

Acceptability of Rehabilitation Exoskeleton from the Perspective of Users with Spinal Cord Injury and Healthcare Professionals: a Mixed Methods Systematic Review

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Abstract.

Objective: The objective was to document the acceptability of rehabilitation exoskeletons from the perspective of users with spinal cord injury (SCI) and healthcare professionals (HP). **Methods:** This mixed-methods systematic review considered quantitative, qualitative and mixed methods studies that included adults with SCI using an exoskeleton for gait rehabilitation, as well as HP working within rehabilitation settings with individuals with SCI who used an exoskeleton. A convergent integrated approach per the Joanna Briggs Institute (JBI) was used. **Results:** A total of 22 studies were included. Overall, individuals with SCI and HP expressed a favorable level of acceptability. Participants reported a positive affective attitude, an overall satisfaction, and several psychological benefits. Few burdens, ethical issues and opportunity costs have also been reported in the studies. Maintaining realistic expectations towards exoskeleton use and ensuring the appropriate selection of users is important for intervention coherence. In general, there was a positive perception regarding effectiveness and self-efficacy. Nevertheless, only a limited number of studies focused primarily on measuring acceptability, revealing an important gap in the literature. **Conclusions:** The acceptability of exoskeletons among people with SCI and HP tends to be positive, which is promising for the sustainable implementation of this technology. However, there is still a lack of knowledge about the acceptability of HP, with only two studies conducted among this population. It is crucial to persevere in documenting the acceptability of exoskeletons, notably by standardizing comprehensive approaches for measuring acceptability, and to continue refining this technology.

Keywords: Spinal Cord Injury; Exoskeleton; Rehabilitation; Acceptance; Healthcare Professionals

Introduction

In 2019, there were 9 million of people living with a spinal cord injury (SCI) around the world [1]. Living with an SCI affects physiological and psychosocial abilities, requiring considerable adaptation in daily life to these changes [2]. Resulting impairments and limitations, such as mobility, can reduce social participation and quality of life of these individuals [3]. Despite the rehabilitation process, most individuals with SCI live with persistent mobility limitations [4] That might vary according to the level and degree of the lesion, influencing the potential for walking.

In recent years, exoskeleton technologies have received significant media coverage as a novel and promising technology to support various human functions. An exoskeleton is an overground robotic device is an external structure placed along the segments that increases, aids or improves the user's movement, locomotion, posture or physical activity [5]. While exoskeletons have primarily been utilized in the army and in research settings, they are implemented in healthcare settings around the world for the rehabilitation of people with SCI [6]. Emerging evidence supports that exoskeletons can also be used as movement-retraining devices to accelerate and increase the intensity of gait rehabilitation in people with SCI [7]. The use of exoskeletons thus presents potential benefits in the rehabilitation process, such as increased walking speed, improved balance and muscle strength, and reduced pain intensity and spasticity in people with SCI that persist even after the exoskeleton training is completed [8-12]. However, a substantial proportion of prior studies about the impact of exoskeleton use have adopted an exploratory approach. The additional value of exoskeleton use has not yet been consistently reported.

The rapid implementation of exoskeletons in healthcare settings highlights an urgent need to assess their acceptability. Acceptability is a multidimensional construct that has not been appraised consistently by researchers. Indeed, several definitions and theoretical or conceptual frameworks have been proposed to measure the determinants of acceptability of a technology, such as the Technology

Acceptance Model (TAM) by Davis [13] and the Unified Theory of Acceptance and Use of Technology (UTAUT) by Venkatesh & Bala [14]. More recently, Sekhon et al. conducted an overview of systematic reviews of studies that aimed to define, theorize and measure the acceptability of healthcare interventions [15]. Then, a panel of experts reached a consensus defining acceptability as “a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention” [15]. This research team expanded the concept of acceptability by developing the Theoretical Framework of Acceptability (TFA) tailored to healthcare interventions [15]. This framework ensures the evaluation of intervention acceptability across three distinct timeframes such as pre-intervention (prospectively), during intervention (concurrently), and post-intervention (retrospectively), and considers the perspectives of both intervention providers and users [15]. The TFA facilitates the identification of key dimensions of an innovation that can be optimized to enhance its acceptability [16].

Despite growing interest in exoskeletons, several factors seem to influence their acceptability by users. There are two categories with distinct roles in the utilization, namely individuals with SCI, who wear the device, and healthcare professionals (HP), who operate it. On the one hand, various companies market several models of exoskeletons each with distinct intended purposes and characteristics [17]. These characteristics may possibly influence the perceived usability and ease of use, and consequently, the acceptability of the device [14]. On the other hand, the use and the acceptability of exoskeletons depend on the organizational context in healthcare settings (e.g., culture and values) as well as objectives and expectations regarding the use of this technology [18]. In this regard, a previous study identified that unmet expectations regarding the benefits associated with exoskeleton use was a barrier to device utilization [19]. The perceived acceptability is a key factor influencing the processes of implementation of a health intervention [15]. Indeed, previous studies highlighted that one of the major barriers to the use of a new technology, such as an exoskeleton, is low level of user acceptability [13].

Given that exoskeletons are a new technology increasingly implemented in health care facilities, such as rehabilitation facilities for people with SCI, it becomes imperative to focus on its acceptability to ensure the successful implementation.

Few studies have systematically appraised the acceptability when investigating the user experience of the exoskeleton. Nevertheless, some elements in these previous studies have been reported as determinants of the acceptability according to the TFA, such as ease of use and perceived benefits [20,21]. A comprehensive and integrated understanding of exoskeleton acceptability is currently lacking. There is a pressing need to synthesize existing knowledge and analyze individuals' experiences using an acceptability framework. Since both quantitative (e.g., questionnaire of UTAUT by Venkatesh & Bala [14]) and qualitative (e.g., an interview) studies can shed light on the acceptability of an exoskeleton, a mixed method systematic review offers a comprehensive avenue to delve deeply into the experience of individuals with a SCI and healthcare professionals.

Considering the importance of user acceptability to promote the successful implementation of this technology, it is essential to conduct a knowledge synthesis. The objective of this systematic review was to document the acceptability of rehabilitation exoskeletons for individuals with SCI and healthcare professionals.

Methods

The proposed mixed methods systematic review has been conducted in accordance with the Joanna Briggs Institute (JBI) methodology for Mixed Methods Systematic Review (MMSR) [22] and followed the PRISMA guideline [23]. A convergent integrated approach as defined by JBI (i.e., a combination of qualitative and quantitative data) was used to address the review question [22]. Protocol was registered in PROSPERO (CRD42023401829).

Search Strategy

A three-step search strategy was used in this review supervised by a librarian specialized in systematic reviews (M.G.). An initial limited search of Medline (via Ovid), and CINAHL (via EBSCO) databases was undertaken followed by an analysis of the text words contained in the title and abstract and the index terms used to describe the articles to identify the keywords. The search strategy, including all identified keywords and index terms was adapted for each included information source on March 23, 2023. The databases that were searched included Medline (via Ovid), CINAHL (via EBSCO), Embase, and Web of Science databases. These databases were chosen since they are the main sources of articles in the fields of medicine and rehabilitation, with Web of Sciences being selected as a multidisciplinary database. The full search strategy is provided in Supplemental material Table 1.

Eligibility Criteria

This review considered quantitative, qualitative and mixed methods studies that included adults aged 18 years and older with SCI who used an exoskeleton for gait rehabilitation, and studies involving HP in rehabilitation settings using exoskeleton with SCI patients. Searches were limited to publications in English and French, as members of the research team speak both languages, without any restrictions related to the publication date.

Studies documenting the acceptability of rehabilitation exoskeletons in term of perspective among individuals with SCI and HP who used an exoskeleton as part of rehabilitation were included. The reported results must relate to at least one construct of the theoretical framework of acceptability (TFA) among the seven component constructs (i.e., affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy) [15].

This review excluded: 1) studies that focus on personal, at-home or in-the-community use of an exoskeleton, 2) the following types of articles or study design:

conference proceedings, commentaries, letters, book chapters, animal studies, editorials, reviews and meta-analyses, abstracts, proof-of-concept; and 3) studies focusing on outcomes related to function, design and clinical effectiveness of an exoskeleton without documenting user acceptability to understand the perspective of users. These studies were excluded because exoskeletons used as technical aids in a personal setting or at home do not have the same characteristics, nor the same objectives of use than exoskeleton used in gait rehabilitation. Both of which could influence user acceptability.

Screening and Selection Process

After conducting the literature search, all identified studies were gathered and uploaded into Endnote 20 (Clarivate Analytics, PA, USA) with duplicates subsequently removed [24]. Titles and abstracts were then screened by two independent reviewers (N.F.-B. and J.D.) to assess if the inclusion criteria were met for the review using Covidence software platform [25]. The full texts of selected studies were retrieved and assessed in detail against the inclusion criteria by two independent reviewers (N.F.-B. and J.D.). Full-text studies that did not meet the inclusion criteria were excluded and reasons for exclusion are provided in Figure 1. Any disagreements that arose between the reviewers were resolved through discussion with a third reviewer (M-E.L.). Cohen's kappa coefficient during the title and abstract screening was 0.66, and 0.52 during the full text screening, suggesting substantial and moderate agreement, respectively [26].

Data Extraction

Quantitative and qualitative data were extracted from included studies by two independent reviewers (N.F.-B. and J.D.) using Microsoft Excel (See Table 1). The data extracted included title, author, years of publication, country, study design, setting, objective of the study, details about the population, eligibility criteria, dropouts and related reasons, model of exoskeleton, context of use, main measures, measure of acceptability, overall acceptability, and time points

acceptability. Any discrepancies between the reviewers in the extracted data were resolved through discussion, or with the involvement of a third reviewer (M-E.L).

Data Synthesis and Integration

The convergent integrated approach according to the JBI methodology for mixed methods systematic review was used in this review [22]. This involved assembling the “qualitized” data with the qualitative data [22]. This involved the transformation of the quantitative results into textual descriptions or narrative interpretation to allow integration with qualitative data [22]. Assembled data were categorized and pooled together, in the software Nvivo 14 [27], using a deductive approach from the Theoretical framework of acceptability (TFA) [15]. Data were categorized according to the seven component constructs of TFA, namely 1) affective attitude; 2) burden; 3) perceived effectiveness; 4) ethicality; 5) intervention coherence; 6) opportunity costs, and 7) self-efficacy [15].

Critical Appraisal

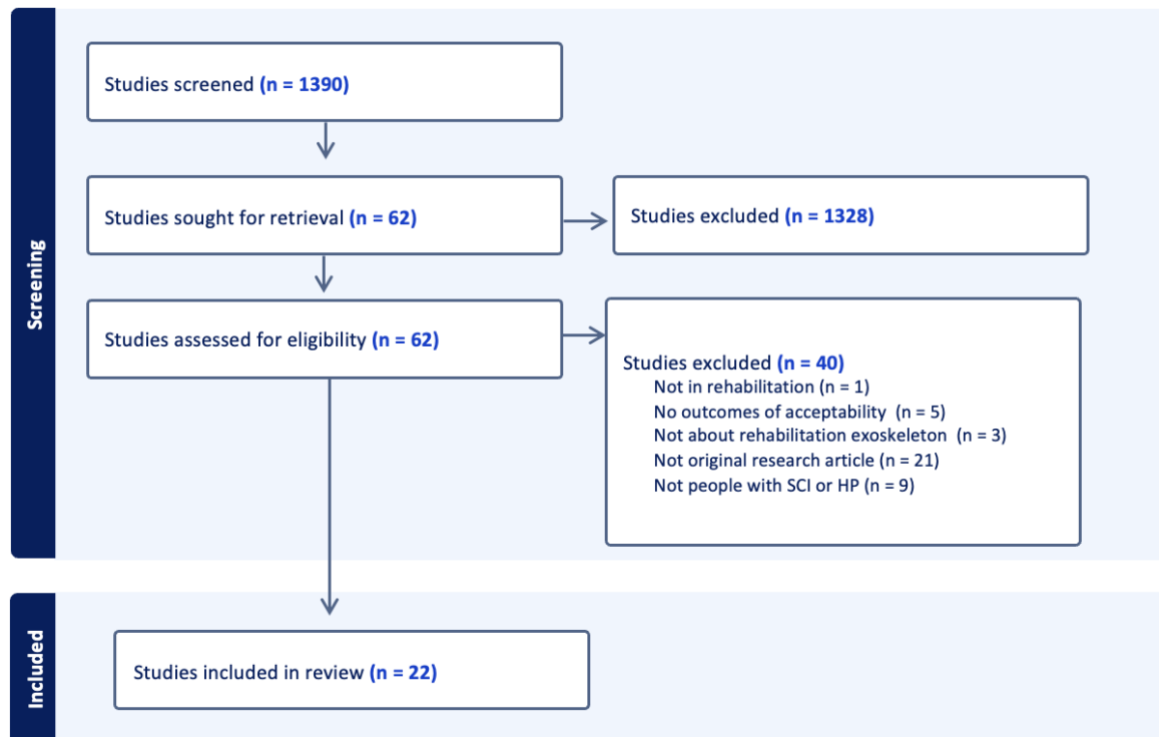
Eligible studies underwent critical appraisal by two independent reviewers (N.F.-B., and J.D.) for methodological quality using the Mixed Methods Appraisal Tool (MMAT) [28]. This tool enables the assessment of the quality of qualitative, quantitative and mixed methods studies in conducting a sensibility analysis according to evaluation criteria rather than calculate an overall score [28]. Any disagreements between the reviewers were resolved through discussion with a third reviewer (M-E.L).

Results

A total of 2338 studies were extracted from the four databases, and among these, 948 were removed manually or by Covidence due to duplicates. Thus, 1390 studies were screened for titles and abstracts and 62 studies were subsequently assessed in full text. Of these, 40 were excluded because they were not conducted in a rehabilitation setting, did not focus on acceptability outcomes, did not involve

the use of a rehabilitation exoskeleton, were not original research articles, or were not among people with SCI or HP. Finally, 22 studies were included in our review [10,20,21,29-47].

Figure 1. PRISMA flowchart



Characteristics of Included Studies.

Detailed characteristics of the included studies can be found in Table 1.

The studies have been published between 2014 and 2022. Only three studies (14%) explicitly had as main goal to measure the acceptability of an exoskeleton [30,31,46], while the remaining studies solely reported certain domains of acceptability. The majority of studies documented the perspective of individuals with SCI (i.e., those receiving the intervention) [10,20,21,29-37,39-41,43-46,48],

whereas only two studies (9%) explored the acceptability of the exoskeleton from the HP standpoint (i.e.. those delivering the intervention) [38,42], representing a total of 216 individuals with SCI and 59 HP. The Ekso exoskeleton (including Ekso GT) was the most commonly utilized in the included studies [10,32-34,39,41,45], followed by the ReWalk, which was the second most used exoskeleton [21,29,35,48]. Some studies, conducted in rehabilitation centers, also included more than one model of exoskeleton (i.e., ReWalk, Ekso, Indego, Lokomat and/or KAFO) [20,37,38,42,44]. Other models of exoskeletons, such as REX [46], Kinesis [43], Lokomat [40], ARKE 2.0 LEPE [36], and H2 portable [31] lower limb exoskeleton were used in the studies included.

The timing of the acceptability assessment regarding the use of the exoskeleton varies among studies. Most studies (n=15; 68%) measured acceptability at only one time point, either during [44] or after the use of the exoskeleton [10,20,29,31,34-40,42,43,45,46]. Two studies measured acceptability before, prospectively and retrospectively the use [21,41], while two other studies (9%) assessed acceptability concurrently and retrospectively [32,33]. Finally, only two (9%) studies conducted assessments of acceptability at three timepoints, i.e., prospectively, concurrently, and retrospectively [30,48].

Five studies (23%) were conducted in Italy [10,32,33,40,44], four (18%) in Canada [21,36,39,45], three (14%) in the United States [20,38,42], and two studies in Spain (9%) [31,43]. Only one study (5%) is multicentric, including the United Kingdom,

Australia, and New Zealand [46]. Finally, studies have been conducted in other countries including the United Kingdom [47], South Africa [41], Korea [37], the Netherlands [35], Germany [29], Australia [30], and Norway [34].

Table 1. Characteristics of included studies (n=22).

Authors (year) (#ref)	Country	Design	Setting	Population	Objective	Model of exoskeleton	Measure of acceptability	Overall outcomes of acceptability
Benson et al., 2016[48]	United Kingdom	Longitudinal, prospective, self-controlled feasibility study	Specialist Spinal Cord Injuries Centre (rehabilitation center, outpatient setting)	n=10 individuals with SCI	Assess the feasibility of conducting a well-powered trial evaluating the neurological and functional effects of using an exoskeleton in individuals with chronic spinal cord injury.	ReWalk	Assistive Technology Device Predisposition Assessment (ATD-PA) questionnaire [49]	The exoskeleton did not meet the expectations of participants regarding perceived benefits.
Birch et al., 2017[46]	United Kingdom, Australia, New Zealand	Prospective, multi-centre, open label, non-randomised, non-comparative cohort study	Neurological rehabilitation centres	n=30 individuals with SCI	Investigates the feasibility, safety and acceptability of using the REX self-stabilising robotic exoskeleton in people with SCI who are obligatory wheelchair users.	REX	Device Acceptability Questionnaire	Participants reported feeling confident, stable, and safe while using the exoskeleton. Most participants found the exoskeleton comfortable and enjoyed their experience and would recommend its use.
Charbonneau et al., 2022[45]	Canada	Prospective observational case series	Acute and tertiary neurorehabilitation units in trauma center	n=9 individuals with SCI	Increase understanding of SCI patient experiences using a robotic exoskeleton in the acute post-injury period.	Ekso GT	Open ended questionnaire (experience walking with an exoskeleton, albeit later in the recovery process)	Contributing to future research and personal goals was a motivation to use the exoskeleton. Participants described the experience as thrilling and motivational and felt their participation contributed to their overall well-being after discharge. Participants reported challenges (e.g., significant effort, difficulties with blood pressure regulation, and anxiety), and benefits (e.g., improved muscle strength,

								mobility, and emotional wellbeing).
Corbianco et al., 2021[44]	Italia	Not reported	Spinal Cord Injury Unit	n=15 individuals with SCI	Evaluate energy cost and psychological impact during a rehabilitation program with two different types of robotic rehabilitation systems (stationary system on a treadmill, Lokomat, and overground walking system, Ekso GT).	Lokomat and Ekso GT	Questionnaire to evaluate the adherence, compliance, motivation, and comfort.	High level in satisfaction and emotion were reported overall. Low level of fatigue, mental effort, and fear or discomfort were observed in the Loko group.
Del-Ama et al., 2014[43]	Spain	Case studies	Not reported	n=3 individuals with SCI	Investigate the feasibility of the hybrid therapy of walking delivered with Kinesis in patients with incomplete SCI.	Kinesis	Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) [50]	Overall, the QUEST items received high scores. The lowest scores were assigned to weight, fitting and comfort (3 over 5). The safety, durability and efficacy received the highest scores. Utility of the exoskeleton was positively perceived.
Ehrlich-Jones et al., 2021[42]	United States	Qualitative, online survey	Regional rehabilitation hospitals and 1 Veteran's Administration (VA) Medical Center.	n=29 HP	Describe clinicians' preferences, clinical practices, training strategies, and clinical decisions on how robotic exoskeleton devices are used with veterans and civilians with SCI.	ReWalk/Exo/Indego Training Center	Open ended questionnaire: focus group (appropriateness, patient characteristics, expectations, training strategies, benefits, preferences, and limitations)	Clinicians reported that patients should have realistic expectations regarding the capabilities of exoskeletons. Clinicians reported potential benefits for therapists including fewer clinicians required during treatments and patients performing more steps with less clinician effort. Limitations reported were fear of falling, slow walking speed, and inability to replace wheelchair.

Evans et al., 2022[41]	South Africa	Qualitative	Spinal cord injury rehabilitation	n=16 individuals with SCI	Discusses the reports by participants in a randomised controlled trial of a novel intervention for SCI rehabilitation in Cape Town, South Africa.	Ekso GT	Open ended questionnaire (motivation, expectations, benefits, barriers, experience, difficulties, and futures recommendations).	Participants reported gratitude, exhilaration, and optimism to use an exoskeleton, including the potential for improvement such as the possibility of walking again. Participants reported feeling vulnerable while in the exoskeleton and the necessity to have realistic expectations.
Fundarò et al., 2018[40]	Italia	Observational retrospective cross-sectional study	Neurorehabilitation and Neurophysio pathology Unit	n=21 individuals with SCI	To evaluate the psychosocial impact of the Lokomat in an in-patient rehabilitation setting and to assess whether the psychosocial impact of RAGT is different between pathological sub- groups and if the Lokomat influenced functional variables	Lokomat	Long version of Psychosocial Impact of Assistive Device Scale (PIADS) questionnaire [51]	Mean (SD) PIADS total and subscales score for SCI patients: total PIADS score: 34.8 (22.8); subscale 1, competence :16.6 (10.8); subscale 2 adaptability:8.9 (5.8); and subscale 3, Self-esteem:10.1 (7.5).
Gagnon et al., 2019[39]	Canada	Survey	Institut de réadaptation Gingras-Lindsay-de-Montréal.	n=14 individuals with SCI	To quantify clients' satisfaction and perception upon completion of a locomotor training program with an overground robotic exoskeleton	Ekso	Questionnaire measuring overall satisfaction, perceived learnability, perceived health benefits and risks and motivation.	The participants reported being satisfied (mean [SD]) with the exoskeleton (satisfaction domain, 95.7 [0.7%]), positive feedback about the exoskeleton (exoskeleton domain, 82.3 [6.9%]), ability to learn to perform sit-stand transfers and walk with the exoskeleton (learnability domain, 79.6 [17%]), perceived health benefits resulting from the training program (health benefit domain, 67.9 [16.7%]),

								little fear (fear and risk domain, 16.7 [8.2%]). Overall findings suggest that exoskeletons should be offered as part of rehabilitation program to individuals with an SCI.
Heineman et al., 2018[38]	United states	Qualitative	Four SCI model systems	n= 30 HP	To describe clinicians' experiences, evaluations, and training strategies using exoskeletons in rehabilitation and wellness settings.	Ekso, ReWalk, and Indego	Open ended questionnaire: focus groups (about: experiences, strategies, benefits, risks, limitations, and changes).	Participants reported risks of using exoskeleton (e.g., disappointments and falls), benefits (e.g., standing upright), motivation and goals (e.g., exercises and personal training) to use an exoskeleton.
Kinnett-Hopkins et al., 2020[20]	United Stated	Qualitative	Three regional rehabilitation hospitals and referrals from Veterans Affairs (VA) hospitals	n=28 individuals with SCI	To gain insight into the experiences, perspectives, concerns, and suggestions on the use of robotic exoskeletons by civilians and veterans living with SCI who have experience with these devices.	Ekso, Indego, ReWalk	Open ended questionnaire: focus group (experiences, perspective, benefits, barriers, concerns, limitations, suggestions)	Participants reported that exoskeletons were useful, but not practical for daily life. Psychological benefits and physiologic improvements (e.g., bowel and bladder function) were reported as well as barriers (e.g., fatigue, spasticity, and spasms), and dissatisfaction (e.g., inability to use exoskeletons independently and safely).
Kwon et al., 2019[37]	Korea	Random cross-over design	SCI ward at the National Rehabilitation Center	n=10 individuals with SCI	This study aimed to confirm whether ReWalk-gait is more efficient than KAFO-gait. The secondary outcomes were to evaluate spatiotemporal variables (walking distance and speed) and usability.	ReWalk, KAFO	A usability evaluation questionnaire for gait-assistive devices (safety, effect, efficiency, and satisfaction	The mean (SD) reported satisfaction of participants for ReWalk-gait was not superior to KAFO-gait. Safety: KAFO gait, 3.53 (0.65) vs. ReWalk gait, 3.35 (0.83), p=0.26. Effectiveness: KAFO gait, 3.57 (0.74) vs. ReWalk Gait, 3.18 (0.65), p=0.17.

								Efficiency: KAFO gait, 3.30 (0.70) vs ReWalk gait: 2.98 (0.49), $p=0.14$. Satisfaction: KAFO gait, 4.16 (0.76) vs. ReWalk gait, 3.53 (0.75), $p=0.008$. Participants also indicated that ReWalk was bulky, difficult and complicating to wear alone and to operating, and that exoskeleton was expensive.
Lemaire et al., 2017[36]	Canada	Case studies	Ottawa Hospital Rehabilitation Centre	n=2 individual with SCI	To evaluate ARKE exoskeleton training within a rehabilitation centre environment.	ARKE 2.0 LEPE	Questionnaire measuring overall satisfaction with exoskeleton for walking, sitting, standing, and turning; experience when learning to use ARKE; confidence when using ARKE; feeling of security; feelings of control; experience while transferring.	Participants reported high satisfaction of learning, comfort, pain, fatigue, and overall experience of sitting-standing and moderate to high satisfaction for walking. Participants reported challenge to learn to safely walk. Participants reported no pain or mild pain, but fatigue.
Manns et al., 2019[21]	Canada	Qualitative	Not reported	n=11 individuals with SCI	To explore the expectations and experiences of persons with spinal cord injury, training with the ReWalk w.	ReWalk	Open ended questionnaire (expectations, goals, perspectives, and effects)	Participants reported walking with an exoskeleton was a positive experience. Participants enjoyed training for day-to-day tasks to a greater extent than training tasks that did not directly map into daily habits. Participants reported no or low expectations, and aimed to improved balance, and

								strength, and confidence standing. However, participants had long-term hope of walking. Participants reported important level of physical and mental effort to use the exoskeleton. Participants reported less pain and decrease in spasticity, increase well-being attributable to using the exoskeleton, but also sadness after training session.
Muijzer-Witteveen et al., 2018[35]	Netherlands	Survey	Sint Maartenskliek Hospital	n=10 individuals with SCI	To evaluate current experiences with wearable exoskeletons and the potential of sensory feedback from the user point of view.	ReWalk	Open ended questionnaire (experience, problems and preference about instructions)	Participants reported technical problems, skin damage, challenges fitting in the exoskeleton and difficulty walking over uneven grounds.
Platz et al., 2016[29]	Germany	Prospective, single-group observational	SCI Centre	n=7 individuals with SCI	To document the results of the device-training in terms of the achieved milestones for device use, user satisfaction, and effects on quality of life.	ReWalk	Satisfaction questionnaire [52]	Neither a high degree of satisfaction nor dissatisfaction with the device-training were reported, while others reported a fair degree of satisfaction for other items. Participants reported the exoskeleton was safe after completing the training and comfortable. Skin lesions were observed in 4 participants, pain in 2 participants, but no falls were reported.
Postol et al., 2021[30]	Australia	Feasibility study (pre-post intervention trial)	Not reported	n=3 individuals with SCI	To evaluate the feasibility of therapy with a free-standing exoskeleton for those with SCI, and to determine the potential	REX	Closed questionnaire (safety, likeability, comfort, useability and desire to	Participants reported the intervention was highly acceptable. The participants reported a desire to continue using the exoskeleton. One

					health-related benefits of this intervention. More precisely, to assess the study procedures for their acceptability, to estimate likely rates of recruitment and retention of subjects, and to determine any health-related benefits in order to guide the development of a future powered trial.		continue using the device).	participant reported high scores for perceived safety, comfort and useability. Negative feedback regarding the exoskeleton was its slow pace and big size. Positive feedback included being able to “look people in the eye”, doing exercises normally unachievable and standing straight. The overall satisfaction scores were inconsistent between participants and time points.
Quiles et al., 2020[31]	Spain	Case study	National Hospital of Paraplegics	n=1 individual with SCI	Investigate the changes in gait pattern through 3d gait analysis and change in the quality of life of subjects with SCI	Ekso	Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) [50]	Participant reported distrust and fear at the beginning of the use of the exoskeleton. Participants reported being satisfied or very satisfied regarding dimensions, weight, and safety. Participants reported being more or less satisfied with the ease in adjusting, the durability, and the comfort. No breathing difficulties were reported while using the exoskeleton.
Sale et al., 2016 [32]	Italy	Pilot single case experimental (pre-post) study	Not reported	n=3 individuals with SCI	To evaluate the efficacy, the feasibility and the changes in the mobility and in the de-adaptations of a new rehabilitative protocol for EKSOTM a robotic exoskeleton device in subjects with SCI disease with an impairment of lower limbs	Ekso	Satisfaction Questionnaire (including fatigue and pain) [53]	All participants reported strong positive comments regarding the emotional and psychosocial benefits. Participants felt safe and comfortable after using the exoskeleton, but also reported reduced fatigue and pain.

					assessed by gait analysis and clinical outcomes.			
Sale et al., 2018 [33]	Italy	Prospective quasi-experimental pre-post study.	Outpatient	n=8 individuals with SCI	To investigate the acceptability of overground robot-assisted walking and its effect on pain and spasticity.	Ekso	Participant Satisfaction Questionnaire (Comfort, pain, fatigue, enjoyment, perceived advantages, motivation, and suggestions) [54]	Participants reported diminished spasticity in their legs after training with the exoskeleton. Participants did not report difficulties to use the exoskeleton, felt safe and comfortable as well as did not experience considerable pain.
Stampacchia et al., 2016[10]	Italia	Nonrandomized study (pre-post)	Not reported	n=21 individuals with SCI	To investigate the acceptability of overground robot-assisted walking and its effect on pain and spasticity.	Ekso	Participant Satisfaction Questionnaire (Comfort, pain, fatigue, enjoyment, perceived advantages, motivation, and suggestions) [54]	For the questionnaire on the acceptability of the exoskeleton, participants reported high scores for the positive sensations/opinions, and low scores of the negative experiences.
Thomassen et al., 2019[34]	Norway	Qualitative	In-patient rehabilitation Hospital	n=3 individuals with SCI	To generate new knowledge regarding user experiences of standing and walking with Ekso	Ekso	Open ended questionnaire (expectations, prior knowledge, donning and doffing exoskeleton, walking, possibilities, and limitations)	Participants reported good acceptability of the exoskeleton, including high score on positive feelings regarding well-being (e.g., motivation, empowerment), feeling of safety, and reported benefits (e.g., increased strength and controls). Participants reported decrease in the muscle spasticity and pain.

Methodological quality

The evaluation of the quality of quantitative, qualitative, and mixed methods studies included in this review are available in Supplemental (Table 2). There were seven qualitative studies (32%) [20,21,34,38,41,42,45] included in the present review. Overall, qualitative studies were of good quality, with an adequate sample size and sufficiently detailed data. For example, Charbonneau et al., 2022, presented a reflexivity statement [42,45]. Ten studies (45%) were non-randomized quantitative studies [10,29,30,33,37,40,43,44,46,48]. The latter encompassed small samples ranging from one participant to thirty participants (e.g., [43,48]), with the majority failing to consider confounding variables in the study design or analysis of results (e.g., severity and level of SCI or time since injury). Finally, six studies (27%) were descriptive quantitative studies [31-33,35,36,39]. As in the non-randomized studies, some of the measurement tools used to assess domains of acceptability were not gold standards, or an appropriate rationale for the choice of measure was not provided. In addition, some studies omitted the presentation of inclusion criteria, as well as the details concerning dropouts and their associated reasons.

Findings of the review

Results were integrated into the seven domains in coherence with the TFA definitions [15]. Main results are presented according to these seven domains in Figure 1 (which summarizes the main results and definition of domains [55]) and detailed accordingly in the following subsections.

Figure 1. Summary of the main results.

Affective Attitude <i>How an individual feels about the intervention</i> (+) General satisfaction (n= 6) (+) Safe (n=7) (+) Comfortable (n=5) (+) Psychological benefits (n=7) (+) Being eye-to-eye with others (n=5) (-) Short time duration of use (n=2)	Burden <i>The perceived amount of effort that is required to participate in the intervention</i> (-) Pain (n=4) (-) Fatigue (n=7) (-) Massive device (n=5) (-) Risks of fall-related injuries (n=2)	Ethicality <i>The extent to which the intervention has a good fit with an individual's value system</i> (-) Danger of experiencing disappointment (n=3) (-) Accessibility issue (n=1) (-) Difference between perception and expectations (n=1)	Intervention Coherence <i>The extent to which the participant understands the intervention and how it works</i> (-) Need to have realistic expectations (n=1) (-) Lack of information during the training (n=1)
Opportunity Costs <i>The extent to which benefits, profits or values must be given up to engage in the intervention</i> (-) Would like to use exoskeleton outside rehabilitation (n=2)	Perceived Effectiveness <i>The extent to which the intervention is perceived as likely to achieve its purpose</i> (+) Less pain (n=4) (+) Increased blood circulation (n=4) (+) Muscle strength and stretching (n=7) (+) Better bowel and bladder control/function (n=5) (-) Slow gait speed (n=4)	Self-efficacy <i>The participant's confidence that they can perform the behaviour(s) required to participate in the intervention</i> (+) Use getting easier (n=3) (+) Learning to use is not complicated (n=2) (+) Wearing and adjusting are simple (n=2) (-) Difficulties in walking on small slopes and over uneven grounds (n=1)	

Affective attitude

Six studies (27%) stated that people with SCI were generally satisfied with the use of the exoskeleton [10,30,32,39,40,44]. Among these studies, only three (14%) [10,30,40] had as main their objective to measure the acceptability of this technology, describing it as acceptable. However, satisfaction of the use of the exoskeleton varied in other studies [20,30]. For example, Kinnett-Hopkins et al., 2020 [20] highlighted that a few participants reported dissatisfaction with the technology, particularly because they could not use it independently at home and feel safe. Expectations and goals for the use of the exoskeleton, when reported, were different among the studies. Indeed, two studies (9%) reported that the reason to participate in a research study and using an exoskeleton was to benefit other people in their rehabilitation in the future [21,45]. Interestingly, two studies (9%) reported that participants participated in research projects involving the use of an exoskeleton with the goal of walking during rehabilitation [20,45]. Three studies (14%) reported that not all initial expectations regarding the use of an exoskeleton in rehabilitation were met [35,42,48].

Participants of seven studies (32%) reported feeling safe while using the exoskeleton [29,32-34,36,43,46]. In contrast, four studies (18%) reported a fear of falling [21,31,41,42] and one of them further specified that this fear of falling occurred especially at the beginning of the training with the exoskeleton [31]. In addition, in five studies (23%), participants reported that the exoskeleton was comfortable [29,32,33,39,46]. However, participants in the study of Quiles et al., 2020 reported being neutral with the comfort of the exoskeleton [31]. Thomassen et al., 2019 specified that the feeling of safety was due to being well strapped to the exoskeleton [34].

Seven studies (32%) [20,32,34,36,39,41,45] have reported various psychological benefits and positive impacts on the well-being of people with SCI who have used an exoskeleton during their rehabilitation. Empowerment, motivation, and increased self-confidence were positive feelings reported [34,45]. In addition, being at the same eye level as others [20,21,30,39,45], the positive experience of standing and gives the sensation of walking again [20,30,34,38] and feeling liberated by the open space around them [34]. However, two studies (9%) [34,45] have highlighted feelings of frustration and disappointment notably due to the short-lasting positive sensations related to the use of the exoskeleton (e.g., better control of movements and gastrointestinal function). Participants would have liked to use the exoskeleton for a longer period to optimize the effects [21]. Finally, the feeling of being completely locked into the device and the unnatural feeling when wearing the device was reported in one study [34].

Burden

Among the studies reporting dropouts and their reasons, skin breakdown problems, talus fracture, not enjoying the device, fear, or time restraints [31,43,48] were reported. Seven studies (32%) noted that people with SCI felt tired during or after the use of an exoskeleton due to high physical and cognitive demands (e.g., concentration, cognitive exertion, and mental effort) [20,21,29,32,34,36,39,45]. Two studies (9%), including one conducted among HP, reported the risks of fall-

related injuries for individuals with SCI [20,38]. In addition, five studies (22%) reported that the exoskeleton was too massive [20,21,30,34,37]. While participants in three studies (14%) [29,32,33] reported that the use of the exoskeleton did not result in significant pain, four other studies (18%) reported pain [29,34,36,45], potentially leading to unpleasant training experiences [45]. Finally, the high cost of the exoskeleton [20,37], technical bugs [35] of equipment to use the exoskeleton and skin damage have been reported [29,35]. HP also reported the demand for support and training necessary to use the device [38,42]

Ethicality

Few studies have reported on ethical issues surrounding the use of exoskeletons. However, three studies (18%) reported the danger of experiencing considerable disappointment following false hope for people with SCI using an exoskeleton, such as walking independently [20,38,41]. Evans et al., 2022 reported that this could be particularly present in the context of poor access to services [41], in addition to accessibility issues for an exoskeleton [38]. Moreover, Kinnett-Hopkins et al., 2020 reported potential ethical issues due to the difference between the perception and expectations of able-bodied individuals toward exoskeletons that could differ from those of people with SCI [20]. More precisely, people with SCI may be pressured to conform to able-bodied normative views to an extent grater to the actual benefits of the exoskeleton, which could lead to unrealistic expectations.

Intervention Coherence

According to clinicians in the study of Ehrlich-Jones et al., 2021, people with SCI using an exoskeleton in rehabilitation need to have realistic expectations toward the outcomes of the device use to maintain intervention coherence and to avoid being disappointed [42]. In this regard, the appropriateness of the use of the exoskeleton to ensure intervention coherence depends, among other things, on patient goals [42]. Moreover, participants with SCI in the study of Muijzer-

Witteveen et al., 2018 reported a lack of information regarding how to use the exoskeleton during the training. [35].

Opportunity Costs

No study has clearly indicated that benefits, profits, or values, such as other valuable rehabilitation activities, have to be given up in order to use an exoskeleton. Nevertheless, even if participants of the study by Manns et al., 2019 enjoyed their experience while using this technology, they noted, as a limitation, that the exoskeleton could not be used outside of rehabilitation settings. In this regard, Kinnett-Hopkins et al., 2020 reported that the exoskeleton had limited use outside rehabilitation [20]. Thus, the use of exoskeletons is limited to a rehabilitation context and the ability to use it cannot be transferred to real-life context.

Perceived Effectiveness

Studies reported various perceived improvements in impairments and physical benefits of the use of an exoskeleton in individuals with SCI [39,45], such as increased muscle strength [20,21,34,39,41,45], improved bowel and bladder function [20,21,38,41,45], increased blood circulation [21,34,41,45] and feeling warmth [21,34]. In addition, participants of four studies (18%) have reported experiencing reduced pain or improved pain management while using the exoskeleton [20,21,38,45]. However, Manns et al., 2019 specified that pain came back two months after the end of the training with the exoskeleton [21]. Studies reported mixed results regarding self-reported improvement in spasticity among participants. Indeed, four studies indicated improvement while one study reported no change [20,21,32,33,41]. HP highlighted various factors they perceived as influencing the successful use of the device including motivation, general health, learning style, confidence, and body awareness [42]. Despite the exoskeleton's effectiveness, participants in four studies have noted specific limitations of the device, particularly a slow walking speed [20,30,34,42].

Self-Efficacy

Three studies (18%) reported that the use of an exoskeleton improved over time (i.e., more difficult at the beginning but less at the end) [20,21,45]. Participants from two studies (9%) reported feeling confident while using an exoskeleton [29,46]. Participants from Sale et al., 2016 and Sale et al., 2018 indicated that learning to use the device was not complicated [32,33]. Furthermore, wearing and adjusting the device was simple [32,33]. However, other studies reported various experiences, such as difficulty to transfers in exoskeletons [34], and difficulty to wear and operating it alone [37]. Lemaire et al., 2017 also reported challenge to learn to safely walk with the exoskeleton [36]. In addition, participants in the study of Muijzer-Witteveen et al., 2018 reported difficulties with determining the body position in addition to difficulties in walking on small slopes and walking over uneven grounds [35]. Finally, participants in Gagnon et al., 2019 also reported that it was easy to perform sit-stand transfers [39].

Discussion

The objective of this mixed methods systematic review was to document the acceptability of rehabilitation exoskeletons for individuals with SCI and HP. Overall, the acceptability of exoskeletons from the perspective of people with SCI and HP was generally positive. However, only two studies focused on acceptability of HP, limiting the generalization of this conclusion among this population. A positive affective attitude was reported with good general satisfaction and several psychological benefits. There was a generally positive trend in perceived effectiveness and self-efficacy. In addition, few burdens, ethical issues and opportunity costs have been reported in the present review. Therefore, future studies should focus on these factors to better understand the acceptability of this device. Plus, only three studies aimed to measure acceptability as their primary objective, which highlights an important gap in the literature [30,31,46].

The results of the present synthesis are overall consistent with previous studies documenting the acceptability of health intervention using technologies in

individuals with SCI. For example, studies examining the use of teleconference for testing cognitive abilities, or hand-cycling high-intensity interval training for people with SCI identified positive acceptance [56,57], potentially indicating a good technology acceptance from this population. Thus, the present findings contribute to the understanding that individuals with SCI perceive technologies used in their rehabilitation as acceptable. However, as with the use of exoskeletons, it is important for the intervention to maintain realistic expectations of technology use and to ensure the selection of the right user. These considerations are also important for the use of other technologies in rehabilitation, such as virtual reality [58].

Individuals having regular contact with HP or other individuals with SCI can also influence the acceptability of the device and explain the positive acceptability as reported by Evans et al., 2022 and Manns et al., 2019 [21,41]. Indeed, a previous study highlighted the positive impact of professional and peer support during the rehabilitation process [59]. Also, determining whether exoskeletons are considered equally acceptable by HP as by people with SCI is difficult, since only two studies involving HP were included in this review. Considering the important role of HP in initiating the use of an exoskeleton in rehabilitation, more studies are needed to explore the acceptability of exoskeletons from the HP's point of view. In addition, future studies should be carried out using a qualitative approach using a conceptual framework to explore acceptability [60]. Indeed, this will allow for an in-depth and systematic exploration of the complexity of the acceptability of this innovative and evolving technology. Finally, some exoskeletons have been studied more than others according to the included studies (e.g., Ekso and ReWalk), and future studies should be conducted on various exoskeletons, considering their specific characteristics and designs.

In the present review, factors limiting the acceptability of exoskeletons included, for example, the bulkiness of the device, pain, and technical problems. Similarly, others health technologies, such as artificial intelligence and functional electrical

stimulation in physical rehabilitation have reported preoccupation regarding technological problems (e.g., battery lifetime) [61,62]. These issues decreased usability and potentially cause frustration among users, leading to interruptions in care, which could negatively influence the acceptability of the technology [62,63]. Considering the importance of the device and intrinsic characteristics per se in determining its acceptability, suggestions for manufacturers to improve their devices have been reported in previous studies. These potential improvements include characteristics such as a lighter weight, a system to reduce fall risk, adding the capacity to ascend and descend stairs with the exoskeleton and being more adjustable [20,34,38,42]. To facilitate adoption and implementation of exoskeletons in rehabilitation, users must be involved right from the start of the development and all implementation stages [64]. Furthermore, studies in the present review included relatively homogeneous samples of individuals with complete and incomplete SCI considering the eligibility criteria for the use of an exoskeleton. Consequently, elderly people, people with a larger body mass index and children were never eligible in the included studies. In this regard, Postol et al. reported that one of the main reasons for the exclusion of potential participants was due to their physical characteristics (i.e., weight and height) that did not fit with the device [30]. In addition, participants in the studies were not distinguished based on their prognosis (e.g., potential for walking). There may be variations in expectations regarding exoskeletons, which would be interesting to investigate in the future. To ensure increased acceptability and equity for all, greater adaptability of the technology to various individuals with SCI and context will be crucial, in addition to an unequivocal demonstration of the added value of using an exoskeleton in rehabilitation. Besides, according to the Consolidated Framework for Implementation Research (CFIR), adaptability is an important criterion for successful implementation [65].

Numerous methodological factors may have influenced the results of studies included in the study, and consequently, the present knowledge synthesis. First, social desirability biases, especially in the case of an innovative technology with

limited access [66], may influence the acceptability of participants. Moreover, there may be selection biases. For example, many of the studies included in this review did not report dropout rates and reasons for dropping out, which would have provided a better understanding of acceptability. Third, various tools and approaches were used to measure acceptability concepts among the included studies. For example, two studies used the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) [31,43], while this tool only measures certain aspects of acceptability, i.e., satisfaction toward assistive technology [67]. More precisely, opportunity costs and ethical issues are important aspects of acceptability which have not been widely discussed in the literature to date making it difficult to provide overall acceptability results [15]. Considering that the exoskeleton is a rapidly evolving technology that is increasingly implemented in rehabilitation settings, future studies should use a uniform and comprehensive measurement tool for acceptability to observe how its acceptance grows in various users.

To the best of our knowledge, this systematic review is the first to incorporate a theoretical framework of acceptability to combine the results of previous studies. Another strength of our synthesis is the comprehensive search strategy that included both quantitative, qualitative, and mixed methods studies to explore acceptability in depth. However, the limitations of our work must also be addressed. First, we experienced challenges in categorizing the study's results across the seven domains of the TFA, given the broad definitions of these domains. However, the analysis was conducted by two independent reviewers, and a third person was available in case of disagreements, favoring the mutual exclusion of the domains. For example, one reviewer considered a result to be related to the "Opportunity cost" construct, while another reviewer considered it to be related to the "Perceived Effectiveness" construct. To resolve this conflict, the reviewers consulted the third independent reviewer (M-E. L) to decide while referring to the definition of each construct. Second, the included studies involved small samples of users and validated questionnaires were rarely utilized,

consequently constraining the reproducibility of the studies. In turn, these limitations limit the generalizability of the conclusion of the present study. Third, the MMAT quality appraisal tool items are subject to interpretation and less objective [68]. Finally, we were unable to conduct additional searches on the Scopus multidisciplinary database, as our university does not subscribe to this database.

Conclusions and Recommendations

The perspective of exoskeletons appears favorable among individuals with SCI and HP. This acceptability is promising for the sustainable implementation of this device. However, it is crucial to continue research efforts into the acceptability of exoskeletons, notably by standardizing ways of comprehensively measuring acceptability, and to further develop this technology for optimal use and benefit of people with SCI. There is also a need to better document the acceptability of HP.

Conflicts of Interest

The authors declare no conflict of interest.

Funding

This work received funding from the Praxis Spinal Cord Institute (Research Grant No: G2020-33) and the Social Sciences and Humanities Research Council (Research Grant No: 892-2021-2033).

Acknowledgments

N.F-B was supported through a scholarship from the Réseau provincial de recherche en adaptation-réadaptation (REPAR) and hold a master training award from the Canadian Institutes of Health Research (CIHR) and from the Quebec Health Research Funds (FRQS) (# 311138) in partnership with the Unité de soutien au système de santé apprenant (SSA) Québec. J.D was supported through a scholarship from FRQS. M.S was supported through a scholarship from the Centre interdisciplinaire de recherche en réadaptation et intégration sociale

(Cirris). Salary supports for F.R were provided by the FRQS Senior Research Scholar program.

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