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The Effects of Lower Limb Orthoses on Health Aspects of the Spinal Cord Injury Patients: A Systematic Review Using International Classification of Functioning, Disability, and Health (ICF) as a Reference Framework

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Abstract

Background: One of the most important approaches in the rehabilitation of spinal cord injury (SCI) patients is the use of different orthoses. To date, no review has been published that analyzed the effects of orthoses on health aspects of spinal cord injury clients using the International Classification of Functioning, Disability and Health (ICF).

Methods: A systematic literature search was done in some databases, including Medline, PubMed, Cochrane centered register of the controlled trial (CCTR), Cochrane database of systematic reviews (CDSR), a database of abstracts of reviews of effects (DARE), Embase, Google Scholar, and ISI Web of Knowledge. SCI was used in conjunction with terms like orthotic device, mechanical orthoses, external power orthoses, assistive devices, and functional electrical. The time frame for this search was from 1970 to 2022.

Results: A total of 200 papers were found. Based on the titles and abstracts, 100 related papers were detected. After careful evaluation of the papers, 47 studies were selected for final analysis—53 papers were excluded due to duplication, non-English language, and lack of full-text.

Conclusion: The results of 32 studies (70% of studies) support the efficiency of orthoses in walking and standing of SCI patients. In most of the included studies, the efficiency of orthoses was evaluated mostly based on body functions and structures, and their impact on other outcomes such as participation and quality of life (QoL) of SCI patients was unclear.

Keywords: International Classification of Functioning, Disability, and Health, Spinal Cord Injury, Orthotic Device, Exoskeleton Device, Functional Electrical Stimulation

Conflicts of Interest: *None declared*
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Introduction

Due to injuries to spinal cord, patients miss their abilities to stand and walk (1). Depending on the level of lesion, they have problems in performing their daily activities (2, 3). The incidence of spinal cord injuries (SCIs) varies in different countries between 4 and 65 new cases per million populations each year (1, 4-6). It has been estimated that

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↑What is "already known" in this topic:
It is common to use various lower limb orthoses in the rehabilitation of spinal cord injury patients. The effectiveness of these orthoses has been reported in many studies. However, the effectiveness of orthoses on different levels of patients' functions is not clear.

→What this article adds:
The results of this review showed that most of the studies only focused on the effect of lower limb orthoses on biomechanical factors, such as kinetic and kinematic parameters. The efficiency of lower limb orthoses was evaluated mostly based on body functions and structures and their impact on other outcomes such as participation and quality of life (QoL) of spinal cor injury (SCI) patients was unclear. Therefore, it seems necessary for therapists and researchers to consider the effects of orthoses on all aspects of patients' function.

more than 250,000, 86,000, and 40,000 SCI patients are living in the U.S., Canada, and the UK, respectively (1). It has been estimated that the number of SCI will increase to 121,000 in Canada by 2030.

It has been claimed that those with SCI have some problems, including problems with digestive system, cardiovascular system, bowel and bladder function, skin integrity, and psychological health issues (7, 8). Additionally, they struggle with muscle spasms and a reduction in joint range of motion (joint contracture). They must therefore employ a variety of therapies and procedures to both enhance their state of health and carry out their daily activities (3, 9-13).

It should be emphasized that the main aim of rehabilitation of those with SCI is to increase their independency and improve their health status (9, 14). For SCI patients, it is advised to utilize a variety of conventional treatments, including occupational and physical therapy exercises, orthoses and exoskeletons to help them move around, functional electrical stimulation, virtual reality, action observation, and stem cell therapy (15, 16). However, based on the available literature and the reviews published on the performance of SCI with various methods of ambulation, most SCI patients do not use assistive devices (orthoses, FES, hybrid devices, and exoskeleton) for ambulating from place to place (9, 17). The main reasons are slow walking speed, high energy consumption during walking, too much force applied on the upper limb, and independency to use their assistive devices (9). However, most of this evaluation only focuses on some parameters such as gait and stability performance. The aims of rehabilitation are to increase the independency of the patients in their daily activities, improve their social participations, and increase their quality of life (QoL) (3). Moreover, it is important that all members of the rehabilitation team have a comprehensive understanding of various levels of function (environmental and client factors affecting function). Therefore, the performance of SCI patients and the efficiency of treatment approaches should be evaluated with regard to all aspects of functions, such as activities of daily living and participation.

One of the frameworks that can be used to evaluate the efficiency of various assessment and treatment approaches for the clients with different disorders is the international classification functioning disability and health (ICF) (18, 19). It is an international standard system that can be used to describe and measure health and functional status. Based on this model, function can be categorized as body functions and structures, activity, and participation (19). ICF consists of 2 parts, each with 2 components. Part 1, functioning and disability, is included into (a) body functions and body structures, (b) activities and participation. Part 2, contextual factors, is included into (a) environmental and (b) personal factors. Problems or difficulties in these parts are known as impairments, activity limitations, and participation restrictions, respectively (19). Dimensions of functioning and disability are thought to be affected by health conditions and contextual factors (personal and environmental factors).

The efficacy of the lower limb orthoses was only evaluated based on their efficiency while walking and standing. However, based on this model, other parameters should also be evaluated. Use of the ICF model was used by Burger, 2011, in the orthotics and prosthetics field (20). He confirmed that the ICF can be used in orthotics and prosthetics clinical practice. McKnee and Rivards highlighted the importance of biosychological approach to orthotic intervention (21). The ICF model was also used by Ivanyi et al to determine the effects of orthoses, footwear, and walking aids on the performance of the patients with spina bifida. They concluded that the efficiency of ankle foot orthoses and crutch on the gait and walking outcomes is only on body functions and structure based on the ICF model. Nevertheless, studies on the impact of these assistive technologies on other ICF levels are lacking (22). There is no study in the literature that evaluated the efficiency of various rehabilitation methods on the performance of SCI patients, based on the ICF model. Therefore, the aim of this study was to evaluate the efficiency of various assistive devices, mechanical orthoses, and exoskeleton based on ICF as a reference framework in this group of the patients.

Methods

This was a systematic review. We conducted this review based on the preferred reporting items for systematic reviews and meta-analyses approach (23). A search was done in some databases, including Medline, PubMed, Cochrane centered register of controlled trial (CCTR), Cochrane database of systematic reviews (CDSR), database of abstracts of reviews of effects (DARE), Embase, google Scholar, and ISI Web of Knowledge.

Some keywords developed by the national library of medicine were selected in this study. These keywords included orthotic device, mechanical orthoses, external power orthoses, assistive devices, and functional electrical stimulation combined with spinal cord injury and paraplegia. This search was done between 1970 and 2022.

Eligibility Criteria

Eligibility criteria for selection of the studies were based on population (studies on SCI), linguistic range (only studies reported in English were reported), and type of orthoses (mechanical orthosis, FES, and exoskeleton). As the number of studies on this topic was very limited, the nature of studies and outcome variables were not considered in selection of the studies.

Type of Studies

Although randomized control trials were the primary focus of this analysis, other types of studies were also included because there were not enough of them. The final list excluded certain low-quality sources of evidence such as abstracts, conference articles, editorials, comments, and expert opinions.

Participants

There was no limitation for the age of participants in this study. All type of SCI patients, except congenital SCI, were considered in this study. However, those able to walk with orthoses or other types of assistive devices were considered in this study.

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Types of Intervention

All studies focus on mechanical orthoses, FES, hybrid, and exoskeleton were selected in this study.

Type of Outcome

The main outcome measures selected in this study was based on categorizes of the ICF. It means that the ICF components, including body functions, body structures, activities and participation, and environmental factors, were considered in this study. Therefore, some outcomes such as gait performance— kinetic, kinematic, energy consumption, force applied on leg and crutch—independency of the patients in performing daily activities, participation, and psychological health were considered in this study. Also, the health status of the patient, such as cardiovascular system and performance during daily activities, were also selected in this study. It should be emphasized that all of the ICF model components were considered in this study.

Secondary Outcome

Any adverse effects of use of orthosis reported in the literature were considered as a secondary outcome.

Selection of Studies

Two researchers separately screened the studies based on the inclusion criteria. However, selection of the studies was mostly based on abstracts and titles.

Data Extraction and Management

We followed the patient/population, intervention, comparison and outcomes (PICO) style in this review (Table 1). However, the studies were categorized based on the ICF components.

Table 1. Search strategy with PICO

PICO	Search terms
Participants	Spinal cord injury OR paraplegia
Interventions	Mechanical orthoses OR external power orthoses OR assistive devices OR functional electrical stimulation
Comparisons	Not applicable
Outcomes	Body functions and structures OR activities OR participation OR environmental factors OR gait performance OR daily activities OR QOL

Quality Assessment and Determination of Risk of Bias: The quality of the studies was appraised based on Down and Black scale, which is a valid tool to check the quality of the studies. Based on this scale, it is possible to determine trustworthiness, and relevance of the published papers. This scale has a high degree of reliability to assess the quality of various research studies. This scale contain 11 items includes inclusion criteria and source, random allocation, allocation concealment, baseline comparability, subjects blinding, therapists blinding, assessment blinding, follow up, intention to treat analysis, between group comparison and point estimate and variability.

Results

On this topic, 200 papers had been produced, and 100 papers were identified based on the titles and abstracts. After careful evaluation of the papers, 47 studies were selected for final analysis—53 papers were excluded due to duplication, non-English language, and lack of full-text. Figure 1 displays the flowchart of this study. The quality of the 17 studies on the use of external powered orthoses ranged from

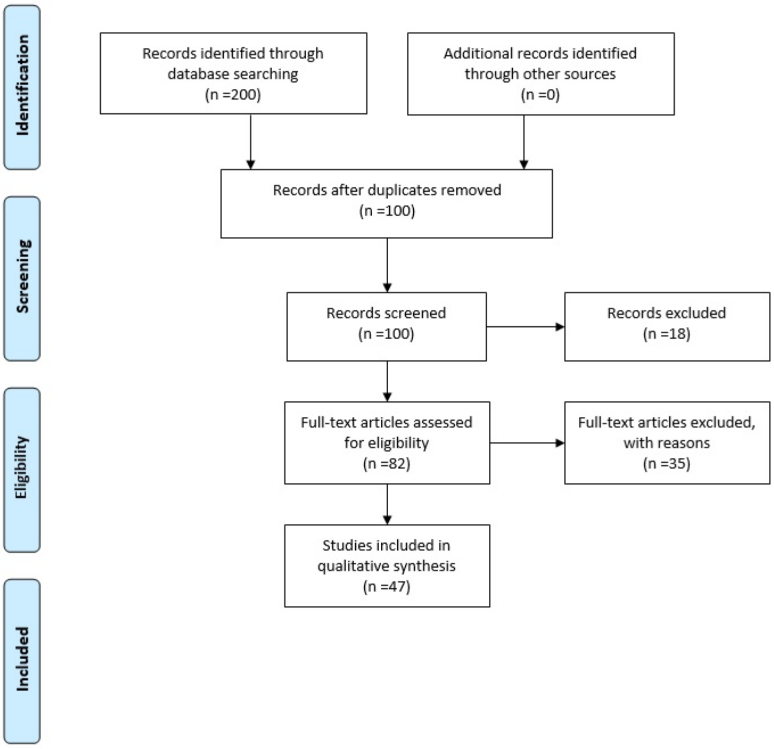

Fig. 1. Flowchart of the study

Table 2. The outputs of the studies on external power orthoses

Reference No.	Method	Results
(24)	Participants: 11 patient, level of lesion: T8-L2 Age: 46.9 Intervention: BWSTT with hybrid assistive limb® (HAL®) exoskeleton Comparison: walking function, cortical excitability	Betterment in walking parameters and normalization of the excitability of the primary somatosensory cortex
(25)	Participants: 2 patient, level of lesion: T6-T7 Age:49-54 Intervention: hydraulic orthotic mechanisms Comparison: hip knee angle, knee angular velocity, upper limb support force, and impact force	The results showed that this mechanism can normalize the upper limb support forces, the maximum angular velocity of the knee and the maximum impact force during the stand-to-sit maneuver
(26)	Participants: 3 patient level of lesion: T4-T11 Age:54-59 Intervention: A self-contained muscle-driven exoskeleton Comparison: Stepping Walking speeds, cadences	This exoskeleton is a possible treatment to rehabilitate stepping SCI patients
(27)	Participants: 2 patient level of lesion: T4-T12 Age: 40-57 Intervention: VariLeg Comparison: basic walking skills, walking and stair climbing	Both subjects gained good skills in fundamental balancing and walking. In complex mobility tasks, such as climbing ramps and stairs, only low(needing help) to moderate(able to perform tasks independently in 25% of efforts) skills level were obtained
(28)	Participants: 12 patient level of lesion: C6-T10 Age: 37.5 Intervention: ReWalk exoskeleton Comparison: walking progression, sitting balance, skin sensation, spasticity, strength of the corticospinal tracts	Walking in the ReWalk can improve function in some of incomplete spinal cord injury patients
(29)	Participants: 1 patient level of lesion: C4 Age: 21 Intervention: powered exoskeleton Comparison: parameters of physical activity	Using of exoskeleton may be a sure and possible method for individuals with higher levels of SCI
(30)	Participants:32 patient level of lesion: T4-L2 Age: 37 Intervention: Indego powered exoskeleton Comparison: indoor and outdoor walking donning/doffing the exoskeleton	The results showed improvements in walking speed, independence in walking in indoor and outdoor situations and donning/doffing the exoskeleton.
(31)	Participants: 45 patient level of lesion: T3-L2 Age:35 Intervention: powered exoskeleton Comparison: spasticity, pain, bladder/bowel function, MAS, Satisfaction with Life Scale, QOL, community integration	The results showed that the use of exoskeleton may reduce spasticity, increase return to society and finally improve the QOL
(32)	Participants: 1 patient level of lesion: T10 Age: not reported Intervention: a powered lower-limb orthoses Comparison: Walking performance	This orthoses help walking in paraplegic subjects
(33)	Participants: 1 patient level of lesion: T10 Age:- Intervention: powered lower limb exoskeleton Comparison: stair ascent and descent	maximum hip and knee joint torque necessities of 0.75 Nm/kg and 0.87 Nm/kg, respectively, and maximum hip and knee joint power necessities of approximately 0.65 W/kg and 0.85 W/kg, respectively.
(34)	Participants: 1 patient level of lesion: T10 Age:- Intervention: lower limb exoskeleton Comparison: legged mobility	The results showed that the increase in speed and decrease in effort are more considerable during walking than during gait transitions.
(35)	Participants: 11 patient level of lesion:C4-T7 Age:18-62 Intervention: elliptical- and exoskeletal-assisted stepping Comparison: hip and knee sagittal-plane kinematics lower-limb EMG recordings, oxygen consumption	In spite of particular differences in kinematics and EMG activity, metabolic activity was same within stepping in each robotic device.

9 to 21 (Table 2). However, most of these studies were case studies or case series with limited number of participants. Another strategy adopted for the patient with SCI was the use of mechanical orthoses. There were 9 studies on the use of mechanical orthoses for patients with SCI (Table 3). The quality of these studies were between 9 and 19. Functional

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Table 3. Continued

Reference No.	Method	Results
(36)	Participant: 6 patient level of lesion: T5-T12 Age:33.2 Intervention: ReWalk exoskeleton Comparison: Safety, Falls, status of the skin, status of the spine and joints, blood pressure, pulse, ECG Pain and fatigue	Subjects were able to walk a distance of 100 meters with the ReWalk™ without any side effects.
(37)	Participant: 21 patient level of lesion: C7-L2 Age:48.1 Intervention: a powered robotic exoskeleton Comparison: Pain, Spasticity and Subjective experience	This exoskeleton was well accepted by SCI patients and had significant effects on pain and spasticity
(38)	Participant: 4 patient level of lesion: C6-T10 Age:25-53 Intervention: Powered lower extremity exoskeleton Comparison: walking velocity, Spasticity, Temporal-spatial parameters	The results demonstrated a decrease in the walking speed and an increase in the muscle activity of the patients while walking
(39)	Participant: 1 patient level of lesion: T7 Age: - Intervention: hybrid orthoses Comparison: Standing, Walking, stair climbing	This orthosis allows patients to stand, walk and climb stairs
(40)	Participant: 1 patient level of lesion: T8 Age: 22 Intervention: powered hip orthoses Comparison: speed of walking, step length, cadence Vertical and horizontal compensatory motions	The hip actuator created definite effects on the kinematics and temporal-spatial parameters of walking

Table 3. Outputs of the studies on mechanical orthoses

Reference No.	Method	Results
(41)	Participants: 1 patient level of lesion: not reported Age: 49 Intervention: the models of human muscle energy expenditure Comparison: energy consumption	By using computer modeling and analysis, useful measurements such as energy consumption can be obtained
(42)	Participants: 9 patient level of lesion: T6-T12 Age:39.8 Intervention: mechanical function of the reciprocal link in RGOs Comparison: speed of walking, step length and hip joint range of motion	This orthosis improves walking indicators in people with spinal cord injury
(43)	Participants: 74 patient level of lesion:T5-T12 Age: 27.45 Intervention: RGO Comparison: functional walking, gait velocity, donning and doffing time	Although this orthosis has good features such as faster speed, ease of use, and greater patient independence, it is not considered as a replacement for a wheelchair.
(44)	Participants: 293 patient level of lesion: not reported Age:53.9 Intervention: leg orthotic therapy Comparison: Activities of daily living	leg orthoses may improve the daily activities of spinal cord injury patients after the acute period
(45)	Participants: 280 patient level of lesion: not reported Age:30-60 Intervention: orthotic devices Comparison: User satisfaction	The results showed that there is a need to improve orthoses, especially in terms of ease of use.
(46)	Participants:22 patient level of lesion: T3-T12 Age: 21-44 Intervention: HGO/RGO Comparison: gait parameters, pulse rate and oxygen consumption, standing up, climbing up and down a curb sitting in a wheelchair, use a car, Economic assessment	The results indicated that the RGO had a good appearance, while the HGO had a better donning and doffing speed. The RGO was almost 50% more expensive than HGO

electrical stimulation is another method that can be used to enable SCI patients to stand and walk. Ten studies reported and evaluated the efficiency of this method on the gait performance of the SCI patients. Based on the Down and Black tool, the quality of the papers published on this topic varied between 9 and 25 (Table 4).

Comparison of different mechanical orthoses on the gait performance of SCI patients was evaluated in 5 studies. The quality of these studies based on the Down and Black tool varied from 10 and 20. For the SCI participants, a novel technique called stance control technology was applied.

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Table 3. Continued

Reference No.	Method	Results
(47)	Participant: 21 patients level of lesion: C8-T12 Age:33 Intervention: RGO-II hybrid orthosis Comparison: cardiovascular adaptation, constipation, spasticity, osteoporosis	The results showed that the physiological benefits created by using this orthosis only improve the effects of immobility and no physiological improvement occurs as to spasticity and osteoporosis.
(48)	Participant: 5 patient level of lesion: T8-L12 Age: 20-32 Intervention: ARGO with dorsiflexion-assisted AFOs Comparison: postural sway, fear of falling	This orthosis improves static postural stability, walking speed and endurance but it increases the fear of falling. In general, this orthosis should be considered as an effective orthosis in the rehabilitation of people with spinal cord injuries
(49)	Participant: 1 patient level of lesion: T10 Age: 20 Intervention: a new medial linkage reciprocating gait orthosis Comparison: gait velocity, step length and cadence, Functional independence	The results showed that this orthosis can improve the functional independence of paraplegic patients

Table 4. Outputs of the studies on FES

Reference No.	Method	Results
(50)	Participants: 1 patient level of lesion: C8 Age:32 Intervention: FES Comparison: ambulation capacity	recovery in ambulation
(51)	Participants: 6 patient level of lesion: C3-L1 Age:20-40 Intervention: FES Comparison: quadriceps spasticity, lower limb muscle strength Postural stability in standing, spatial and temporal values of gait physiological cost of gait, ADL	The results showed a decrease in quadriceps spasticity, an increase in muscle strength and stride length and a decrease in the physiological cost of gait
(52)	Participant: 4 patient level of lesion: T3-L1 Age:24-38 Intervention: FES Comparison: stride length gait velocity	The results indicated that FES can improve direct response of the ankle and hip, knee and ankle flexion response. Simultaneously, in order to reduce fatigue, the frequency of the quadriceps muscles was reduced to 16 Hz
(53)	Participant:3 patient level of lesion: C6-T8 Age:28-42 Intervention: hybrid functional electrical stimulation orthoses Comparison: energy cost and step length	As a result of using this new new hip joint, energy cost reduction and stride length increase were reported.
(54)	Participant: 34 patient level of lesion: C2-T12 Age:56 Intervention: FES Comparison: QOL, Participation	The results of the study showed understanding into the considereded advantages obtained by participating in an RCT comparing exercise to FES .
(55)	Participant: 5 patient level of lesion: T6-T12 Age:42 Intervention: exoskeleton-assisted walking Comparison: oxygen consumption, heart rate, walking economy metabolic equivalent, walking speed, and walking distance	The cardiorespiratory and metabolic demands of walking with this method are similar to doing moderate intensity activities
(56)	Participant: 34 patient level of lesion: C2-T12 Age: 55 Intervention:FES Comparison: Whole body and leg lean mass, whole body fat mass	FES-assisted walking could not change body composition in people with incomplete C2 to T12 spinal cord injury
(57)	Participant: 25 patient level of lesion: C1-L15 Age:36 Intervention: FES Comparison: Spasticity and strength, Muscle, fat, and bone measurements, blood count, metabolic profile, and fasting lipid, medication, use and complications, quality of life, functional status	The results of the study showed that significant physical benefits can be obtained by using FES, such as increasing functional performance, increasing muscle size, reducing spasticity, and improving quality of life.

One study with a quality rating of 13 was undertaken expressly to examine the use of this technique (Table 5). The results of the quality assessment of the articles are presented in Table 6.

Comparisons between FES and mechanical orthoses were done in 2 studies. The quality rating of these papers was between 9 and 15. There was only 3 studies on the comparison between external powered orthoses and mechanical orthoses. The quality of these studies based on the Down and Black tool varied from 18 and 20.

As can be seen from Tables 7 to 10, the selected studies were also categorized according to the levels of the ICF. According to this classification, there were 25 studies based on body functions and structures. Six studies focused on activities and participation of the patients. There were 15 studies that covered both levels of the ICF, including activities and participation and body functions and structures.

The following results were obtained according to the outputs of these studies:

Both knee-ankle-foot orthosis (KAFO) and reciprocating gait orthosis (RGO) had the same effects on QoL.

Energy expenditure in walking with isocentric reciprocating gait orthosis (IRGO) may be less than standard RGO.

A self-contained muscle-driven exoskeleton may be a feasible intervention to restore stepping in SCI.

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Table 4. Continued

Reference No.	Method	Results
(58)	Participant: 34 patient level of lesion: C2-T12 Age: 56.59 Intervention: functional electrical stimulation therapy assisted walking Comparison: bone biomarkers and bone strength	FES-assisted walking could not change body composition in people with incomplete C2 to T12 spinal cord injury
(59)	Participant: 35 patient level of lesion: T12 or higher Age:53 Intervention: FES Comparison: walking speed	Daily use of FES can improve walking speed in incomplete SCI

Table 5. The results of studies on comparison mechanical orthoses, comparison power orthoses and mechanical orthoses, comparison FES and mechanical orthoses and stance control orthoses

Reference No.	Method	Results
(60)	Participants: 22 patient level of lesion: thoracic Age: 39.13 Intervention: RGO/HKAFO Comparison: Quality of Life	Although subjects who used RGOs or HKAFOs had the same QOL score, those who used RGOs showed better emotional stability, communication, and emotional independence.
(61)	Participants: 4 patient level of lesion: paraplegia Age: 29.8 Intervention: RGO / Modified Isocentric RGO Comparison: energy cost of ambulation	The results showed that compared to the standard RGO, energy costs of ambulation are lower in Isocentric RGO
(62)	Participants: 4 patient level of lesion: T6-T10 Age: 34.5 Intervention: MLRGO / IRGO Comparison: Gait parameter Postural stability	The results demonstrate that compared to IRGO, the use of MLRGO can lead to greater improvement in walking speed and endurance in spinal cord injury patients.
(63)	Participant: 4 patient level of lesion: T8-T12 Age:34.4 Intervention: new medial linkage orthosis/ isocentric reciprocating gait orthosis Comparison: Walking speed and heart rate	Compared to IRGO, all participants had a faster walking speed, walked more distance, and had lower PCI when wearing MLO.
(64)	Participant: 12 patient level of lesion: T4-L5 Age: 18-60 Intervention: hip energy storage walking orthosis(HESWO) Comparison: walking speeds, walking distance, and energy expenditure	The results showed that HESWO is alternative option for paraplegic walking.
(65)	Participants: 13 patient level of lesion: T1-L5 Age: 17–45 years Intervention: KAFO (KAFO-gait) or a ReWalk robot (ReWalk-gait) Comparison: spatiotemporal variables energy expenditure	Although subjects wearing robot (ReWalk) walked with lower energy consumption compared to KAFO, there was no difference between the two interventions in terms of client satisfaction.
(66)	Participant: 6 patient level of lesion: C8-T11 Age: 19-34 Intervention: WPAL/ MSH-KAFO Comparison: Energy efficiency	The results of the study showed that WPAL is an applied and effective type of robotics that can be used in the rehabilitation of paraplegia patients.
(67)	Participant: 1 patient level of lesion: T8 Age: 22 Intervention: powered gait orthosis Comparison: Joint angles, Step length, walking speed, cadence and compensatory motion	The results of using this new orthosis show improvement in all of gait parameters compared to IRGO.
(68)	Participants: 19 patient level of lesion: not reported Age: 42.7 Intervention:FES/ Hinged AFO Comparison: gait speed and endurance	Both types of interventions improve walking ability, however, the use of FES increases foot clearance values.
(69)	Participant: 5 patient level of lesion: C2-T6 Age:24-37 Intervention:FES/RGO Comparison: Walking speed, energy consumption, energy cost	During long walking, using the hybrid system has more advantages. However, the presence of limitations in RGO can reduce adoption
(70)	Participants: 3 patient level of lesion: not reported Age: 48.3 Intervention: microprocessor stance and swing control orthosis Comparison: ADL	This new orthosis can make patients perform many activities of daily living in an easier and safer way

Use of Varileg enables SCI patients in walking and climbing ramps and stairs.

Rewalk enables SCI patients to walk with lower energy expenditure than KAFO.

Exoskeleton is a safe method for the locomotion of SCI patients.

Power exoskeleton improves speed and independency in walking in indoor and outdoor spaces.

RGO is not considered as an alternative for SCI patients for ambulation.

Orthoses should be improved to enhance comfort ability.

No physiological improvements were observed in using hybrid devises.

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Table 6. Result of quality assessment based on the down and black scale

Reference No.	Reporting	External validity	Internal Validity - Bias	Internal Validity - Confounding	Power	Total
(24)	9	1	4	1	0	15
(25)	7	1	4	1	0	13
(26)	6	1	3	1	0	11
(27)	6	1	3	1	0	11
(28)	10	3	5	3	0	21
(29)	5	1	3	1	0	10
(30)	10	1	4	3	0	18
(31)	8	3	4	1	0	16
(32)	4	1	3	2	0	10
(33)	4	1	3	1	0	9
(34)	4	1	3	1	0	9
(35)	8	1	4	2	0	15
(36)	9	3	4	3	0	19
(37)	8	3	4	2	0	17
(38)	6	1	4	2	0	13
(39)	5	1	4	1	0	11
(40)	5	1	4	1	0	11
(41)	5	1	3	1	0	10
(42)	8	1	4	1	0	14
(43)	9	3	5	2	0	19
(44)	9	3	4	3	0	19
(45)	8	3	3	2	0	16
(46)	5	1	2	1	0	9
(47)	7	3	4	3	0	17
(48)	8	1	4	2	0	15
(49)	5	1	4	1	0	11
(50)	5	1	2	1	0	9
(51)	8	2	3	2	0	15
(52)	5	1	2	1	0	9
(53)	8	1	4	2	0	15
(54)	10	3	6	4	0	23
(55)	8	3	4	1	0	16
(56)	10	3	6	5	0	24
(57)	10	3	5	3	0	21
(58)	10	3	6	5	1	25
(59)	9	3	5	2	0	19
(60)	11	3	4	2	0	20
(61)	10	1	4	2	0	17
(62)	8	1	4	1	0	14
(63)	6	1	2	1	0	10
(64)	9	3	5	2	0	19
(65)	8	3	4	4	1	20
(66)	8	3	4	3	0	18
(67)	5	1	4	1	0	11
(68)	8	1	4	1	1	15
(69)	6	1	1	1	0	9
(70)	7	1	4	1	0	13

Walking with robotic exoskeleton may have positive effects on spasticity and pain reduction.

Discussion

Different treatment approaches have been used to return the abilities of SCI patients to stand and walk and also to improve their abilities in performing their daily activities. The performance of SCI patients standing and walking with various assistive devices has been evaluated in numerous studies in the literature. However, a small number of them assessed the degree of involvement and QoL in this particular group. The primary goal of this review was to assess the effectiveness of assistive technologies utilized by SCI patients using the ICF model. As can be seen from the results of this study, there were 47 papers on this topic with a quality varied between 9 and 25. The main reasons for the score of quality assessment were limited number of the patients in the studies and type of studies (mostly the studies were cross sectional). Moreover, no attempts were done to blind the participants and researchers regarding the type on interventions. The power of studies was not reported in most of the studies. The length of follow-up should also be taken into account. The majority of these studies evaluated performance immediately after the use of assistive tools. Therefore, it is challenging to draw a firm conclusion about the effectiveness of different assistive technologies due to the poor quality of the studies that are currently available.

As can be seen from Tables 1 to 4, various approaches have been used for SCI patients to stand and walk, including mechanical orthoses, FES, hybrid, and exoskeleton. Nearly 47 papers have been found on the use of these methods for rehabilitation of SCI patients.

There were 9 studies with a quality of 9 and 19 on the use of mechanical orthoses for SCI patients (Tables 2, 5).

The results of performance of the SCI patients in walking with various mechanical orthoses are shown in Table 2. As can be seen from this table, the walking speed of the SCI patients varied between 14.4 and 33 m/min and the energy cost varied from 3/28 to 3/56 beats/m, based on the PCI index. Based on the available literature, the performance of the patients in using HKAFO orthoses, especially hip guidance, and RGO orthoses, was better than other available mechanical orthoses. However, in most of the available or-

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Table 7. Results of ICF classification on studies of external power orthoses

Reference No.	Study Design	Measurement Instrument	Outcome Measure	ICF Level
(24)	cross-sectional	paired-pulse somatosensory evoked potentials (ppSEP) 10-m walk test timed-up-and-go test 6-min walk test lower extremity motor score	cortical excitability walking parameters	Activities Body functions and structures
(25)	Case-crossover	hydraulic orthotic mechanisms	Stand to sit Hip knee angle knee angular velocity upper limb support force impact force	Body functions and structures
(26)	Case-crossover	finite state machine	Stepping Walking speeds cadences	Body functions and structures
(27)	Case-crossover	No information	walking skills stair climbing	Body functions and structures activities
(28)	cohort study	10MWT 6MWT Physiological Cost Index (PCI) Heart rate MMT SCATS VAS	walking progression sitting balance skin sensation spasticity strength of corticospinal tracts	Activities Body functions and structures
(29)	Case report	dual-energy X-ray absorptiometry (DXA)	Walk time total number of steps up-time	Body functions and structures
(30)	cohort study	10MWT 6MWT TUG 600-meter walk test	indoor and outdoor walking donning/doffing the exoskeleton	activities
(31)	cross-sectional	Self-report	spasticity pain bladder/bowel function MAS Satisfaction with Life Scale QOL community integration	Body functions and structures participation
(32)	Case report	Embedded system	Walking	Body functions and structures
(33)	Case report	hip and knee joint torque	stair ascent and descent	Body functions and structures
(34)	case study	TUG 6 MWT 10 MWT	legged mobility	Body functions and structures activities
(35)	cross-sectional	Electrogoniometers Portable metabolic system	hip and knee sagittal-plane kinematics lower-limb EMG recordings oxygen consumption	Body functions and structures
(36)	cohort	FIM	Activities of daily living	activities
(37)	cross-sectional	Numeric Rating Scale Ashworth questionnaire	Pain Spasticity Subjective experience	Body functions and structures
(38)	cross-sectional	MMT ASHWORTH Motion Analysis sEMG	walking velocity Spasticity Temporal-spatial parameters	Body functions and structures
(39)	Case report	observation	Standing Walking stair climbing	activities
(40)	Case report	Vicon digital motion capture	speed of walking step length cadence Vertical and horizontal compensatory motions	Body functions and structures

thoses, the performance was evaluated only based on walking and standing performance. There was limited evidences on how the clients use their orthoses. Moreover, it is not well understood that how the use of these mechanical orthoses influences the participation of the patient and their QoL.

Table 8. Results of ICF classification on studies of mechanical orthoses

Reference No.	Study Design	Measurement Instrument	Outcome Measure	ICF Level
(41)	Case report	the models of human muscle energy	energy consumption	Body functions and structures
(42)	Case-crossover	Vicon digital capture system	speed of walking step length hip joint range of motion	Body functions and structures
(43)	cross-sectional	Garrett score	functional walking gait velocity donning and doffing time climb stairs	Body functions and structures activities
(44)	cohort	FIM	Activities of daily living	activities
(45)	cross-sectional	Quebec User Evaluation of Satisfaction with Assistive Technology	satisfaction	Not covered
(46)	Trial crossover	ergonomic tests biomechanical assessments	gait parameters pulse rate and oxygen consumption standing up climbing up and down a curb sitting in a wheelchair use a car Economic assessment	Body functions and structures activities
(47)	cross-sectional	arm crank ergometer Ashworth score Dual photon absorptiometry	cardiovascular adaptation constipation spasticity osteoporosis	Body functions and structures
(48)	RCT	force plate system modified Falls Efficacy Scale	postural sway fear of falling	Body functions and structures activities participation
(49)	Case report	questionnaire	gait velocity step length and cadence Functional independence	Body functions and structures Activities

Another question that has been made is how much of a difference there is between standing and walking performance when using mechanical orthoses and other systems of locomotion. The mean values of walking speed of SCI patients in using external power orthoses were between 18 to 64 m/min and for FES it varied from 6.6 to 24/2 m/min. Compared with mechanical orthoses, the SCI patients had a more speed in using external power orthoses. The majority of these orthoses are too large for SCI patients to use, hence, their willingness to use external power orthoses is minimal. Based on the results of the studies presented in Tables 1 to 4, it can be concluded that the mechanical orthoses may be more suitable to be used by SCI patients in standing and walking. However, this is mostly based on general evaluations of the performance, meaning that the effects of the mention systems on social and participation were not evaluated in the studies. It can be inferred from the aforementioned studies that mechanical orthoses appear to improve standing and walking performance for SCI patients. However, the body function level of the ICF is the sole factor used in this analysis. The other aim of this review was to evaluate the available studies based on the ICF model. The ICF consists of 3 levels—body functions and structures, activities, and participation. There were 6 studies on the level of activities and participation (only 1 study was related to participation), 15 studies were on both levels of body function and structures and activity and participation, and 25 studies were related to only body function and structures (Tables 9-12). It is stated that the majority of the included studies evaluated the effectiveness of orthoses mostly based on body functions. These studies evaluated a few outcome metrics, including walking speed, energy consumption, and stability. There have been a few studies on the other ICF levels, including participation and activity.

In the ICF, it is important to have a holistic view on functional performance of the patients, and the efficiency of the treatment approach should be evaluated based on all ICF levels. As a result, when evaluating the effectiveness of orthoses, it is also important to consider how they affect patients' involvement, QoL, and overall wellness. In most of these studies, performance was evaluated immediately after using assistive devices (24). However, if orthoses are solely used in a clinical context, patients will not be able to alter their social connections or general mobility in society, two key aspects of life satisfaction. Considering that the purpose of prescribing orthoses is ultimately to improve the QoL and satisfaction (25), it is necessary to evaluate the effectiveness of orthoses in other environments other than the clinic (such as community, home, and work place). As a result, it's crucial to assess the patients' performance after a follow-up period. According to Juszczak et al (2018) study, using a powered exoskeleton may reduce spasticity, however, improvements in secondary impairments like spasticity did not lead to a substantial improvement in participation and QoL (24).

Based on the study of Jefferson et al (2011), achieving a satisfactory QoL is a primary goal of treatment and rehabilitation for the patients with SCI (26). Participation is more correlated with QoL than it is with injury severity or functional ability (26). Therefore, the primary question raised

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Table 9. Results of ICF classification on studies of FES

Reference No.	Study Design	Measurement Instrument	Outcome Measure	ICF Level
(50)	Case report	American Spinal Injury Association Impairment Scale	ambulation	Body functions and structures
(51)	cross-sectional	MMT upright motor control test Maximum voluntary contraction Ashworth scale pendulum test physiological cost index (PCI) modified Barthel index	quadriceps spasticity lower limb muscle strength postural stability standing, spatial and temporal values of gait physiological cost of gait ADL	Body functions and structures activities
(52)	cross-sectional	EMG kinesiological measurements	stride length gait velocity	Body functions and structures
(53)	Case series	VICON-VX system	energy cost step length	Body functions and structures
(54)	RCT	Spinal Cord Independence Measure Satisfaction With Life Scale LOTCA Craig Handicap and Assessment Reporting Technique Reintegration to Normal Living Index perceptions of intervention(s) outcomes	QOL Participation	Body functions and structures activities participation
(55)	Case series	maximal graded exercise test 6MWT	oxygen consumption heart rate walking economy metabolic equivalent walk speed, and walk distance	Body functions and structures activities
(56)	RCT	dual-energy X-ray absorptiometry peripheral computed tomography	Whole body and leg lean mass and whole body fat mass	Body functions and structures
(57)	Retrospective cohort	ASIA composite motor–sensory score (CMSS) isokinetic dynamometer MRI SF36 FIM	Spasticity and strength Muscle, fat, and bone measurements blood count, metabolic profile, and fasting lipid medication use and complications quality of life functional status	Body functions and structures activities participation
(58)	RCT	DXA pQCT	bone biomarkers and bone strength	Body functions and structures
(59)	Case series	10 meter walking speed	walking speed	Body functions and structures

here is how much the orthoses affect this patient group's social participation and integration. There were 3 studies that examined the ICF's degree of engagement together with other factors including QoL, community integration, and satisfaction. According to a study by Barati et al (2020), improvement in some parameters, such as kinetic and kinematic (gait), is not related to other factors, such as social participation (27). The aim of using orthoses and other assistive devices is not just improvement in gait performance. In another study done by Sunder et al (2013), the efficiency of FES and exercise was compared on a group of SCI patients, based on both body functions and participation (28). The results of this study showed that although those with FES had a better gait performance, there was no significant difference between the participation and QoL between the groups. The effect of using FES on QoL was also evaluated by Cristiana et al. They confirmed that FES in chronic SCI may improve QoL (29). Few studies evaluated the effects of using orthoses on participation and QoL of the SCI patients. According to the studies that are presently available, it appears that the majority of researchers and clinicians assessed the patients using impairment-based

Table 10. Results of ICF classification on studies of comparison mechanical orthoses, comparison power orthoses and mechanical orthoses, comparison FES, and mechanical orthoses and stance control orthoses

Reference No.	Study Design	Measurement Instrument	Outcome Measure	ICF Level
(60)	Cross-sectional	Sickness Impact Profile	Quality of life	Participation
(61)	Case-crossover	heart rate physiologic cost index (PCI) respiratory exchange ratio	energy cost of ambulation	Body functions and structures
(62)	Case-crossover	Force plate mFES	Gait parameter Postural stability	Body functions and structures activities
(63)	Case series	Physiological cost index (PCI)	Walking speed and heart rate	Body functions and structures
(64)	RCT	energy expenditure observation	Walking speeds Walking distance energy expenditure	Body functions and structures
(65)	Random cross-over design	6MWT 30MWT	spatiotemporal variables energy expenditure	Body functions and structures
(66)	Case series	physiological cost index (PCI) heart rate (HR) and modified Borg score 6MWT	Energy efficiency	Body functions and structures
(67)	Case report	observation	Joint angles Step length, walking speed, cadence and compensatory motion	Body functions and structures
(68)	Cross-sectional	Six-minute walk distance	gait speed and endurance foot clearance	Body functions and structures activities
(69)	Case series	Douglas bag technique	Walking speed energy consumption energy cost	Body functions and structures
(70)	Case-crossover	Orthosis Evaluation Questionnaire Activities of Daily Living Questionnaire	ADL	Activities

techniques, which mostly focused on impairments rather than the patients' living environments (30).

It was also made abundantly clear that most researchers focused on gait and walking performance while highlighting the superiority of their orthoses rather than how the patients used them. The lack of proper tools to assess involvement and QoL is another factor that needs to be taken into account in this context. Ullrich et al (2012) showed that the methods and tools to evaluate the participation of SCI patients is not enough and yet existing measurement tools in this population have significant limitations. They emphasized to develop appropriate tools that can be used to evaluate the participation of the SCI patients (31).

Based on available studies, it can be concluded that use of some approaches such as mechanical orthoses, FES, hybrid system, external power orthoses enable SCI patients to stand and walk. However, their performance is not compatible with that of healthy patients. Because of significant energy consumption, slow walking pace, and excessive stresses placed on the upper limb, the majority of patients choose not to utilize their orthoses. Based on the comments of the SCI patients, most patients preferred not to use any orthoses. It was found that most research solely focused on biomechanical aspects, such as kinetic and kinematic factors, after taking levels of ICF into account. It is unclear how much those factors affect the patient's involvement in daily activities and the community. Orthoses' impact on QoL was not also assessed. Based on the available literatures, it cannot be concluded which type of ambulation approaches influence other levels of the ICF.

It is important to acknowledge that this systematic study has significant limitations. The significant drawback was that the majority of studies that were accessible were case studies. Furthermore, the majority of the studies had poor quality. The other limitation associated with this analysis was limited access to the full texts of the studies.

Conclusion

Despite the fact that there were 47 studies on the subject of using different assistive devices for patients with SCI, the majority of them solely addressed biomechanical elements like kinetic and kinematic characteristics. Due to this, there is a significant gap in the evaluation of the effects of using these devices on some criteria, such as participation and QoL of SCI patients. Given that the goal of rehabilitation therapies is to increase QoL and patient satisfaction, it is important to consider how well orthoses affect all facets of patients' health, not only physical structures and functions. The available data supports the idea that mechanical orthoses can help people with SCI stand and walk, and that they perform better than conventional approaches. However, social integration and QoL were unaffected. Because of this, the majority of SCI patients either want to

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ambulate in a wheelchair or choose to utilize no assistive aids at all.

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Ethical Considerations

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (SUMS). The ethics code: IR.SUMS.REC.1399.781.

Abbreviations

10MWT: 10-meter walk test
6MWT: 6-min walk test
PCI: Physiological Cost Index
MMT: Manual muscle testing
SCATS: Spinal Cord Assessment Tool for Spastic Reflexes
EMG: Electromyography
ECG: Electrocardiogram
HESWO: Hip energy storage walking orthosis
VAS: Visual analog scale
DXA: Dual-energy X-ray absorptiometry
TUG: Timed-up-and-go test
AFO: Ankle foot orthosis
HESWO: Hip energy storage walking orthosis
MLRGO: Medial linkage reciprocating gait orthosis
IRGO: Isocentric Reciprocating Gait Orthosis

Conflict of Interests

The authors declare that they have no competing interests.

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