<u>Technical Note</u>

Design and Evaluation of Hybrid Passive Spring Damper Ankle Foot Orthosis for Gait Performance in Drop Foot Patients: A Feasibility Study

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ABSTRACT

Passive and hybrid passive Ankle foot orthoses (AFOs) are the prevalent prescription in drop foot patients to prevent toe dragging during the swing phase. While, these AFOs have some limitations like inability to overcome foot slap, limitation in forward propulsion and inappropriate power generate at the push off. The aim of this study was to design a novel spring damper and evaluate the immediate effects of this AFO on improving the ankle kinetic and kinematic in drop foot patients. This AFO was generated from carbon composite frame and foot section with posterior hinge and spring damper actuator that controlled plantar flexion resistance at the early stance, freely dorsi flexion movement with the ability to store energy during mid-stance movement as well as restore this energy at the pre swing phase. This AFO was assessed on ten drop foot patients who used Posterior Leaf Spring AFO conditions and walked at their self-comfortable walking speed. Then the ankle kinetic and kinematic data in two conditions of with PLS (Posterior Leaf Spring) AFO, and novel spring damper AFO were assessed. Results showed a significant improve in the immediate effect of the kinetic and kinematic parameters. In conclusion, spring damper AFO improved all ankle angles in entire gait cycle as well as the ankle moments and power. Therefore, this AFO should be consider as a selective AFO in drop foot patients.

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Keywords

Orthotic Devices; Braces; Gait; Rehabilitation

Introduction

A nkle foot orthoses (AFOs) are prevalently prescribed in drop foot patients in order to improve foot clearance during swing and the ankle position at the initial contact and ankle dynamic stability during the stance phase [1]. Passive AFOs, like posterior leaf spring AFOs, improve stability and prevent toe dragging during the swing phase by limiting the ankle joints at a fixed position. However, these AFOs have some disadvantages like limited the ankle joint range of motion and the excessive knee flexion moment during the loading response [2]. To overcome some of these disadvantages, a variety of hybrid passive AFOs were designed and fabricated with some extra elements such as springs and dampers than passive ones [3]. Therefore, the mechanical property of these AFOs could be interfered with the normal behavior of the ankle [4].

In normal walking during the initial contact to loading response, controlled plantar flexion was performed by eccentric contraction of dorsi flexor muscle, emulated by some hybrid passive AFOs like "Gait Solution AFO" with damper elements, introduced by Yamamoto [4, 5]. Furthermore, in normal walking at the mid-stance, the controlled dorsi flexion was performed by eccentric contraction of plantar flexion muscle, leading to energy storing, which was imitated by some hybrid passive AFOs like ¹Rehabilitation Research Center, Department of Orthotics & Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran

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Hasan Saeedi, Ensieh Pourhoseingholi

klenzak AFO [5, 6].

Moreover, in normal walking at the preswing, the burst ankle power generation was happened. Whereas, the most existing damper or spring based AFOs were unable to perform enough push-off power (third rocker) [7]. The main reasons of this inability is the lack of energy storage in the damper based AFO or short time of energy absorption in some spring based AFOs as well as instantaneous energy release after raising the foot without significant effect on power generation [8].

With respect to this evidence, a novel hybrid passive with ability of resisting to plantar flexion, storing-restoring energy and freely range of motion as well as power generation at the swing phase was needed.

The aim of this study was to design a novel spring damper and evaluate the immediate effects of this AFO on improving the ankle kinetic and kinematic in drop foot patients.

Material and Methods

AFO fabrication

Novel hybrid passive storing restoring ankle foot orthosis

The novel AFO is an AFO with a storing restoring actuator weighs about 400 g weight (Figure 1). This novel designed AFO which was composed of two separate carbon composite sections and linked together by a side bar to establish the attachment for actuator mechanism, however, other parts, including actuator connection and posterior hinge were made from titanium to decrease total AFO weight compared to the most existing hybrid passive AFOs (Figure 1). The actuator mechanism was composed of modifiable springs and adjustable hydraulic shock absorbers. A stainless-steel articulation was placed at the back of the AFO without limiting or interfering ankle joint which was slightly protruded the posterior part from patients dress. We could also design an adjustable slider in front of the shank cuff which could be moved up and down on the rail in order to compensate for the differential motion between AFO and paretic limb (Figure 2).

The novel AFO consists of elements as follows:

1) A carbon composite anterior shell: this part of AFO was made of carbon composite, coated with a neoprene layer, encompassed around the shank. The purpose of this was to create an interaction between the AFO and the patient's limb and to create a stable surface for the rail mechanism (Figure 2).

2) The rail mechanism was used to provide the motion difference between the AFO and the shank to increase the range of motion in sagittal plane. (Figure 2).

Initial adjustment of the rail position can be accomplished by several holes embedded in the mechanism.

3) A posterior articulation was decided to place the AFO joint at the posterior part of AFO in a point away from the anatomical joint to maximize the range of motion without the anatomic ankle joint limitation (Figure 2).





Design and Evaluation of Spring Damper Ankle Foot Orthosis



Figure 2: Mechanical elements of the novel spring damper Ankle foot orthose (AFO)

4) The removable steel spring was used to absorb or store energy due to its structural elasticity (Figure 2).

5 The adjustable hydraulic viscous damper system was used for energy damping, which could be adjusted according to the need and activity level of the patient (Figure 2).

6) The foot section was individually constructed and attached to rest of the AFO by a set of screws, which was easily removed (Figure 2).

Functional algorisms of novel AFO in gait cycle

In the initial contact to the loading response, as a result of dorsi flexion eccentric moment absence, the controlled plantar flexion was generated by hydraulic damper until neutral ankle angle, which was prevented foot slap.

In the middle to late stance, novel AFO acted in two steps as following: the first step started from loading response to mid stance in which novel AFO reached the neutral angle from plantar flexion at the previous phase with no spring or damper movement around the joint and only with the aid of the posterior free hinge and rail length difference, providing no impediment to movement. In the next step, from the mid to the late stance, the spring engaged and stored energy until push off.

In the push off sub phase, the stored energy by both the spring and damper were engaged to generate controlled push off power (Figures 1 and 2).

Functional algorisms of novel AFO in gait cycle

During the initial contact to the loading response, the controlled plantar flexion was generated by hydraulic damper until neutral ankle angle that prevented foot slap.

During the middle to late stance, novel AFO acted in two steps, including: the first step starting from loading response to mid stance, in which novel AFO reached the neutral angle from plantar flexion at the previous phase, with no spring or damper movement around the posterior articulation and rail length difference. In the next step, from the mid to the late stance, the spring engaged and stored energy until push off.

Participants

The study sample was included ten right foot drop feet patients (7 men; 3 women), recruited from the occupational therapy center, rehabilitation school of rehabilitation, Iran University of Medical Sciences, Tehran, Iran. All the patients filled up and signed an informed consent form before the start of this study, and the study protocol was approved by the Medical Ethics Committee of Iran in University of Medical Sciences with the ethic code 808063. Each participant had a confirmed diagnosis of drop foot with any reason for the central and peripheral nervous system.

The inclusion criteria were a clinically observed unilateral drop-foot using PLS (Posterior Leaf Spring) AFO as a routine AFO and ability to walk at least 20 min without assistance. Exclusion criteria consisted of significant heart or metabolic disease, previous abnormalities in visual/vestibular functions, emotional instability, and previous fracture of both lower limbs, leading to difficulty in walking, severe poly neuropathy, presence of muscle spasms or contractures in lower extremity joints.

Study design and procedure

Fifteen retro-reflective spherical markers

Hasan Saeedi, Ensieh Pourhoseingholi

were set according to the biomechanical model of Helen Hayes [9] at the anatomical landmarks on the posterior sacrum, the bilateral anterior superior iliac spine (ASIS), the medial and lateral femoral condyles. These markers help to ensure that six infrared cameras of the motion capture (Qualisys workstation AB, Gothenburg, Sweden 2013) tracked the joint angles correctly at a sampling rate of 100 Hz. To determine the ground reaction force (GRF), force plates (Kistler Holding AG, Winterthur, Switzerland, Model 9286B), embedded into the floor were employed at a sampling rate of 1000 Hz. This force plate was synchronized to the motion capture system [10-12].

At the beginning of the examination, the patients were asked to walk at least for 10 to 20 min with their own PLS AFOs/shoes and newlydesigned AFO/own shoes at their self-selected convenient speed. After that, in each condition retro-reflective spherical markers were set at anatomical landmarks according to Helen Hayes's model. Each patient walked with his/her own shoes and both AFOs for 10 meters to track the motions using the motion capture system. Then the patients rested for 2 min to record each set of data. Every trial was repeated three times.

Data processing

Motion and force data were low-pass filtered at 14 Hz and 39 Hz, respectively, using fourth-order, zero-lag, and Butterworth filters, determined by the residual analysis method described by Winter [12]. GRF trajectory data were low-pass filtered using a 4th-order Butterworth filter with cutoff frequencies of 50 and 6 Hz, respectively. After, the link segment model was defined; a biomechanical inverse dynamics model was applied to compute joint kinematics and kinetics. Kinematic joints were determined using Euler angles with the pelvis, hip, knee, and ankle kinematics defined by Cardan rotation sequences. Therefore, for each subject, kinematic (joint angles) parameters were recorded. The vertical component of GRF was employed to make sure about sufficient toe clearance at the swing phase with AFO during trials. The outcomes were normalized by body mass.

Statistics

All statistical analysis was performed using SPSS software 19.0, with a significant P-value set at 0.05. The data were tested for normal distribution using the Kolmogorov–Smirnov test. For normal and abnormal distribution, an independent t-test and non-parametric Wilcoxon test were used, respectively.

Results

This study recruited drop foot patients with the mean age of 65.18 (SD: 12.56), the mean time of 7.4 years after diagnosis and the mean comfortable selected speed in novel and PLS AFO were 1.81 (SD: 0.5) and 0.7 (SD: 0.63) m/s, respectively. According to the result of this study, the ankle angle at the loading response in the novel and PLS AFO were -15.28 (SD: 0.81) and -9.90 (SD: 0.85) degree, respectively. According to the result of this study, the ankle angle at the mid to terminal stance in the novel and PLS AFO were 15.52 (SD: 0.98) and 5.44 (0.28) degree, respectively and the ankle angle at the pre-swing in the novel and PLS AFO were -23.58 (SD: 1.31) and -14.0 (1.72) degree, respectively. Moreover, ankle angle at the mid swing in the novel and PLS AFO were -8.44 (1.53) and -5.48 (SD: 0.49) degree, respectively (Table 1).

Discussion

The main objective of the current study was to develop a novel designed AFO with conceptual mechanical actuator to overcome some drawbacks of traditional passive and hybrid passive AFOs in drop foot patients.

The findings of the present study indicated a significant improvement in the peak of the ankle plantar flexion and peak power absorption in spring damper AFO than PLS AFO, confirmed with other studies [2, 11, 12].

The adjustable damper element of spring damper AFO emulated the eccentric contraction of dorsi flexor muscles in producing controlled plantar flexion, to prevent foot slap.

In this regard, Yamamoto compared the oil damper AFO and auricular AFOs with plantar flexion lock and found that the ankle joint

Table 1: Result of the kinematic and kinetic parameters in the affected side with a novel Ankle Foot
Orthose (AFO).

Parameter description	Novel AFO	PLS AFO	P-value
Ankle angle at the initial contact (degree)	-2.94(4.56)	3.14(4.66)	0.07
Ankle angle at the loading response (degree)	-15.28(0.81)	-9.90(0.85)	0.00
Ankle angle at the mid to terminal stance (degree)	15.52(0.98)	5.44(0.28)	0.00
Ankle angle at the pre swing (degree)	-23.58(1.31)	-14.0(1.72)	0.00
ISW Ankle angle at the initial swing (degree)	-3.10(0.31)	-2.66(0.54)	0.00
Ankle angle at the mid swing (degree)	-8.44(1.53)	-5.48(0.49)	0.26
Ankle angle at the terminal swing (degree)	3.88(0.49)	0.49(0.89)	0.42
Dorsi flexion eccentric moment at the loading responses N/Kg	-1.22(0.34)	2.08(0.22)	0.00
Power absorption at the loading responses W/Kg	-0.90(0.21)	0.12(0.04)	0.00
plantar flexion concentric moment at the mid to terminal stance N/Kg	11.06(1.28)	3.78(1.11)	0.00
Power generation at the pre swing W/Kg	2.02(0.25)	0.18(0.08)	0.00

AFO: Ankle Foot Orthose, PLS: Posterior Leaf Spring

gradually approached the peak of plantar flexion with the oil damper AFO without excessive flexion in the knee and hip joints. Based on the results of this study, during the mid to late stance phase, the peak ankle dorsi flexion, the ankle eccentric dorsi flexion moments and the peak power absorption significantly increased using novel AFO than PLS, confirmed in other studies. During these phases, the free movements of the posterior hinge and anterior rail increased the ankle range of motion especially in dorsi flexion direction and optimized energy storage at the spring elements, which was confirmed in some studies on passive (dynamic, carbon) and hybrid passive (Klenzak and modified Klenzak) AFOs. In contrast, some passive AFOs with an inflexible or stiff mechanical elements impeded this phase and reduced the moment and power at this phase. During the late stance to pre-swing, the peak ankle plantar flexion and the ankle power generation significantly increased with Novel AFO than PLS, confirmed with some studies [13]. During these phases, the coordinated performance of spring and damper elements of the actuator released the energy which was stored from previous phases proportionally and generated the controlled push off power [14] at this phase. These results were in line with other studies on some passive and hybrid passive AFOs with structural flexibility (dynamic, carbon) or spring element in the energy storage section (modified Klenzak and modified Klenzak AFO) [15].

The findings of the present study indicated that a novel AFO significantly increased the peak plantar flexion concentric moment and power generation in the late stance to pre-swing than PLS AFO, which was confirmed with some studies [11]. The possible cause of this increase was the effectiveness co-activation of damper and spring elements in improving the plantar flexion power at these phases.

To the best of our knowledge, no study has introduced spring damper AFO with the ability to provide controlled plantar flexion at the loading response, free angular movement at the ankle joint during mid stance and has also improved push off power at the pre swing phase.

There are some limitations in this study, including the limitations on interaction and synergy of the kinetic and kinematic parameters without attention to muscle electromyography and the small sample size of this study, i.e. the larger sample size and long-term daily use in associated with gait training was needed.

Conclusion

In conclusion, since most AFOs are designed to prevent ankle plantar flexion (with plantar flexion resistance) at the swing phase, the majority of passive or hybrid passive AFOs are designed in the dorsi flexion at the swing phase to ensure toe clearance from the ground. These types of AFOs can greatly reduce the power generation at this phase without preventing foot slap. Novel AFO combined damper and spring elements and managed to resolve these problems to some extent.

Authors' Contribution

E. Pourhoseingholi conceived the idea. Introduction of the paper was written by H. Saeedi and E. Pourhoseingholi. E. Pourhoseingholi and H. Saeedi gather the images and the related literature and also help with writing of the related works. The method and result implementation was carried out by E. Pourhoseingholi. The research work was proofread and supervised by E. Pourhoseingholi. All the authors read, modified, and approved the final version of the manuscript.

Conflict of Interest

None

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