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Assessment of the Effect of Improved Medial Linkage Reciprocating Orthosis Compared to Isocentric Orthosis on the Motor Function in Spinal Cord Injury Patients

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Abstract

Background: Spinal cord injuries (SCI) result in profound mobility impairments, particularly the inability to walk. Traditional orthotic devices, while aiding mobility, often lead to high energy expenditure and discomfort. This study aimed to develop a novel orthosis that enhances comfort, improves movement parameters, and reduces energy consumption by incorporating medial linkage joints and reciprocal mechanisms into the existing Medial Linkage Reciprocating Gait Orthosis (MLRGO). The effectiveness of this new device was evaluated against both the Isocentric Reciprocating Gait Orthosis (IRGO) and conventional Knee-Ankle-Foot Orthoses (KAFOs) in a case study with three participants.

Methods: This case study involved three patients with thoracic SCI, selected through convenience sampling. The new MLRGO was designed in the initial phase, followed by a comparative analysis involving the new MLRGO, IRGO, and KAFOs. Parameters assessed included average step length, walking speed, cadence, physiological cost index (PCI), static balance, and the time required for donning and doffing the orthoses, using standardized assessment tests. Repeated measures ANOVA with Bonferroni correction was used to compare group means, with a significance level of P value< 0.05.

Results: The new MLRGO significantly enhanced walking speed (P=0.037 vs. IRGO, P=0.006 vs. KAFOs), distance (P=0.036 vs. KAFOs), average step length (P=0.084 vs. KAFOs), and cadence (P=0.098 vs. KAFOs) compared to both the IRGO and KAFOs. Furthermore, it demonstrated superior energy efficiency relative to KAFOs (P=0.050), although no significant differences were found when compared to the IRGO. The new MLRGO also reduced donning (P=0.008 vs. IRGO) and doffing times (P=0.008 vs. IRGO), achieving performance levels comparable to KAFOs.

Conclusion: The findings suggest that the new MLRGO facilitates a more natural and efficient walking pattern in patients with SCI compared to the IRGO and KAFOs. However, due to the small sample size, further studies are needed to confirm its efficacy as a promising alternative for rehabilitation in individuals with lower limb paralysis.

Keywords: Orthotic Devices, Spinal Cord Injuries, Gait, Motor Function, Energy Efficiency, Rehabilitation

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Introduction

Spinal cord injury (SCI) transforms the lives of numerous people by causing different levels of motor and sensory impairment. Individuals with SCI face their most challenging obstacle because they lose their capability to stand or walk, thus affecting their independence and quality of life significantly (1). SCI disrupts daily activities such as mobility,

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↑What is "already known" in this topic:
Individuals with spinal cord injuries have a strong desire to regain their ability to walk. Orthotic devices are essential for aiding their mobility. However, the current issues associated with these devices often lead to user non-compliance, highlighting an urgent need for improved mobility solutions that enhance the quality of life.

→What this article adds:
Our findings indicate clinically significant advancements with the new MLRGO for patients with spinal cord injuries. The MLRGO enhances cadence and walking speed, likely due to improved axis alignment and reciprocal motion. This underscores the importance of trunk stability for mobility in spinal cord injury patients. Overall, the findings highlight the MLRGO's potential to significantly improve mobility outcomes and quality of life for individuals living with SCI.

self-care, and social interactions, placing a substantial burden on individuals and their families. SCI used to result in high mortality rates due to infections and pressure sores, which modern medical care now better manages (2). Research shows that SCI prevalence across the world spans widely between 223 and 755 cases per million people, while the annual incidence ranges from 10 to 83 cases per million (3). In Iran, a meta-analysis reported an annual incidence of 10.5 per million (4). The medical category of incomplete tetraplegia represents 30.1% of all reported SCI cases alongside complete paraplegia, which constitutes 25.6% (5).

Most people who experience SCI strongly want to recover their ability to walk. Effective recovery relies on rehabilitation methods. Physiotherapy and occupational therapy help patients regain strength, coordination, and mobility (6). Orthotic devices play a critical role in supporting mobility during rehabilitation. Although orthotic technology has evolved since the 1960s, it has not fully addressed user needs for functionality, comfort, and aesthetics (7).

The literature shows that knee-ankle-foot orthoses (KAFOs) and isocentric reciprocating gait orthoses (IRGOs) have multiple documented limitations (7, 8). Users experience significant discomfort and fatigue because these devices are heavy, bulky, and energy-intensive. These limitations, combined with challenges in accessing specialized care in regions like Iran, highlight the need for innovative solutions. The existing problems with orthotic devices cause users to become non-compliant, demonstrating an immediate requirement for better mobility systems that improve the quality of life for people with SCI (9, 10). SCI complications surpass mobility problems, affecting urinary, sexual, gastrointestinal, thermoregulatory, and voluntary movement functions, underscoring the need for comprehensive rehabilitation strategies (11). To address these limitations, Ahmadi et al. (12) developed medial linkage reciprocating gait orthoses (MLRGOs), which use reciprocal motion systems and improved axis alignment to enhance user satisfaction. However, the saddle-shaped seating in these devices causes discomfort and limits range of motion (ROM). Future orthotic innovations should focus on lightweight materials like carbon fiber, biomechanical sensors, and modular designs to enhance comfort and functionality.

This research project establishes a new Medial Linkage Reciprocating Gait Orthosis (New MLRGO) through advances upon the original work by Ahmadi et al. (12). The New MLRGO brings three main enhancements: a lighter structure (1240 g vs. 1500 g), reduced size, improved matching of orthotic axes with human anatomy, and larger ROM (40° vs. 30°). The research conducted a comparative study of the new MLRGO with traditional IRGOs and KAFOs to determine its impact on spatial-temporal parameters, energy consumption, and user convenience for thoracic-level SCI patients.

Methods

Participants

This study was a pilot study to examine the performance of a newly designed joint. The research design used a case study method to study patients with thoracic SCI. The study included participants with a verified thoracic SCI diagnosis (ASIA B, incomplete) (13), aged 19–44 years, with a minimum injury duration of six months. Inclusion criteria included hip flexor and quadratus lumborum muscle strength of 3–5, functional joint mobility, independent standing ability, normal upper limb function, and symmetrical hip joints. Participants were recruited via rehabilitation clinic announcements and social media outreach. Eligible participants were screened when written informed consent was obtained. The study protocol was approved under Ethics Code: IR.IUMS.REC.1403.930.

Procedure

The study was conducted in two phases. In the first phase, the new MLRGO was designed, involving material selection (aluminum 7075, stainless steel 304), prototyping, and testing for functionality and comfort. The second phase compared the new MLRGO, IRGO, and KAFOs on performance, comfort, and satisfaction. To minimize fatigue and carry-over effects, orthoses were tested in random order. Blinding was not feasible, but data analysis was performed by an independent researcher to reduce bias.

Participants underwent a 4-week training regimen (3 sessions/week, 2 hours/session), including passive stretching, balance exercises, and supervised standing/walking, led by qualified physiotherapists or occupational therapists. This training ensured safe and effective adaptation to the orthoses.

Orthosis Specifications

Three orthotic systems were evaluated: new MLRGO, IRGO, and KAFOs (Figure 1**)**. The new MLRGO, based on Ahmadi et al. (12), was modified to be lighter (1240 g vs. 1500 g), more compact, with a hypothetical axis 65 mm from the seat, width of 55 mm, and ROM of 40° (10° more than the original).

Figure 2 illustrate the lightweight design, axis alignment (65 mm from the seat), and key components of the new MLRGO. Unlike the original MLRGO, the saddle-shaped seat was removed to enhance comfort. Components included a middle section for reciprocal propulsion, bearing covers, links to KAFOs, a locking mechanism, and cable structures.

Figure 1. Orthoses Utilized in This Study, A) new MLRGO, B) IRGO, C) KAFO

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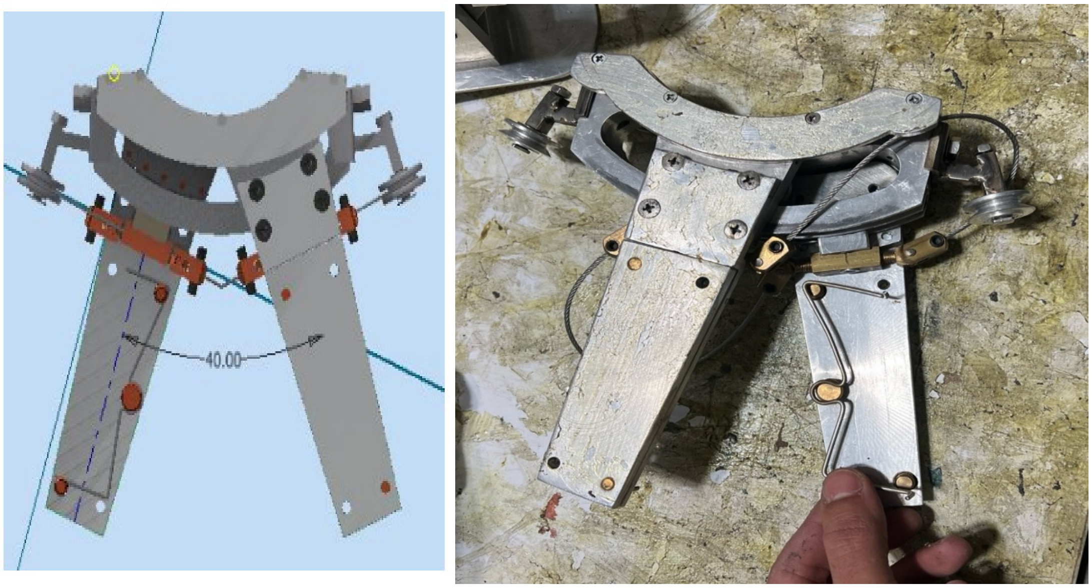

Figure 2. The joint of new MLRGO

Data Collection Tools

Outcomes included distance walked (m), average step length (m), cadence (steps/min), walking speed (m/s), static balance, energy consumption (ml/kg/min), and donning/doffing duration (seconds).

Distance Walked and Step Length: Measured via the 2-Minute Walk Test (14). Distance was recorded, and step length was calculated by dividing distance by step count.

Cadence and Walking Speed: Assessed via the 10-Meter Walk Test (15), with steps counted for cadence and time recorded for speed.

Static Balance: Evaluated using the Berg Balance Scale (ICC=0.95 for SCI) (16), with 14 activities scored up to 56 points.

Energy Consumption: Calculated using the Physiological Cost Index (PCI) via Polar Electro heart rate monitors (17). PCI = (walking heart rate – resting heart rate) / speed.

Donning/Doffing Duration: Timed with a stopwatch during orthosis application/removal.

Statistical Analysis

Data were analyzed using SPSS version 26. Quantitative data are expressed as mean ± SD. Normality was confirmed with the Shapiro-Wilk test. Repeated measures ANOVA with Bonferroni correction was used to compare group means, with a significance level of p value< 0.05.

Results

Demographic and Clinical Characteristics

Table 1 summarizes the characteristics of the three participants (mean age: 30 ± 4.5 years, height: 171.3 ± 5.8 cm, weight: 67.6 ± 10 kg). Injuries were at T6, T8, and T12 (ASIA B), with a mean post-injury time of 34.6 ± 9 months.

Spatial-Temporal Gait Parameters

Table 2 presents individual and mean gait parameters. The new MLRGO outperformed others, with a mean distance walked of 12.05 ± 0.95 m (vs. IRGO: 11.14 ± 1.32 m, KAFOs: 9.67 ± 1.23 m), step length of 0.61 ± 0.09 m (vs. IRGO: 0.55 ± 0.11 m, KAFOs: 0.40 ± 0.14 m), cadence of 43.39 ± 2.37 steps/min (vs. IRGO: 42.62 ± 2.83, KAFOs: 32.09 ± 2.35), and walking speed of 0.47 ± 0.04 m/s (vs. IRGO: 0.42 ± 0.03 m/s, KAFOs: 0.26 ± 0.05 m/s).

Energy Consumption and Static Balance

Table 3 shows individual and mean data. Static balance scores were similar (new MLRGO: 23.3, IRGO: 23.0, KAFOs: 23.3; *P*=0.607). Energy consumption was lower for new MLRGO (2.91 ± 0.29 ml/kg/min) compared to KAFOs (3.49 ± 0.41 ml/kg/min; *P*=0.050), but higher than IRGO (2.56 ± 0.36 ml/kg/min; *P*=0.125).

Table 1. Demographic and Clinical Characteristics of Participants

Participant	Gender	Age (years)	Height (cm)	Weight (kg)	Level of Injury	Degree of Injury	Time Post-Injury (months)
Participant 1	Female	26	171	64	T12	Complete (B)	31
Participant 2	Male	35	180	79	T6	Complete (B)	28
Participant 3	Female	29	163	60	T8	Complete (B)	45
Mean ± SD	-	30 ± 4.5	171.3 ± 5.8	67.6 ± 10	-	-	34.6 ± 9

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Table 2. Spatial-Temporal Gait Parameters of the Orthoses

Type of Orthosis	Participant	Distance Walked (m)	Avg. Step Length (m)	Cadence (steps/min)	Walking Speed (m/s)
New MLRGO	Participant 1	12.08±0.68	0.64±0.01	41.21±1.31	0.49±0.02
	Participant 2	11.08±0.73	0.51±0.02	45.92±2.26	0.43±0.01
	Participant 3	12.99±0.67	0.7±0.02	43.05±2.85	0.51±0.01
	Mean ± SD	12.05±0.95	0.61±0.09	43.39±2.37	0.47±0.04
IRGO	Participant 1	11.55±0.2	0.6±0.005	39.71±1.21	0.43±0.03
	Participant 2	9.66±0.49	0.41±0.02	45.37±1.44	0.38±0.005
	Participant 3	12.22±0.14	0.63±0.04	42.8±1.06	0.44±0.02
	Mean ± SD	11.14±1.32	0.55±0.11	42.62±2.83	0.42±0.03
KAFOs	Participant 1	10.17±0.56	0.48±0.02	30.84±1.52	0.27±0.02
	Participant 2	8.27±0.29	0.23±0.02	30.63±1.75	0.21±0.02
	Participant 3	10.59±0.42	0.5±0.005	34.82±0.54	0.31±0.03
	Mean ± SD	9.67±1.23	0.40±0.14	32.09±2.35	0.26±0.05

Table 3. Energy Consumption and Static Balance of Orthoses

Type of Orthosis	Participant	Static Balance	Energy Consumption (ml/kg/min)
New MLRGO	Participant 1	22	2.61±0.09
	Participant 2	23	3.19±0.11
	Participant 3	25	2.92±0.02
	Mean ± SD	23.3	2.91 ± 0.29
IRGO	Participant 1	22	2.27±0.04
	Participant 2	23	2.97±0.08
	Participant 3	24	2.45±0.18
	Mean ± SD	23.0	2.56 ± 0.36
KAFOs	Participant 1	23	3.04±0.05
	Participant 2	23	3.85±0.12
	Participant 3	24	3.59±0.11
	Mean ± SD	23.3	3.49 ± 0.41

Duration of Donning/Doffing

Table 4 details individual and mean times. The new MLRGO had shorter donning (228.11 ± 14.67 s vs. IRGO: 296.88 ± 11.88 s; *P*=0.008) and doffing times (132.06 ± 35.21 s vs. IRGO: 232.08 ± 31.46 s; *P*=0.008), comparable to KAFOs (225.41 ± 15.61 s and 127.42 ± 40.01 s).

Between-Group Comparison of Orthoses

Table 5 summarizes comparisons. Significant differences were found for distance walked (*P*=0.001), step length (*P*=0.035), cadence (*P*=0.005), walking speed (*P*=0.000), energy consumption (*P*=0.001), donning (*P*=0.000), and doffing (*P*=0.001).

Table 4. Duration of Donning and Doffing of Orthoses

Type of Orthosis	Participant	Donning (s)	Doffing (s)
New MLRGO	Participant 1	242.71±13.57	115.82±4.29
	Participant 2	228.28±12.61	107.90±5.30
	Participant 3	213.36±14.53	172.47±13.06
	Mean ± SD	228.11±14.67	132.06±35.21
IRGO	Participant 1	298.61±15.77	206.79±4.87
	Participant 2	284.23±15.26	222.14±12.76
	Participant 3	307.81±12.46	267.32±5.29
	Mean ± SD	296.88±11.88	232.08±31.46
KAFOs	Participant 1	239.91±13.93	112.75±5.15
	Participant 2	227.43±16.01	96.81±3.75
	Participant 3	208.89±13.19	172.69±8.45
	Mean ± SD	225.41±15.61	127.42±40.01

Table 5. Between-Group Comparison of Orthoses with *P*-Values

Parameter	*P*-Value (Overall)	*P*-Value (New MLRGO vs. IRGO)	*P*-Value (New MLRGO vs. KAFOs)	*P*-Value (IRGO vs. KAFOs)	% Change (New MLRGO vs. IRGO)	% Change (New MLRGO vs. KAFOs)
Distance Walked (m)	0.001	0.232	0.036	0.009	+7.68%	+19.88%
Average Step Length (m)	0.035	0.209	0.084	0.046	+11.17%	+35.43%
Cadence (steps/min)	0.005	0.536	0.098	0.115	+1.80%	+25.85%
Walking Speed (m/s)	0.000	0.037	0.006	0.013	+11.52%	+44.42%
Energy Consumption (ml/kg/min)	0.001	0.125	0.050	0.042	-12.10%	-20.01%
Static Balance	0.607	0.506	0.753	0.800	-	-
Time to Don (s)	0.000	0.008	0.066	0.008	-30.60%	+1.2%
Time to Doff (s)	0.001	0.008	0.066	0.008	-3.6%	+4.26%

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Discussion

The present study evaluated the efficacy of the newly developed MLRGO compared to conventional IRGO and KAFO in thoracic-level spinal cord injury patients. The findings highlight significant advancements with the new MLRGO for SCI patients. The new MLRGO improved cadence by 1.80% over IRGO and 25.85% over KAFOs, though differences were not always significant, aligning with Arazpour et al. (18), who noted similar trends in orthotic comparisons. Walking speed increased by 11.52% vs. IRGO (*P*=0.037) and 44.42% vs. KAFOs (*P*=0.006), likely due to enhanced axis alignment and reciprocal motion, corroborating Harvey et al. (19), who emphasized trunk stability in IRGOs.

Participants covered 19.88% more distance with the New MLRGO compared to KAFOs and 7.68% compared to IRGO (non-significant), consistent with studies on mobility enhancement (20, 21). These improvements suggest that the New MLRGO may facilitate more efficient forward progression and increased stride regularity in individuals with thoracic SCI. Enhanced joint alignment and reciprocal linkage likely contributed to these mobility gains, reducing compensatory trunk movements and promoting a more fluid gait pattern.

Energy consumption was 12.10% higher with IRGO but 20.01% lower with KAFOs, reflecting the mechanical efficiency of reciprocal motion (22). While IRGO remains slightly superior in energy economy, its bulkiness and reduced comfort may limit real-world use. The observed energy savings with the New MLRGO over KAFOs indicate a favorable trade-off between metabolic cost and functional mobility, particularly for users aiming to engage in moderate ambulation over short distances.

Although not directly measured, the removal of the saddle-shaped seat was expected to reduce pelvic pressure and enhance comfort and mobility. This ergonomic refinement was based on user-reported discomfort with the previous model and intended to improve hip freedom during walking. Static balance was found to be comparable across all orthoses, suggesting similar postural control under stationary conditions. However, static tests may not fully capture dynamic gait stability. Therefore, future investigations should incorporate dynamic balance assessments and gait variability metrics to better evaluate real-world functional stability, as recommended by Ijzerman et al. (23).

Previous studies, like those by Leung et al., emphasized user comfort for long-term orthotic acceptance (24). The new MLRGO's lightweight design and reduced donning/doffing times (30.60% and 3.6% faster than IRGO, respectively) enhance usability. Its potential clinical applications include improved rehabilitation for paraplegic patients, reducing fatigue and increasing independence.

Limitations include the small sample size (n=3), short follow-up, and variable injury levels, which limit generalizability. The high cost and difficulty in recruiting eligible patients further constrained the study. Future research should involve larger, homogeneous cohorts, longer follow-ups, and dynamic balance assessments to validate these findings and explore user satisfaction. Additionally, integrating sensor-based feedback systems or active assistive components may further enhance gait adaptability and user confidence. Investigating patient-reported outcomes such as perceived comfort, psychosocial impact, and device preference could provide valuable insight for future orthosis optimization and clinical translation. Larger RCTs comparing the new MLRGO to IRGOs/KAFOs in diverse spinal cord injury populations (e.g., paraplegia vs. tetraplegia) are warranted. Moreover, long-term adherence studies tracking patient compliance, comfort, and functional outcomes over 6–12 months may provide better insights into the effectiveness of the new MLRGO. Finally, dynamic balance assessments using tools like the Mini-BESTest or obstacle-course walking trials are also recommended.

Conclusion

The new MLRGO significantly improves walking parameters and energy efficiency for patients with SCI compared to KAFOs, with advantages over IRGO in speed and usability. Its lightweight, compact design makes it a promising alternative for rehabilitation in individuals with lower limb paralysis. However, due to the small sample size, further studies are needed to confirm these findings and assess long-term outcomes, including dynamic balance and user feedback.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

M.A, T.B, and A.RM contributed to conceptualization, methodology, investigation, and writing the original draft. A.RM contributed to data curation and formal analysis. B.H and A.D contributed to supervision, validation, and reviewing and editing the manuscript. All authors have read and approved the final manuscript.

Ethical Considerations

All procedures performed in this work followed the ethical standards of the committee of the Iran University of Medical Sciences (Ethical Code: IR.IUMS.REC.1403.930).

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request. Due to privacy and ethical restrictions, the data are not publicly available..

AI Use Statement

The authors used Monica AI to assist with

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grammar, clarity, and language editing during manuscript preparation. The authors reviewed and edited all AI generated suggestions and take full responsibility for the final content of the manuscript.

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