Design and Preliminary Evaluation of a New Ankle Foot Orthosis on Kinetics and Kinematics parameters for Multiple Sclerosis Patients

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ABSTRACT

Background: The damage of the central nervous system due to Multiple Sclerosis (MS) leads to many walking disorders in this population. However, current ankle-foot orthoses prescribed for improving walking disorders for these patients are not clinically cost-efficient.

Objective: This study aimed to design and fabricate a dynamic ankle foot orthosis and a new spring-damper joint mechanism that could adapt the walking problems of MS patients and evaluate the immediate effect of the new orthosis on the speed, range of motion, moment, total work and ground reaction force during walking.

Material and Methods: In this case-series study, after the design and fabrication of a new orthosis, the kinetics and kinematics of walking of four patients with MS were assessed in a case series study.

Results: Walking speed improved with the new orthosis in two participants. The sagittal range of motion (ROM) increased for most of the participants. The sagittal moments increased for hip, knee and ankle joints in most of the measurements. The total joint work showed noticeable difference in the ankle joint. The increased values of vertical component of the ground reaction force (VGRF) were negligible and the increase in the impulse of VGRF was noticeable for only one participant.

Conclusion: The new orthosis had positive effects kinetic and kinematic parameters of walking such as the increased velocity by two subjects and also a more normal sagittal ROM, moment and work, suggesting the potential usefulness of the new orthotic device for MS population.

Citation: Keyvani Hafshejani A, Aminian Gh, Azimian M, Bahramizadeh M, Safaeepour Z, Biglarian A, Keivani M. Design and Preliminary Evaluation of a New Ankle Foot Orthosis on Kinetics and Kinematics parameters for Multiple Sclerosis Patients. *J Biomed Phys Eng.* 2020;10(6):783-792. doi: 10.31661/jbpe.v0i0.2007-1136.

Keywords

Multiple Sclerosis; Kinetics; Kinematics; Ankle-Foot Orthosis; Gait

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Received: 5 July 2020
Accepted: 19 August 2020

Introduction

Multiple sclerosis (MS) is a chronic autoimmune disease, leading to demyelination of the central nervous system (CNS) and severe neurological disability [1-3]. The patients experience motor, sensory and cognitive impairments; the impairment of proprioception is more frequent than other sensory inputs [4, 5]. The CNS pathology is associated with decreased muscle tone or spasticity of foot and ankle muscles, resulting in limited range of motion (ROM) of hip, knee and ankle joints, decreased ankle power and poor push-off, drop foot or toe-drag at swing phase and also decreased speed of walking [6, 7]. Therefore, the patient's mobility and ability to do activities of daily living, functional independence, and quality of life are affected extensively [8-11]. Proprioception impairment is associated with balance impairment [5]. About 85% of MS patients complain of walking impairment and need to mobility aids such as functional electrical stimulation (FES) and ankle-foot orthosis (AFO) [12, 13].

The passive AFO is a simple plastic polypropylene device, controlling ankle motion [14]. The most ankle control is provided by solid AFO, which limits all of the ankle motions while the least control is provided by the posterior leaf spring AFO (PLS). The use of solid AFO by MS patients improves toe clearance, but it has unacceptable outcomes such as decreased walking speed, dynamic balance and pain followed by skin irritation [15-17]. Walking by PLS may improve walking speed, but this orthosis has limited application only for non-spastic patients [18, 19]. The functional electrical stimulation of the peroneal nerve may improve walking by the increase of speed, ROM, and decrease exertion level [16, 20, 21]. Renfrew et al., compared the clinical and cost-effectiveness of using solid AFO and FES on function and energy cost of walking of MS population immediately and after one year of using each one [13, 16]. They found improvement in walking speed and decrease in oxygen cost of walking for both interventions. However, the effects of FES have been assessed immediately and the effects of solid AFO have been investigated after 12 months. They concluded that the use of FES is more cost-efficient. The MS population who used FES reported limitations in design and application, electrode positioning and financial implications of FES [22]. However, the functionality and comfort of orthotic devices have much importance for the MS population, and it seems a new orthotic design with an immediate clinical improvement of kinetic and kinematic parameters is needed [15].

The dynamic AFOs are another type of AFOs which allows ankle motions in the sagittal plane and could help to ankle movement by employing spring-damper mechanism [23]. Since the ankle-foot movements in the sagittal plane are associated with frontal plane movements, a motion variance of anatomic and orthotic joints is inevitable and there is also a none-accordance between mechanical and anatomical ankle movements, leading to translation of dynamic AFO on the tissue [24]. Moreover, the MS population walk slow and have less capability to accommodate environmental barriers; therefore, the fitness of orthotic joint action with their speed of walking is necessary [25]. The orthosis should also compensate for the lack of ankle proprioception. Therefore, the aims of the current study were as follows: a) to design and fabricate a new a dynamic AFO with a speed adoptable spring-damper mechanism which accommodates to ankle motion and provides feedback and b) to examine the immediate effect of using the new orthotic device on walking speed and kinetic parameters of MS population.

Material and Methods

Subjects

Four MS volunteers accept to participate in this case series study. The inclusion criteria were as following: the age of 20-50, the ability to walk independently for at least 20 meters, the ability to stand on tiptoes, the maximum spasticity of grade II (Ashworth scale) with plantar flexor muscles, the MS disease progression at the first relapsing-remitting stage and the extended disability scale of 4 to 6. The exclusion criteria were low dynamic balance based on the Timed Up and Go test, any history of the cardiac-respiratory disease and fixed flexion contracture of the hip, knee and ankle joints. The patient recruitment was from July to September in 2019 from the Sina Hospital, Tehran, Iran. The ethics committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran approved the study (reference number: IR.USWR.REC.1398.072). All participants were agreed and signed the informed consent form.

Intervention

The new dynamic AFO designed for this study had two parts of the footplate and a shell for shin (Figure 1). The new orthotic ankle joint connected the two parts. The orthotic ankle joint was equipped with these components: a spring-damper mechanism, a rail mechanism to accommodate with anatomical ankle joint, a rail and wagon mechanism to remind proper push-off time, a rattler mechanism to provide environmental feedback of ankle position to the patient and an eye bearing and flat spring. There were two springs with different hardness coefficients, a harder spring to help push-off, and a less hard spring for returning the ankle joint to neutral position at the swing phase (Figure 2a).

The outer edge of the damper was threaded and the clinician could adjust the amount of energy damping and speed of walking based on the patient's need (Figure 2a). The orthotic ankle joint was equipped with a rail mechanism, resulting in orthotic accommodation with sagittal movements of the anatomical ankle joint (Figure 2b). Each spring and the damper had a retainer (Figure 2a). The retainers were connected with a fine rail and two wagons to each other; therefore, the retainers could slide to each other (Figure 2c). The sliding led to the movement of the spring and damper in relation of each other. The rail and wagon mechanism aimed to remind proper push-off time. The rattler mechanism consisted of a bigger geared rack, a smaller geared rack, and a small spring

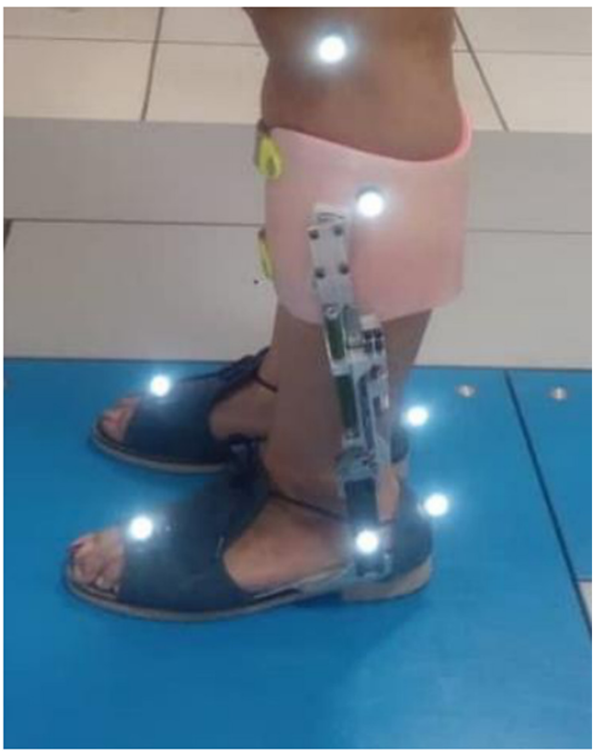

Figure 1: The new ankle-foot orthosis (AFO) designed at this study.

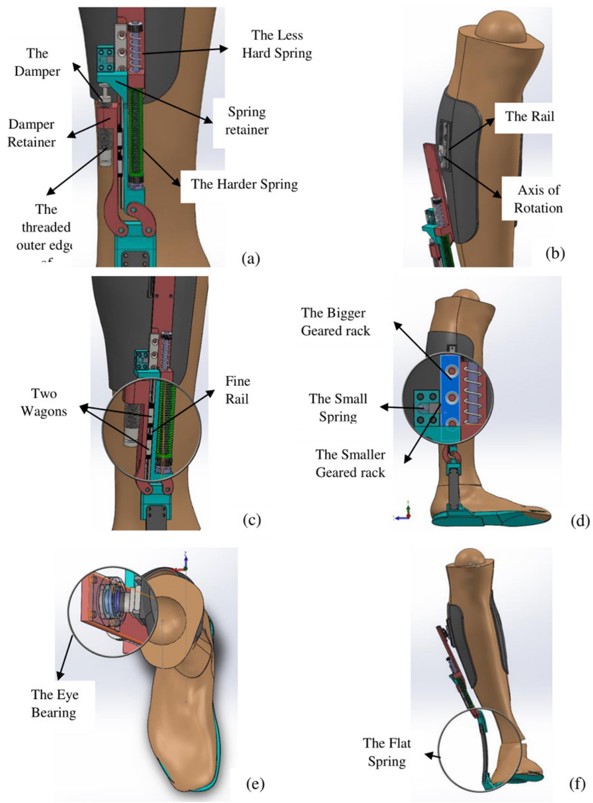

Figure 2: a) Spring-damper mechanism, b) the rail for accommodation, c) the retainers, d) the fine rail and wagons, e) the rattler mechanism, f) the flat spring

(Figure 2d). When the orthotic joint moves, the two-geared rack would slide on each other. Then the small spring and the smaller geared rack would be pulled back and placed on the next gear. The saved energy of small spring speeds up returning to a neutral position and makes a tiny sound due to vibration. The vibration is proportional to the range of plantarflexion/dorsiflexion and provides feedback. The eye bearing and flat spring (Figures 2e and f) provide three-dimensional movements in all cardinal planes.

Data Collection

A pair of new AFO (Figure 1) was designed and fabricated for each participant. Each participant walked 10 min with her orthosis to accommodate with the orthosis. Then forty-two ultra-violet markers were attached based on the model stated for the Visual 3D software to the patient's anatomical landmarks. There were single anatomical landmarks such as xiphoid process, the 7th cervical vertebra, the sacrum, and bilateral landmarks such as forehead sides and the acromion process, anterior superior iliac spine, posterior superior iliac spine, medial and lateral sides of knee joint, medial and lateral malleoli, back of the calcaneus, the head of first and fifth metatarsus and hallux for both right as well as left sides. Four marker clusters were also attached to anterior-lateral sides of both thigh and shin for both right and left sides. The patient walked in a 10 meters distance in two situations of with/without the new orthosis. The tests were in random order and the patients had 10 min of rest between tests. Each data collection was repeated three to six times. The data collection was done at the biomechanical laboratory of the Movaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies, Tehran, Iran. The Vicon® motion analysis system with six ultraviolet cameras and two force platforms were used for kinetic and kinematic evaluations; both systems are highly valid and reliable [26, 27].

Data Analysis

The main variables of this study were walking speed, sagittal ROM, moment and total work of the hip, knee and ankle joints, vertical component of the ground reaction force (VGRF) and impulse of VGRF. The data were processed using the Nexus software, version 2.9. Then the data of one stride was selected to extract the critical values using the Excel software, version 2016. The sum of the absolute value of the area under the power plot was calculated to assess the total work. The area under the VGRF plot was also calculated to assess the impulse of VGRF. Finally, the data were evaluated for each participant.

Results

Among 30 MS patients, four females with bilateral involvement were employed for this study after interviewing and assessing. Their demographic information is stated in Table 1.

Subject 1

The participant walked with a back knee which decreased somewhat by using the or-

Table 1: The demographic information of participants

Subject number	Age (year)	Weight (kg)	Height (centimeter)	MS duration (year)
1	38	63	159	13
2	41	45.5	164	11
3	36	74	170	15
4	35	92	171	16

thosis. Her walking speed decreased by 27%. The range of all motion increased especially hip flexion and ankle dorsiflexion; (Table 2). The moments of hip extension, knee flexion, and both of ankle plantarflexion/dorsiflexion increased. The increase of total work was negligible for hip and knee joints (less than 25%) but noticeable (174%) for ankle joint (Table 3). The increase of VGRF was also negligible (less than 15%) and the increase of impulse of VGRF was 30.62%.

Subject 2

Their walking speed decreased by 19%. The

Table 2: The kinematic parameters of walking speed sagittal range of motion (ROM)

		Subject number	Without Orthosis	With Orthosis	Percentage of Differences
Walking speed (m/s)		1	0.48	0.35	-27
		2	0.68	0.49	-19
		3	0.26	0.51	49.01
		4	0.61	0.71	10
Hip	Flexion (degree)	1	4.52	11.59	154.87
		2	28.13	24.73	-12.09
		3	46.27	29.94	-35.29
		4	1.30	5.78	344.62
	Extension (degree)	1	29.42	30.28	2.92
		2	9.55	11.68	22.30
		3	*-	-	-
		4	27.79	32.30	16.23
Knee	Flexion (degree)	1	15.26	18.10	18.61
		2	38.33	45.82	19.54
		3	23.71	12.37	-47.83
		4	8.41	28.49	238.76
	Extension (degree)	1	19.15	10.64	-44.44
		2	4.24	2.92	-31.13
		3	-	-	-
		4	18.86	10.58	-43.90
Ankle	Plantar flexion (degree)	1	15.63	20	27.96
		2	13.43	0.10	-99.26
		3	13.97	18.40	31.71
		4	24.30	9.19	-62.18
	Dorsiflexion (degree)	1	9.79	15.8	61.39
		2	6.37	11.60	83.10
		3	15.52	18.24	17.53
		4	7.01	11.52	64.34

*The values were not extractable

Table 3: The Sagittal kinetic parameters of Moment (N.M) and total work (J)

			Subject number	Without Orthosis	With Orthosis	Percentage of Differences
Sagittal Moment (N.m)	Hip	Flexion (N.m)	1	-260.14	-172.41	-33.72
			2	-168.52	-258.54	53.42
			3	-417.01	-405.54	2.75
			4	-271.93	-256.98	-5.5
		Extension (N.m)	1	540	757.11	40.21
			2	409.8	317.58	-22.5
			3	315.25	373.43	18.46
			4	561.97	581.45	3.47
	Knee	First peak (N.m)	1	-58.97	-955.91	1521.01
			2	280.96	255.63	-9.02
			3	443.04	396.79	-10.44
			4	-395.98	-943.30	138.22
		Midstance minima (N.m)	1	-170.12	-767.52	351.16
			2	-262.53	-303.46	15.59
			3	209.52	230.84	10.18
			4	-333.55	-737.01	120.96
		Second Peak (N.m)	1	-336.39	-834.38	148.04
			2	160.08	154.79	-3.30
			3	249.27	347.41	39.38
			4	-353.90	-836.34	136.32
	Ankle	Dorsiflexion (N.m)	1	-66.86	-15.57	-76.71
			2	-240.60	-99.29	-58.73
			3	-102.15	-53.45	-47.67
			4	-40.81	-69.62	70.60
		Plantar Flexion (N.m)	1	446.08	959.28	115.05
			2	340.69	1211.78	255.45
			3	751.31	892.29	18.76
			4	346.15	1112.73	221.46
Sagittal total work (J)	Hip		1	5.33	6.05	13.51
			2	2.19	4.26	94.52
			3	4.53	6.29	38.85
			4	5.36	6.11	13.99
	Knee		1	5.01	6.22	24.15
			2	1.90	2.61	37.37
			3	1.67	2.93	75.45
			4	9.04	7.01	-22.46
	Ankle		1	4.49	12.56	179.73
			2	1.54	5.74	272.73
			3	3.63	7.15	112.8
			4	3.57	6.72	88.24

range of hip extension, knee extension, and ankle dorsiflexion increased, but the range of hip flexion, knee extension, and ankle plantarflexion decreased (Table 2). The moments of all motions decreased except for ankle plantar flexion which increased by 255.45%. The moment of hip flexion and ankle dorsiflexion had a noticeable decrease. The increase of total work was noticeable especially for the ankle joint (Table 3). The critical points of the VGRF plot were unclear. As a whole, the increase of the first peak of VGRF was negligible (less than 10%); however, the increase of impulse of VGRF was noticeable (Table 4).

Subject 3

Their walking speed increased noticeably. The range of hip and knee flexion decreased; however, the range of ankle dorsiflexion and plantarflexion increased that all of the changes were less than 50% (Table 2). The moments of hip flexion, the first peak of knee flexion, and ankle dorsiflexion decreased and the moments of other motions increased that all of the changes were less than 50% (Table 3). The total work increased for all of the joints and the increase was noticeable for both of the knee and ankle joints (Table 3). The critical points of VGRF decreased negligibly. The increase in the impulse of VGRF was also negligible (less than 12%).

Subject 4

Their walking speed increased somewhat. The range of all motions increased except for knee extension and ankle plantar flexion. The increased range of flexion for hip and knee joints and ankle dorsiflexion was noticeable (more than 50%) (Table 2). The moments of all motions increased except for hip flex-

Table 4: The critical values of vertical component of the ground reaction force (VGRF) and the impulse of VGRF

		Subject number	Without Orthosis	With Orthosis	Percentage of Differences
VGRF (N.m)	First peak (N.m)	1	10.63	11.11	4.52
		2	9.37	10.13	8.11
		3	10.30	10.22	-0.78
		4	10.73	11.63	8.39
	Midstance minima (N.m)	1	7.96	9.02	13.32
		2	-	-	-
		3	9.59	9.50	-0.94
		4	9.26	9.18	-0.86
	Second Peak (N.m)	1	9.56	10.20	6.70
		2	-	-	-
		3	9.61	9.66	0.52
		4	10.29	10.53	2.33
Impulse of VGRF (N.s)		1	139.44	182.14	30.62
		2	100.71	187.21	85.89
		3	257.25	287.60	11.80
		4	195.58	197.76	1.12

ion with a negligible decrease of 5.5%. The increase of moments was noticeable for both knee and ankle joints (Table 3). The total work increased for the hip and ankle joints; in addition, the increase was noticeable in the ankle joint. The total work of knee joint decreased somewhat (Table 3). The critical points of VGRF increase negligibly (less than 10%). The increase in the impulse of VGRF was also negligible (less than 1.12%).

Discussion

The case series study examined the immediate effects of a new mechanical AFO on kinematics and kinetic parameters designed based on the needs of the MS population. The results of the study showed that the new orthosis improved the walking speed of two participants, the sagittal ROM increased for most of the participants and the sagittal moments increased for hip, knee, and ankle joints in most of the measurements. The results also showed noticeable difference in total joint work in the ankle joint. The increased values of VGRF were negligible and the increase in the impulse of VGRF was noticeable for only one participant. Therefore, it seems the new orthosis has the potential to help the walking ability of the MS population.

Renfrew et al., stated MS patients need to use solid AFO at least 12 months to assess a significant increase in walking speed [13]. In this study, walking by the new orthosis led to increasing speed of walking for two participants, and decreasing speed less than 30% for the other two participants. Subject 4 walked 49% faster with the new AFO. This may be due to increase ankle ROM and moment, decreased hip flexion, lesser back knee, and a noticeable increase of knee flexion [28]. The decreased speed of walking for subject one may be due to the increased mid-stance minima of VGRF [29]. Walking with new orthotic devices led to an increased range of hip extension, ankle dorsiflexion, and knee flexion for all participants. The decrease of knee extension or back knee was a desirable outcome. These verify the usefulness of spring mechanism equipped for reminding push-off, the rail mechanism equipped for accommodation to sagittal movements and the rattler mechanism.

The sagittal moments increased for the most of the parameter comparison, especially for ankle plantar flexion. The total sagittal work increased for all of the joints that the most and least incremental total sagittal work was observed for the ankle joint and the hip joint, respectively. This was in contrast to the findings of Bregman et al., who analyzed the effects of walking by spring AFO [30]. It seems the more possible range of motion with the new AFO leads to more power generation and absorption with the ankle joint. The limited increase of the second peak of VGRF contradicts the diminished behavior of the MS population at the terminal stance [6, 28]. The increase of VGRF impulse was negligible for two subjects, but it was noticeable for subject 2. The few increases of total vertical force could verify the effects of customized damping, eye bearing, and flat spring mechanism.

This study didn't compare the effect of new AFO with common interventions of FES and simple passive AFOs; such comparisons may help to better decision making concerning the clinical and cost-effectiveness of the intervention. This study only evaluated the immediate effects of new AFO and the long-term effects may be different and have better results. Therefore, it is suggested that a long-term study is performed using this new AFO for these patients in the future. If the patients walked with a predefined speed, it was possible to have better evaluation of the orthosis effect on moments and power [31].

Conclusion

The mixed effect of spring-damper, rail, and wagons to accommodate orthotic motions with physiologic ankle joint, rattler mechanism, flat spring and, eye bearing led to acceptable immediate effects on kinetic and kinematic parameters of walking. It seems, by matching orthosis to patient's demands, mechanical orthosis has the potential to have a challenge with FES.

Acknowledgment

The authors would like to thank the staff of the biomechanical laboratory of the Movaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies, Tehran, Iran.

Conflict of Interest

None

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