use aspect, I think what it really boils down to is us just being able to have open and honest conversation. It's not necessarily trying to discourage anybody from buying a device that they want, but ... asking them... 'Realistically, what are your expectations? What do you expect to be able to do in this? And then, letting them know whether or not ... A) the device is safe to use with or do in. But ... B) taking into consideration ... is there a support person. Their 65-year old mom who might be in good shape but ... cannot necessarily offer maximum assistance if this person needs a significant amount of assistance ... we have to have this conversation from the very beginning.

Participants reported that treatment goals typically focused on standing, stepping, and gait training. One center selectively provides inpatients with 6 sessions of exoskeleton training. One therapist described his or her approach:

Our current model that we are using in inpatient is they get six sessions ... patients love getting up with the device, and then they kind of don't want to do anything else ... In an inpatient's world you have a lot of other things that have to be addressed as well, so we have kind of a limited access to it.

A typical episode of outpatient exoskeleton therapy consists of 20 to 30 sessions. The minimum number of staff involved in an exoskeleton therapy session across centers was 2, although on occasion more staff were involved, depending on patients' needs.

Standardized assessments used across centers included the 10-m and 6-minute walk tests; individual centers reported using a variety of balance, exertion, and manual motor tests to assess outcomes associated with exoskeleton training.

Clinicians discussed the issues they consider when recommending various locomotor training strategies:

If I'm only able to do 10 minutes of gait training in a robot, and I can get 35 minutes in on a treadmill, I think there is a dose difference there.

Clinicians discussed strategies to integrate exoskeletons into rehabilitation therapy services and the motivational influence of exoskeletons. One clinician stated:

... that speaks volumes to motivating them to do a lot of their other functional tasks, because some of the other goals they might not want to work on, but we can kind of use it as like a "carrot" and be like: "All right, if you do this transfer, and work on this transfer this day, then by the end of the week we will be able to try to get you up on the robot".... I think that has a big ... influence on a lot of other stuff we try to do.

Topic 2: Exoskeleton Benefits and Risks

Focus group participants identified a variety of perceived physiological, psychological, and social benefits and risks associated with exoskeleton use (Table 4). In addition to improved gait while in the exoskeleton, they related patient claims of improved cardiorespiratory function, reduced pain, improved bowel and bladder function, and improved self-confidence and self-image. Therapists also identified several risks including fall-related injuries, skin irritation, and high patient expectations. One participant commented regarding patients' perceived benefits:

[Reduced] pain and spasticity seem to be the top two. We have had some folks talk about their bowel and bladder, so it changes in how quickly they feel they can manage their bowel program. I had one person talk about sensation changes in their bladder. But again, they were also getting a lot of other interventions at the same time.

Another clinician added:

We've noticed changes in sensation in bowel and bladder for sure. So ability to either sense ... a full bladder, a need to cath or to sense the bowel program.

Clinicians also perceived health and wellness benefits.

Dynamic weight bearing is beneficial for ... full health ... getting just up and out of their chairs in an upright position. It's just for the cardiorespiratory function and also placing everything on the heart because a lot of people will also end up getting that ... from ... dynamic weight bearing. And then ... one thing that definitely should not be discounted is the psychosocial benefits, just being upright and feeling what it's like to walk again.

Clinicians observed reductions in medication for spasticity and infections, saying:

We have seen people significantly reduce the amount of medications that they were taking, either it was for spasm or for example, UTI. We had a couple of people when we did our big 40-person trial that had frequent UTIs, and when they were up training with the exoskeleton, their UTI significantly went away. We followed up a month later, and their UTI is back again.

Participants identified psychosocial benefits across all focus groups as a salient aspect of working with robotic exoskeletons. For example, one clinician observed the motivating influence of exoskeleton use:

The ability that some feel that they can stand up ... and actually being told that they will never ever walk again, and hearing that news, and here they are up walking, and they are like: "Can you videotape this? Can you video it?" So, I think ... psychosocial[ly] ... this gives them that hope that ... "Someday I may be able to walk again."

Another focus group participant observed:

If they feel like this [is] something that will make them get better, and stronger, and walk more and, ..., in a better pattern, then they will give it a try and they will be willing to see what it has to offer for them.

Several therapists identified the psychosocial benefit of being upright and facing others eye-to-eye as a reported benefit:

Feeling more engaged in social situations rather than ... being in a chair looking up and you can't really hear what people are saying in a crowded room. That some of those psychological changes of ... being able to look at people eye-to-eye. I know we hear that a lot, but it really is extremely important to our folks that are used to being at chair level.

A common comment people say, "It's just nice to look someone in the eyes, and not be looking up at the world."

Participants also described the critical role of patients' expectations, the risks of disappointment, and how expectations change over time.

... The other thing that I think is really critical are patient expectations. I think in this room we are all 100 percent, it's about the patient, but we also have to be open and honest with them about how they can really use these systems, and unless they come and try it, they won't know. We had a guy that wanted to purchase one of the systems, and his goal was to get up and ... use it all day at work ... drive with it in his car and all of that, and this was somebody that was part of our research program previously. And I don't know if he forgot or what, but it was about almost a year between the end of research and when this individual chose to buy one of the systems, and then when he came to try the system it was like: "Oh, well, I don't think I would use this every day." ... They have this fantasy it's going to get rid of their wheelchair or whatever, and that's just not the case, and that's another important aspect of giving patients a choice.

Participants noted the challenges patients encountered in seeking services to use an exoskeleton:

From a funding standpoint, it's very challenging for anybody to get funding to purchase one, and then to ... find places where therapists are trained on how to use them, but then also be able to access them even if they don't have that funding.

Another therapist noted the potential burden on volunteer caregivers using an exoskeleton:

One thing to also keep in mind is how taxing is it for the caregiver or the therapist to provide the assistance and the training.

This comment contrasts with sources that anticipate reduced physical burden on caregivers and therapists during training. 19

Topic 3: Exoskeleton Preferences

Focus group participants identified several enhancements they would like to see in exoskeletons (<u>Table 4</u>). Some patients also anticipate technology improvement, as one therapist noted:

He was still hesitant to purchase the [device] at this time. He was more interested in seeing what future technology [may bring] ... maybe something a little bit less cumbersome, looking for something more streamlined. So he wants his other equipment. I think he is just waiting for future technology.

DISCUSSION

Clinicians at each SCIMS center revealed similar practice patterns in terms of how they integrate robotic exoskeletons into physical therapy services. All SCIMS centers adhere to manufacturers' and Food and Drug Administration's (FDA's) guidance on device use but deploy exoskeletons in different settings and adopt different clinical evaluations. This variability likely reflects both institutional culture and the minimal evidence from randomized controlled trials and clinical studies to guide implementation and standardize practice guidelines. 5 Clinicians who deliver robotic exoskeleton therapy mostly include physical therapists with specialist

certification achieved through manufacturers' training. Many centers employ exercise specialists in addition to physical and occupational therapists. ReWalk certifies individuals without a clinical background. While clinician training and costs were not a focus of the focus group discussion guide, the costs associated with the delivery of robotic exoskeleton therapy reflect clinicians' education and training, and therefore costs vary according to the qualifications of the personnel who provide the training. Clinicians recognized the marketing value of offering exoskeletons, noting that some patients sought out the collaborating facilities for physical therapy services because they offered use of robotic exoskeletons. Therapists recognize that some patients who express interest in exoskeletons may not meet the criteria for use of these devices. As with any intervention, therapists offer education and guidance about approaches that are most appropriate to the patients' functional status, goals, and prognosis for achieving those goals.

Clinicians identified a variety of secondary benefits from exoskeleton use. They observed psychological and social benefits including satisfaction from making eye contact while standing to improved bladder and bowel sensation and function, which allows greater ease in social activities. According to the clinicians, patients do not voice secondary benefits as reasons for pursuing exoskeleton therapy, but many were pleased with these benefits.

Clinicians observed that robotic exoskeleton technology continues to evolve rapidly, limiting their adoption of devices to avoid early obsolescence. Although currently there are only 4 devices that are FDA approved, the software and hardware of these devices have changed numerous times in the last decade, making standard evaluations, fitting, and training difficult. To complicate issues further, the FDA will likely approve a dozen new devices in the coming years. Thus, larger institutions are creating exoskeleton teams with therapists with training, certification, and up-to-date information on the evolving rehabilitation robotics market.

Participants reported that patients voiced awareness of the pace of technological development as a consideration in device purchases. For example, Shepherd Center's use of exoskeletons is evolving quickly as its staff considers optimal and cost-effective ways to integrate them in therapy services. Ultimately, patient demand for robotic exoskeletons motivates facilities to investigate purchase and use of this modality. For example, TIRR Memorial Hermann provides access to exoskeleton use for inpatients so that they may try a novel technology for overground walking that they might not have access to after discharge. Patients' ability to purchase a personal mobility exoskeleton reflects a variety of considerations including individuals' resources. Locomotor training with exoskeletons also increased rapidly during the course of this study, with the AbilityLab reporting considerable growth of device use after moving to a new facility with expanded inpatient, outpatient, and home training clinics.

Several study design features limit the generalizability of the findings. Results reflect the experience of only 4 centers, all of which are part of the SCIMS; they may not be representative of all hospitals providing SCI rehabilitation nationally. Clinicians had the opportunity to decline study participation, though nearly all clinicians involved in robotic exoskeleton service delivery participated. Despite efforts to create a nonevaluative climate, the group format may have limited their willingness to voice opinions that conflicted with leadership and peer perspectives.

This study focused on therapists' perspectives due to their unique understanding and skill with exoskeleton use and physical functioning. Future studies should seek patients' perspectives in device selection and evaluation. We need a fuller understanding of the individual-, facility-, and societal-level costs and benefits associated with robotic exoskeleton use in clinical and wellness applications.

CONCLUSIONS

This study provides insight into the issues facilities face and the considerations clinicians use in delivering robotic exoskeleton therapy and extends our knowledge of users' perspectives. 20 The 4 SCIMS centers involved in the study have similar practice patterns in terms of how they integrate overground robotic exoskeletons into physical therapy services. While they adhere to manufacturers' and FDA's guidance on device use, only 1 study center deploys exoskeletons during inpatient rehabilitation currently. Clinicians at all

study centers described patients' report of bowel, bladder, and psychosocial benefits in addition to improved gait. The study centers educate patients on rapid technology development when they recommend devices to patients contemplating purchases for personal mobility. An unintended effect of these devices may be to engage patients more fully in their rehabilitation quite apart from walking or promoting neuromotor recovery by offering hope when patients struggle to see a positive future. There is currently little evidence to guide and standardize the integration of exoskeletons into rehabilitation therapy services and a pressing need to generate evidence to guide practice and to inform patients' expectations. A valuable next step would be to convene a technical expert panel to draft consensus guidelines on device use. Clinics considering use of robotic exoskeletons should define the therapy goals that are amenable to the hardware and software capabilities of specific exoskeletons; select patients who are likely to benefit from exoskeleton therapy based on institutional pilot testing, early studies, and manufacturers' guidelines; and develop strategies to ensure that patient expectations are realistic to obtain maximum benefit for therapy and personal mobility. Based on SCIMS Centers' experience, we recommend that facilities sites.

- 1. complete training recommended by device manufacturers;
- 2. become familiar with indications and contraindications for specific devices;
- 3. adjust goals and protocols to individual patient's circumstances and needs;
- 4. notify manufacturers of device malfunctions or repair needs;
- 5. maximize patients' contributions by weaning them slowly off the motors progressively;
- 6. monitor skin at all areas that contact the device before and after use;
- 7. encourage users to provide feedback while using the device and adjust device settings accordingly;
- 8. progress through a device's modes to facilitate learning and achieve specific goals;
- 9. apply gait training strategies with application of frequency, intensity, time, and type (FITT) principle to use the device effectively and optimize patients' outcomes; and
- 10. monitor patients' cardiovascular, integumentary, and neuromuscular responses to exoskeleton sessions.

We recommend that facilities not

- 1. use devices with patients who have open skin lesions or wounds in the areas that contact the exoskeleton;
- 2. use an exoskeleton device with a patient who is uncomfortable with the technology;
- 3. assume that the device will prevent falls-continue to use usual guarding techniques;
- 4. force the fit of the device. If a patient's fit is borderline, err on the side of caution; and
- 5. use the same software program in an exoskeleton for all patients.

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APPENDIX Focus Group Discussion Guide for Therapists With Robotic Exoskeleton Experience

- 1. How do you use robotic exoskeletons in your practice?
- a. What criteria do you use to select patients with SCI for exoskeletons use?
- b. What latitude do you have in selecting patients for exoskeletons use?
- c. What makes/models do you use?
- d. Why do you use these models?
- e. What kinds of modifications would you like to have made to robotic exoskeletons? Why?
- f. How many clinicians are present when a patient is learning to use a robotic exoskeleton? If any, are they therapists? Aides? What are their qualifications?
- g. What does a typical exoskeleton therapy session look like? What's the breakdown of time spent on what activities. (If the answer is "it depends"-ask) It depends on what? Please give an example.

- h. Would you use the same number of therapists and aides for conventional therapy for the patient who uses an exoskeleton based on the answer to the previous question?
- 2. What standardized assessments do you use to assess patients' progress using an exoskeleton?
- 3. Do you work with patients who use exoskeletons in the community?
- a. What motivates patients to use exoskeletons in the community?
- b. What facilitates their use of exoskeletons in the community?
- c. What limits their use of exoskeletons in the community?
- d. What risks have patients experienced using exoskeletons in the community?
- e. What risks are you concerned about?
- 4. What benefits do patients receive from exoskeletons use in the clinic?
- a. What kinds of physical benefits?
- b. What about social benefits?
- c. What about occupational benefits?
- d. Any emotional benefits?
- e. Any other benefits?
- 5. What risks or harm have patients experienced using an exoskeleton?
- a. What kinds of physical harms?
- b. What about social harms?
- c. What about occupational harms?
- d. Any emotional harms?
- e. Any other harms?
- 6. What aspects of the device, patient, or environment facilitate benefit?
- a. Patient characteristics?
- b. Device characteristics?
- c. Environmental characteristics?
- 7. What aspects of the device, patient, or environment limit device benefit?
- a. Patient characteristics?
- b. Device characteristics?
- c. Environmental characteristics?
- 8. Have any of your patients purchased exoskeletons?
- a. What kinds of patients?
- b. What kinds of devices?
- c. What kinds of activities?
- 9. What other aspects of exoskeleton use or therapy that we have not discussed would you like to mention or add?