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What Are the Next Steps in Designing an Orthosis for Paraplegic Subjects?

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Review Article

ABSTRACT

Background: Over the years, various types of orthoses have been designed to assist subjects with spinal cord injury (SCI) to stand and walk. However, the functional performance of the orthoses has not been adequate, that is, patients experience stability problems, consume excessive energy during ambulation, and generally require assistance in donning and doffing the devices. This research is aimed at categorizing the available orthoses designed specifically for SCI patients and to compare the available orthoses according to the energy consumption, stability analysis, and gait parameters.

Methods: An electronic search was done in PubMed, Embase, and ISI Web of Knowledge databases to extract data related to 1960 – 2010. The available orthoses were characterized based on the level of stabilization they provided and the source of power used. The orthoses were compared based on the stability, energy consumption, and gait performance parameters, according to the results of various studies collected from the literature review.

Results: Among various orthoses designed for paraplegic subjects, the mechanical orthoses seemed to have a better performance. Moreover, donning and doffing of the mechanical orthosis was easier for the subjects.

Conclusion: Although the HGO has better functional performance than other available orthoses, the subjects are more willing to use the RGO. The new design of orthoses must allow easy donning and doffing by the users, have enough stability during walking and standing, and enable the patients to change the alignment of the orthosis to suit their needs.

Keywords: Orthosis, spinal cord injury, walking

INTRODUCTION

Spinal cord injury (SCI) is a damage or trauma to the spinal cord that results in loss of function, mobility, and sensation below the level at which the spinal cord has been injured. This disorder is characterized according to the amount of functional loss, sensation loss, and inability of an SCI individual to stand and walk.[1,2]

The annual incidence of SCI varies from one country to another, it differs between 12.7 (France) and 59 (USA) new cases per million, each year.[3-8] In the USA, it is estimated that there are 183,000 to 230,000 individuals living with SCI.[9] In contrast, the total population of individuals with SCI in the UK is about 40,000.[4]

Neurological problems occur in patients with SCI. Distortion of a small portion of the column produces profound motor and sensory changes. In complete SCI, all functions, sensory and motor, are lost below the level of the lesion. In contrast, in incomplete lesions, there is some sensory and motor function below the level of injury.[10-12] The most common complication of SCI is the loss of functional mobility and sensation below the level of injury. However, paralysis, whether partial or complete, may lead to development of complications in other parts of the body. The complications in persons with SCI include:[2] respiratory disorder, gastrointestinal and cardiovascular disorders, skin and musculoskeletal problems, and psychological disorders.

These patients can use orthoses or wheelchairs in order to transfer from one place to another. Clinical experience has shown that wheelchair users often have complications secondary to their injury and also due to long-term sitting.[2] Standing and walking bring some benefit to the SCI patients, such as, decreasing bone osteoporosis, prevention of pressure sores, and improving the function of the digestive system.[13-24] Although walking with orthoses is beneficial for the patients in contrast to using wheelchairs,[25-27] the patients have some problems in using orthoses.

The main problems with orthosis use are the high energy demands it places on the user during ambulation. The walking speed of an SCI patient with an orthosis is significantly less than that of normal walking, as also the mobility with a wheelchair.[28,29] Independent donning and doffing of the orthosis, cosmesis of the orthosis and style of walking are the other issues associated with orthosis users.

This research aims to categorize all available orthoses designed for paraplegic subjects. Moreover, it aims to mention various parameters that can be used to measure the performance of the subjects when using the orthoses. The available orthoses have been compared based on gait, standing stability, and energy consumption analysis. We also tried to find the most important parameters necessary for designing a new orthosis.

METHODS

An electronic search was done in the databases of PubMed, Embase, and ISI Web of Knowledge websites to extract the data related to the years 1960 – 2010. The abstract and title of each individual study was assessed by the author. The first step in selecting relevant articles was done based on whether the title / abstract addressed the research's questions of interest. Figure 1 shows the stages performed in this review project. The second selection step was done according to the following criteria:

- Experimental studies published in English
- Addressing adults and children with paraplegia and / or quadriplegia
- The subjects used orthoses or functional electrical stimulation (FES)

Assessing the quality of the research studies

The quality of the methodology of various related studies was assessed using the Downs and Black tool.[30,31] Two expert reviewers were asked to evaluate the quality of each research through this test. The correlation between the results obtained by the reviewers was 0.9.

It was believed that the difference between the results of various studies was due to sampling errors or the presence of a significant heterogeneity (any kind of variability among studies in a systematic review). The heterogeneity

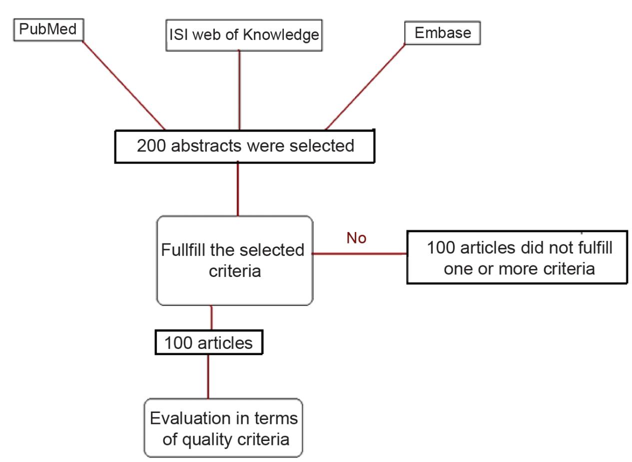

Figure 1: The stages which were selected in this research study

of the results of the studies reviewed here was evaluated by a Q test and I² statistic.[30,31] As the number of studies used in this review was small, a *P*-value of 0.1 was used to determine the statistical significance (instead of the conventional value of 0.05). A low P-value (or a large chi-square relative to the degree of freedom) provides evidence of heterogeneity of intervention effects (variation in effect estimates beyond chance). A rough guide to the degree of heterogeneity is low, moderate, and high at values > 0.25, > 0.50, and > 0.75, respectively.[30,31]

Orthoses used by paraplegic individuals for standing and walking

Various types of orthoses have been designed to enable SCI individuals to walk and stand. The type of orthosis selected by these patients and the type of mechanisms used, depend upon the abilities of the subjects and the level of their spinal cord lesions. The following categorization of orthoses is used to stabilize paralyzed limbs during standing and walking:

- Ankle foot orthosis (AFO)
- Knee–ankle foot orthosis (KAFO)
- Hip–knee ankle foot orthosis (HKAFO)
- External powered orthoses
- Functional electrical stimulation (FES)
- Hybrid orthosis

Assessment methods used to evaluate the available orthoses

Available orthoses for paraplegic subjects have been evaluated by various methods including:

- Independency of the subjects in using the orthosis
- Energy cost of walking with the orthosis
- Cosmesis
- Mechanical reliability of the orthosis
- Gait parameters in walking with the orthosis
- Stability analysis in quiet standing
- Stability analysis while undertaking various hand tasks
- Analysis of the magnitude of the forces applied on the crutch during walking

In evaluating cosmesis, other parameters such as style of walking, the extent to which the orthosis could be disguised under clothing, and also the cosmesis of the orthosis were considered.[32,33]

The available orthoses were compared based on the above-mentioned parameters. The problems of the subjects in using the orthoses were also determined. As most of the above-mentioned parameters were represented in various scales, an attempt was made to change the parameters, to try and show them in a standard manner. For the energy consumption and energy cost, the results of various research studies were converted according to the common conversion relationships mentioned in Table 1.[34]

RESULTS

The available orthoses for paraplegic subjects, according to the literature, can be defined as follows:

Ankle foot orthosis

The AFO orthoses are usually designed to permit safe and effective ambulation of SCI individuals with lesions between L_4 and S_2.[35] They are divided into two main categories, including conventional and plastic orthoses.[36,37] One of the new AFO orthosis, which was specifically designed for paraplegic subjects was the Vannini-Rizzoli stabilizing orthosis (VRSO). It was used for patients with lesions at T_6 or lower. However, a lot of contraindications were considered to select the patients who could use this orthosis.[38]

Knee–ankle–foot orthosis

The KAFO orthoses are prescribed for SCI individuals with lesions below T_{10}. Various kinds of KAFO orthoses, with different types of knee joints and locking mechanisms have been designed for paraplegic subjects. The most common KAFOs include:[37]

- Craig-Scott orthosis[35]
- Orthotic design from the New England Regional Spinal Cord Injury Center (NERSCIC)[39]
- Lightweight modular orthosis[40]

Hip–knee–ankle–foot orthosis

The HKAFO orthoses are used to control the

Table 1: Common conversation relationships

To change	To	Multiply by
Calorie	Jules	4.18
Kilocalorie	Jules	4186
Kilocalorie	Kilogram-meter	427
Kilocalorie / hour	Watt	1.16

selected motions of the hip joint using various kinds of hip hinges, which are inserted between a pelvic band or spinal rigid orthosis and the KAFO segments. The most common used HKAFO orthoses include:

- Reciprocating brace with poly planar hip hinges[41,42]
- Hip guidance orthosis[43,44]
- Ortho-walk pneumatic orthosis[45]
- Louisiana State University reciprocal gait orthosis (LSU-RGO)[27]
- Advanced reciprocating gait orthosis (ARGO)[46]
- Adjustable ARGO orthosis[47]
- ARGO aligned in slight abduction[48]
- Isocentric reciprocating gait orthosis (IRGO)[49]
- Four-Bar Gait control linkage orthosis[50]
- Medial linkage orthosis (MLO)[51,52]
- Moorong MLO (MMLO)[51]
- Hip and ankle linkage orthosis (HALO)[53]

Hydraulic, pneumatic, and electrical powered orthoses

Different orthoses have been designed for SCI subjects. These orthoses use hydraulic or pneumatic control systems or electrical sources of power to help the patients to move their limbs forward during the swing phase. Many of these orthoses were only evaluated in the laboratory and have not been produced commercially, and include:

- Hydraulic reciprocating gait hip–knee–ankle foot orthosis (HRGO)[54]
- Pneumatic active gait orthosis (PAGO)[55]
- Powered gait orthosis (PGO)[56]
- Weight-bearing control orthosis (WBC)[57]
- Two-degree-of-freedom motor-powered gait orthosis[58]
- Driven gait orthosis (DGO)[59]

Functional electrical stimulation

This is the application of external stimulation to paralysed muscles, to restore their function. There are three different types of stimulations which include:[60]

- Electrical stimulation of the ventral roots
- Electrical stimulation of the peripheral nerves
- Electrical stimulation of the muscles themselves

Hybrid orthosis

This type is a combination of mechanical orthosis and electrical stimulation. The hybrid orthoses can be divided into two main groups, which include:

Hybrid orthoses based on the available mechanical orthoses[61-66]

Hybrid orthosis based on the new designed orthoses such as:

- Modular hybrid orthosis[67]
- Spring brake orthosis (SBO)[68]
- Hybrid orthosis with new knee and ankle joint flexion component[69,70]
- Wrapped spring clutch orthosis (WSO)[71]
- Hybrid orthosis designed by Baardman *et al*.[72,73]

The quality of the methodology used in this review article (based on Downs and Black tool) is shown in Table 2. As can be seen from Table 2, the quality of introduction part of the research papers (reporting) was acceptable but the external and internal validities were poor.

The results of stability analysis, gait analysis, and energy consumption tests during walking and standing with various orthoses are summarized in Tables 3 – 12.

Unfortunately, as the number of the researches were very limited, it was impossible to determine the

Table 2: The results of the assessment of the quality of methodology of the research studies selected in this review article

Treatment approaches	Reporting (total score 10)	External validity (total score 3)	Internal validity, bias (total score 7)	Internal validity, confounding (total score 7)
Research based on HGO orthosis	8	1	2	7
Research based on RGO orthosis	8	1	2	7
Research based on ARGO orthosis	9	2	2	6
Research based on other orthoses	8	1	2	7

HGO: Hip guidance orthosis; RGO: Reciprocal gait orthosis; ARGO: Advanced reciprocal gait orthosis heterogeneity of the results of the studies regarding the stability and energy consumption. However, the heterogeneity of the study results based on gait analysis was evaluated with the aforementioned procedures. The results of the heterogeneity test are shown in Table 12. As can be seen from this Table, the level of heterogeneity of the results of the considered studies in this review article is low, and is not significant enough to be considered.

DISCUSSION

Evaluating the quality of the studies

The quality of the report section of the studies on walking and standing in SCI individuals, was acceptable, because in most of them the hypothesis, aims, and objectives of the study were clearly described. Moreover, the characteristics of the subjects, including age and level of injury were well expressed. The main findings of the studies were entirely defined and appropriate statistical tests were used to evaluate the difference between the results.

Unfortunately, since a small number of subjects were selected, the external validity of most of the research done in this regard was not high. In addition, there was a great deal of difference between the performances of SCI individuals with

Table 3: The results of research undertaken with regard to the force applied on the foot and crutch during walking with various orthoses

Research studies	Number of subjects	Level of lesion	Foot force (N / BW)	Crutch force (N / BW)	Foot vertical impulse	Crutch vertical impulse	Type of walking	Type of orthosis
(Ferrarin *et al*., 1993)[74]	5	T1-T10	0.784-1.042	0.288-0.296	0.712-0.794	0.206-0.288	Rec	HGO
(Slavens *et al*., 2007)[75]	5	L3-L4	-	0.447-0.451	-	-	Rec	RGO
(Slavens *et al*., 2007)[75]	5	L3-L4	-	0.556-0.572	-	-	Swi	HKAFO
(Major *et al*., 1981)[44]	1	L2	0.90-1.10	0.35	-	-	Rec	HGO
(Nene and Major, 1987)[76]	9	T4-T9	0.29- 0.98	0.40	-	-	Rec	HGO
(Tashman *et al*., 1995)[77]	1		0.83	0.33	-	-	Rec	RGO
(Melis *et al*., 1999)[78]	10	C5-T12	-	0.15-0.50	-	-	Swi	No orthosis with crutch
(Melis *et al*., 1999)[78]	10	C5-T12	-	0.39-0.74	-	-	Swi	No orthosis with walker
(Ijzerman *et al*., 1997)[85]	5	T4-T12	-	0.39-0.43	-	0.59	Rec	ARGO (1)
(Ijzerman *et al*., 1997)[85]	5	T4-T12	-	0.36-0.40	-	0.57	Rec	ARGO (2)
(Ijzerman *et al*., 1997)[85]	5	T4-T12	-	0.36-0.41	-	0.57	Rec	ARGO (3)
(Ijzerman *et al*., 1997)[85]	5	T4-T12	-	0.33-0.40	-	0.59	Rec	ARGO (4)
(Baardman *et al*., 2002)[72]	2	T4-T8	-	180.3N -289.2 N	-	306-522.2 N.s	Rec	ARGO
(Baardman *et al*. 2002)[72]	2	T4-T8	-	175.2N-308N	-	310.2-529 N.s	Rec	ARGO hybrid

Rec: Reciprocal gait mechanism, Swi: Swing-through gait mechanism, ARGO (1): ARGO orthosis aligned in six degrees of abduction, ARGO (2): ARGO orthosis aligned in zero degrees of abduction, ARGO (3): ARGO orthosis aligned in three degrees of abduction, ARGO (4): ARGO orthosis aligned in six degrees of adduction

Table 4: The stability of the paraplegic subjects in quiet standing with various orthoses

Research projects	Number	Level of lesion	Type of orthosis	COP path length (m)	COP sway ML (mm)	COP sway AP (mm)	Force applied on crutch (N)
(Baardman *et al*., 1997)[79]	9	T_4–T_{12}	ARGO	-	41.72	35.22	43.26
(Baardman *et al*., 1997)[79]	9	T_4–T_{12}	NRGO	-	34.53	37.94	59.3
(Kaoru, 2006)[80]	2	T_9–T_{12}	KAFO	0.51-0.62	-	-	-
(Kaoru, 2006)[80]	2	T_9–T_{12}	MLO	0.123-0.2	-	-	-
(Kaoru, 2006)[80]	2	T_9–T_{12}	RGO	0.116-0.16	-	-	-
(Middleton *et al*., 1999)[81]	9	T_5–T_{12}	Linked KAFO	0.74	1.11	1.75	-
(Middleton *et al*., 1999)[81]	9	T_5–T_{12}	Unlinked KAFO	0.659	1.087	2.07	-

RGO: Reciprocal gait orthosis; ARGO: Advanced reciprocating gait orthosis; KAFO: Knee–ankle–foot orthosis; MLO: Medial linkage orthosis

Table 5: The stability of paraplegic subjects while undertaking various hand tasks

Research project	Type of orthosis	COP sway in AP (mm)	COP sway in ML (mm)	Sway path in AP (m)	Sway path in ML (m)	Time for transverse motion	Crutch peak force (N)
(Middleton *et al*., 1999) [81]	Linked KAFO	4.78	4.94	0.91	0.34	-	-
(Middleton *et al*., 1999)[81]	Unlinked KAFO	5.35	4.4	0.9	0.76	-	-
(Baardman *et al*., 1997)[79]	ARGO	-	-	-	-	11.12	179.75
(Baardman *et al*., 1997) [79]	NRGO	-	-	-	-	11.54	198
Staking plates							
(Middleton *et al*., 1999)[81]	Linked KAFO	5.6	3.74	1.03	1.94	-	-
(Middleton *et al*., 1999)[81]	Unlinked KAFO	5.8	3.24	1.07	0.74	-	-

ARGO: Advanced reciprocating gait orthosis; KAFO: Knee–ankle–foot orthosis

various levels of injury. It was found that there was no attempt made to either blind the participants regarding the intervention they received or to blind the researchers regarding the type of treatment used. Last but not the least, most of the research did not have sufficient power to detect a clinically important effect due to the low number of participants.

The heterogeneity analysis of the results of studies regarding stability, gait analysis, and the force applied on the crutch during walking showed that the level of heterogeneity was less than 25% and was not important enough to be considered [Table 12].

Evaluation of the performance of paraplegics when walking with ankle–foot orthosis and knee–ankle–foot orthosis orthoses

There is no doubt that many paraplegic subjects cannot use AFO orthoses, as many of them have knee extensor paralysis and the AFO cannot provide enough support for this joint. The Vannini-Rizzoli stabilizing orthosis is one of the AFO orthoses especially designed for paraplegic subjects. However, a number of contraindications were considered in selecting the patients to use this orthosis.

The performance of paraplegic subjects during walking with the KAFO orthoses was evaluated by many investigators. The results of the research

Table 6: The gait parameters of the subjects when walking with various orthoses

Research	Number	Level of lesion	Orthosis	Hip ext	Hip flex	Hip abd	Hip add	Pelvis (sajittal)	Pelvis (frontal)	Pelvis (transverse)
(Jefferson and Whittle, 1990)[46]	1	T_5	LSU RGO	33	15	3	8	16	16	23
(Jefferson and Whittle, 1990)[46]	1	T_5	ARGO	35	12	0	10	17	17	26
(Jefferson and Whittle, 1990)[46]	1	T5	HGO	21	16	9	7	11	12	33
(Kawashima *et al*., 2003)[82]	4	T_8-T_{12}	WBC	44.73 (flexion extension excursion)		-	-	-	-	-

RGO: Reciprocal gait orthosis; ARGO: Advanced reciprocal gait orthosis; HGO: Hip guidance orthosis; WBC: Weight bearing control

Table 7: Some gait parameters during walking with various orthoses

Research study	Number	Level of lesion	Orthosis	Pattern of walking	Velocity (m / min)	Stride length (m)	Cadence (Steps / min)	Stance phase percentage
(Yano *et al*., 1997)[57]	1	T_7	WBC	Reciprocal gait	21.2	1.1	38.4	-
(Yano *et al*., 1997)[57]	1	T_7	HGO	Reciprocal gait	8	0.66	24.2	-
(Baardman *et al*., 2002)[73]	1	T_{12}	ARGO with locked knee	Reciprocal gait	12	0.84	28.8	-
(Baardman *et al*., 2002)[73]	1	T_{12}	ARGO with controlled knee	Reciprocal gait	10.8	0.79	26.8	-
(Greene and Granat, 2003)[70]	2	T_6	Orthosis with flex knee	Reciprocal gait	7.2-8.4	0.65-0.8	-	-
(Greene and Granat, 2003)[70]	2	T_{12}	Orthosis with flex knee and ankle	Reciprocal gait	7.8-8.4	0.58-0.82	-	-

HGO: Hip guidance orthosis; ARGO: Advanced reciprocal gait orthosis; WBC: Weight bearing control

showed that the Scott Craig orthosis was a more energy efficient orthosis for walking than the single stopped long leg brace, but 25 to 34% depends on the type of the selected assistive device [Table 10].[84] The reason was that this orthosis was more stiffer than the other types of KAFO orthoses. Moreover, it was seen that the performance of the subjects using KAFO orthoses with posterior and anterior ankle stops and no motion in the ankle was significantly better than those with KAFO, with free dorsiflexion. It can be concluded that the stiffness of the ankle joint of the orthosis plays a significant role in increasing the performance of the subjects and decreasing energy consumption during walking.

Although many SCI subjects can stand and walk using KAFO, especially the Scot Craig orthosis with fixed ankle joints, they cannot use the AFO efficiently.

Evaluation the performance of paraplegic subjects using the traditional and new designs of hip–knee–ankle–foot orthoses

Most paraplegic subjects walk with the traditional HKAFO, with a swing-through gait style. However, they can walk with newly designed HKAFO, with reciprocal gait patterns. Although, the walking speed, stride length, and energy cost are higher

Table 8: The results of some gait parameters when walking with various orthoses

Research study	Number	Level of lesion	Orthosis	Pattern of walking	Velocity (m / min)	Stride length (m)	Cadence (steps / min)	Stance phase percentage
(Melis *et al.*, 1999)[78]	10	$C_5 - T_{12}$	Crutches	Swing trough gait	18-48	0.43-0.67	42-89.3	69 / 31-74 / 26
(Melis *et al.*, 1999)[78]	10	$C_5 - T_{12}$	Walker	Swing trough gait	10-24	0.3	30	73 / 27-95 / 5
(Noreau *et al.*, 1995)[83]	9		KAFO	Swing trough gait	41.7-59.9	1.23-1.5	67-79	64.6-70.7
(Noreau *et al.*, 1995)[83]	9		KAFO	Swing to gait	23.4	0.53	88	83.9
(Slavens *et al.*, 2007)[75]	5	$L_3 - L_4$	HKAFO	Swing trough gait	35.4	0.86	75.43	63
(Slavens *et al.*, 2007)[75]	5	$L_3 - L_4$	RGO	Reciprocal gait	23.4	0.66	67.12	66
(Jefferson and Whittle, 1990)[46]	1	T_5	RGO	Reciprocal gait	18	1.02	35	67
(Jefferson and Whittle, 1990)[46]	1	T_5	ARGO	Reciprocal gait	18.6	0.99	37	67
(Jefferson and Whittle, 1990)[46]	1	T_5	HGO	Reciprocal gait	18	0.98	37	67
(Kent, 1992)[38]	29	$T_2–L_5$	VRSO	Swing trough gait	26	-	-	-
(Merkel *et al.*, 1984)[84]	8	$C_7–T_{12}$	Scot Craig KAFO	Swing trough gait	8.8- 17.5	-	-	-
(Merkel *et al.*, 1984)[84]	8	$C_7–T_{12}$	KAFO with single ankle	Swing trough gait	6.3-15.3	-	-	-
(Ijzerman *et al.*, 1997)[85]	5	$T_4–T_{12}$	ARGO	Reciprocal gait	14.4	0.89	32	-
(Ijzerman *et al.*, 1997)[85]	5	$T_4–T_{12}$	NRGO	Reciprocal gait	13.8	0.83	31.6	-
(Thoumie *et al.*, 1995)[86]	21		RGO	Reciprocal gait	12.6	0.72	34.5	76.5
(Thoumie *et al.*, 1995)[86]	21		RGO with FES	Reciprocal gait	12	0.72	33.61	77.22
(Kawashima *et al.*, 2003)[82]	4	$T_8–T_{12}$	WBC	Reciprocal gait	19.88	-	44	-

RGO: Reciprocal gait orthosis; ARGO: Advanced reciprocal gait orthosis; KAFO: Knee–ankle–foot orthosis; WBC: Weight bearing control; FES: Functional electrical stimulation; VRSO: Vannini-Rizzoli stabilizing orthosis

with the swing-through gait mechanism than with a reciprocal pattern [Table 7],[90] the force applied on the upper limb is higher in the swing-through gait than in the reciprocal gait [Table 3].[75,77,91]

Among a variety of the new orthoses designed for paraplegic subjects, the hip guidance orthosis (HGO) has the best performance [Tables 6, 9, and 10]. In comparison with the reciprocating gait orthosis (RGO), paraplegic subjects walked faster and more comfortably with the HGO.[92] In RGO, the limbs remain parallel during walking. Moreover, the maximum peak value of the vertical displacement of the pelvis when walking with the HGO is half of that when walking with the RGO and advanced

Table 9: Some results of energy consumption tests

Research	Number of subjects	Level of lesion	Type of orthosis	Style of walking	Walking velocity	Energy cost (J / kg / m)	Energy consumption (J / kg / min)
(Waters and Lunsford, 1985)[87]	25	T_1 - T_{12}	Double KAFO	Swing-through gait	26±16	15.278 ±10.25	288.83 ±100.496
(Huang *et al*., 1979)[88]	8	T_4 - T_{12}	Resting	Swing-trough gait	-	-	76.5
(Huang *et al*., 1979)[88]	8	T_4 - T_{12}	Craig-Scott orthosis	Swing-through gait	-	-	234.12
(Nene and Patrick, 1989)[89]	10	T_4 - T_9	HGO orthosis	Reciprocal gait	12.84	16	186
(Cuddeford *et al*., 1997)[90]	26	T_{12} - $L_{3,4}$	RGO	Reciprocal gait	16.2	16.92 ±7.1	239.1±38.66
(Cuddeford *et al*., 1997)[90]	26	T_{12} - $L_{3,4}$	HKAFO	Reciprocal gait	40.8	11.28±2.51	441±64.372
(Cerny *et al*., 1980)[29]	3	T_{11} - L_2	KAFO	Swing-through gait	32.4	20.69	446.84
(Cerny *et al*., 1980)[29]	11	T_{11} - L_2	Wheel chair	-	84.9	4.28	430.54
(Waters and Lunsford, 1985)[87]	No information found	-	Normal subject wheelchair	-	-	3.135±0.418	248.71±48.07
(Waters and Lunsford, 1985)[87]	10	T_1 - T_9	Orthosis SCI	Swing-through gait	-	15.46±10.45	303±89.87
(Waters and Lunsford, 1985)[87]	55	T_1 - T_9	Wheelchair SCI	-	-	3.34±0.627	240.35±64.79

RGO: Reciprocal gait orthosis; ARGO: Advanced reciprocal gait orthosis; KAFO: Knee–ankle–foot orthosis; WBC: Weight bearing control; FES: Functional electrical stimulation; HGO: Hip guidance orthosis; HKAFO: Hip–knee–ankle–foot orthosis

Table 10: The PCI of paraplegic subjects when walking with various orthoses

Research study	Type of orthosis	PCI (beats / metre)
(Stallard and Major, 1995)[61]	HGO	0.95 – 1.65
(Stallard and Major, 1995)[61]	Parawaker 89	0.8 – 1.26
(Ijzerman *et al*., 1997)[85]	ARGO	5.4
(Ijzerman *et al*., 1997)[85]	NRGO	5.8
(Middleton *et al*., 1998)[51]	Walk about	11.5
(Middleton *et al*., 1998)[51]	MMLO	11.5
(Yano *et al*., 1997)[57]	WBC	1.9
(Yano *et al*., 1997)[57]	HGO	3.6

HGO: Hip guidance orthosis; ARGO: Advanced reciprocal gait orthosis; WBC: Weight bearing control; MMLO: Moorong medial linkage orthosis

reciprocating gait orthosis (ARGO).[46] The force applied on the crutch is less when walking with the HGO than the other orthoses [Table 3]. The main reason for better performance of the HGO in contrast to other orthoses is its highest lateral rigidity.[93]

Although the performance of the subjects when walking with the HGO is better than with the RGO, most of paraplegic subjects prefer to use the RGO. The main reason is the cosmetic reason, as the RGO is more cosmetic than the HGO.[94] The AFO and torso parts of the RGO are custom moulded in contrast to the HGO, which are made from metal.

Determining the effect of using reciprocal cable and abduction in the hip joint on the performance of the advanced reciprocating gait orthosis

The results of the research done by Ijzerman and Baardman *et al*. show that the effects of using the cable are not as much as expected [Tables 3, 5, 8–10]. In other words, the difference between the gait performances, stability, and energy consumption when walking with the ARGO, with and without the cable, is not significant. However, cable use has been recommended for the patients with a high level of lesion. The performance of the subjects when walking with the ARGO, aligned in slight abduction,

Table 11: The energy consumption of paraplegic subjects when walking with various orthoses

Research	Number of subjects	Level of lesion	Type of orthosis	Style of walking	Walking velocity	Energy cost (J / kg / m)	Energy consumption (J / kg / min)
(Merkel *et al*., 1984)[84]	8	C_7–T_{12}	Scot Craig KAFO with crutch	Swing through gait	17.5	63.95	-
(Merkel *et al*., 1984)[84]	8	C_7–T_{12}	KAFO with Single stop ankle joint with crutch	Swing through gait	15.3	73.15	-
(Merkel *et al*., 1984)[84]	8	C_7–T_{12}	Scot Craig KAFO with walker	Swing through gait	8.8	26.38	-
(Merkel *et al*., 1984)[84]	8	C_7–T_{12}	KAFO with Single stop ankle joint with walker	Swing through gait	6.3	36.78	-
(Kawashima *et al*., 2003)[82]	4	C_8–T_{12}	WBC	Reciprocal gait	19	119.5	-
(Ijzerman *et al*., 1997)[85]	6	C_4–T_{12}	ARGO	Reciprocal gait	-	-	355.58
(Ijzerman *et al*., 1997)[85]	6	T_4–T_{12}	NRGO	Reciprocal gait	-	-	376.1

ARGO: Advanced reciprocal gait orthosis; KAFO: Knee–ankle–foot orthosis; WBC: Weight bearing control

Table 12: The results of heterogeneity test regarding stability, gait analysis, and energy consumption

Parameters	HGO orthosis		LSU RGO orthosis		ARGO orthosis	
	P-value	I^2	*P*-value	I^2	*P*-value	I^2
Crutch force	0.99	12.45	0.98	0	0.99	0
Gait analysis	0.8-0.136	15-40	0.32-0.95	13.2-20.5	1	0
Energy consumption	0.803	15.02	-	-	0.547	0

HGO: Hip guidance orthosis; ARGO: Advanced reciprocal gait orthosis; LSU RGO: Louisiana State University reciprocal gait orthosis

is significantly better than the orthosis without abduction [Table 3]. It is easier for the subjects to take the swing leg off the ground when it is aligned in some degrees of abduction.

Comparison between mechanical and hybrid orthoses

In hybrid orthoses, the main emphasis of the designers was to improve the function of the orthosis by using knee flexion, ankle and knee motions, and also increasing the stiffness of the orthosis. The results of various researches showed that in most of them the performance of the subjects did not improve significantly; however, the style of walking improved as the patients had knee flexion during the swing phase.[72,73]

Although using FES with the HGO improved the performance of the subjects in using the orthosis, they had some problems including:[61,95,96]

Problems using the electrodes in suitable locations

They achieved inconsistent stimulation

Donning and doffing the orthosis with stimulation electrodes was very time consuming

Cross-stimulation of abdominal muscles occurred

Comparison between external powered and mechanical orthoses

The performance of the external powered orthosis was not as good as the commonly used mechanical orthoses. Moreover, the patients had to use orthoses that were heavy and more difficult to don and doff independently.[45,57,82] They had to change the batteries regularly, which took a lot of time and needed special facilities.

Problems of paraplegic subjects in using the orthosis

Walking with an orthosis is a demanding task in terms of energy expenditure and mechanical work required. This is the main reason for avoiding the use of orthoses.

The donning and doffing of orthoses is another important problem associated with orthosis usage. Herman and Biering found that only three out of 45 patients continued using their orthosis after 10 years. The reason they mentioned for withdrawing from the use of orthoses was the considerable time they needed to spend putting on and taking off the orthosis.[97]

The high percentage of the force applied on the upper limb musculature is another issue that affects the use of orthoses. Depending on the style of walking, between 30 to 55% of body weight is applied on the crutch during walking.[44,78,91,98] The high value of the force, which is transmitted to the upper limb joints, increases the incidence of some diseases and also shoulder pain.

Another problem mentioned by SCI individuals was related to the cosmesis of orthoses. The results of the research carried out by Whittle *et al*. (1991)[94] showed that although the HGO seemed to have a better functional performance than the RGO, it was not selected by many patients, as it was not as cosmetic as the RGO.

CONCLUSION

A variety of orthoses have been designed to enable SCI individuals to stand and walk again. They use different mechanisms to stabilize the paralyzed joints and to move the limbs forward during walking. Different sources of power such as pneumatic and hydraulic pumps, muscular force resulting from electrical stimulation, and electrical motors have been attempted for walking. However, the results of different researches have shown that the performance of the SCI individuals when walking with the mechanical orthosis is better than other type of orthoses.

Different types of mechanical orthoses are available to help these subjects to stand and walk again. However, the two most common ones are the HGO and RGO. The performance of paraplegic subjects using orthoses was evaluated by gait analysis, energy consumption tests, and stability analysis, during quiet standing and also performing hand functions. According to the results of different researches, the performance of SCI individuals when walking with the HGO was better than that of other available orthoses. The main reason was the greatest lateral rigidity of this orthosis, in contrast to other available mechanical orthoses.

Although walking with orthoses brings a lot of benefits to SCI subjects, they prefer to use wheelchairs as their main ambulation method. Many of the SCI individuals withdraw from using their orthoses after they obtained it. The patients reported that walking with orthoses is a demanding task in terms of energy expenditure and the mechanical work required. They also had some other problems including poor cosmesis of the orthoses, especially the HGO, fear of falling, and donning and doffing the orthosis being considerably time consuming, and sometimes needing assistance.

In order to improve the performance of SCI subjects when walking and to increase their willingness to use orthoses, the aforementioned problems need to be solved. The design of a new orthosis must allow easy donning and doffing by the users, have enough stability during walking and standing, decrease the energy consumption during walking, apply the smallest possible force on the upper limb musculature during walking, and be cosmetic. In addition, it must provide the ability for changing the alignment of the orthosis to suit the patient's needs, along with a modular structure, and maximum lateral rigidity.

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