Clinical Evaluation and Gait analysis of Powered Gait Orthosis with Moveable Knee Joint for Paraplegics

Abstract

This study intends to validate the effect of gait training by continuous functional training of paraplegics. A knee joint device is moveable during the swing phase was applied to PGO (Powered Gait Orthosis), which requires little energy when walking and is being studied for the functional walking of patients in order to assess the effects in kinematic and clinical improvement. In the walking of paraplegics, PGO with moveable knee joint have greater kinematic effects than those with a limited joint, and showed improvements in walking speed, number of steps and the length of each step through long-term training. Continuous gait training using PGO with moveable knee joint decreases the BMI (Body Mass Index), which indicates the level of body obesity, and changes the bodily constitution by decreasing the level of body fat and cholesterol. The changes in body weight of the participants showed a decrease over the training period, and bone density in the lumbar spine and the femur increased. Paraplegics with a normal heartbeat rate showed no abnormal increase or decrease in pace when training with PGO with moveable joints, and displayed sustenance or improvement against functional deterioration and contraction of the bladder.

Keywords: Moveable knee joint, Powered gait orthosis, Clinical evaluation, Spinal cord injury, Paraplegic

1. Introduction

Apart from disorders in physical and sensory functions, most of the paraplegics have problems in the function of the autonomic nerves that control the bladder and the colon [1, 2]. The rehabilitation treatment for paraplegics consists of walk training using orthosis devices appropriate for the level of paralysis. The training is effective in preventing contracture in joints, decreasing rigidity, and protecting patients from complications [3]. However, as walking with orthosis requires a lot of energy and is not difficult, there have been many cases where its use was discontinued after the termination of the physical therapeutic walking [4]. Therefore there needs to be an orthosis effective for functional walking after therapeutic walking.

There have been continuous studies on gait orthosis for therapeutic and functional walking for paraplegics. KAFOs (Knee-Ankle-Foot Orthosis) were mainly used before the 1960s, and the concept of RGO (Reciprocating Gait Orthosis) was first devised at Ontario Crippled Children's Centre in 1968. Since then, LSU-RGO using cable link was introduced by Douglas et al. [5] at the University of Louisiana. The linkage section of the joint was improved by Beckman et al. [6] in 1987, and LSU-RGO for adults was developed in 1989 by Salter et al. [7]. In 1990, Advanced RGO (ARGO) was developed by Hugh Steeper in the U.K. [8]. ARGO had an innovative structure for the paralysis patient's gait, but was heavy due to additional devices and required it to be worn a long time. ARGO was improved by Lissens [9], Ijzerman [10] in the late 1990s. In 1992, Isocentric RGO (IRGO) was developed by Motloch et al. [11]. IRGO operated by the reciprocating linker at the joint powered by rotational movement at the central axis of the pelvic band. The orthosis, which was connected to a single-body pelvic band and link, had a high stability in balancing posture, and required less energy due to its simple and light structure [12]. The mechanical RGO developed to aid the paraplegics in walking induced excessive physical energy due to its characteristic of using body movement, and is limited in time and distance. Therefore complex types of RGOs, such as using outside power or electrically stimulating the paralyzed muscles, were researched to assist the walking of paraplegics. To aid their walking, Solomonow et al. [13] developed a hybrid device of an FES (Functional Electrical Stimulator) and a walking aid device in 1989 and studied the muscle reactions and decrease in muscle rigidity of patients with spinal damage. Using FES, however, brought on high muscle fatigue in a short time, making it unsuitable for long walks.

In 1997, PGO (Powered Gait Orthosis) was developed by Ruthenberg et al. [14], which was powered by a DC motor with 1 degree of freedom, and Ohta et al. [15] developed a PGO with 2 degrees of freedom by using a separate small DC motor at the joint. These PGO systems used motors with mechanical links and speed reducers, which made them large and heavy, and required much power for the motors. A separate cable was needed for power and control, making them unpractical. In order to aid the joint flexion, air muscle PGO [16] using fuzzy logic control was developed in 2006 which reduced the power consumption level, but the effects were limited due to the fixed knee joint.

The objective of this study is to validate the effect of regular walking of the paraplegic using a PGO modified to incorporate a moveable knee joint after the termination of physical therapy.

A PGO with air muscles as a power aid is designed to provide flexion and extension movement at the knee using a pneumatic cylinder with spring and a solenoid type lock, and the effect in kinematic and clinical indices in accordance with the period of training will be assessed.

2. Moveable Knee Joint Design

PGO A PGO normally have a fixed knee joint since it provides stability during the stance phase, however it disables flexion of the joint, increasing the movement of the pelvis. This affects the functional gait of paraplegics and makes it difficult for them to walk [17]. There have been cases where a breaking device with linear motor or electric magnet was used for the joint flexion for a functional gait effect, but the devices were large and heavy, putting extra load onto the body and deteriorates the effect of functional gait. In order to solve these problems simultaneously, flexions were prevented at the stance phase, only allowing them for the swing phase as well as extension. A small solenoid (DC24V, 15mm stroke, 45g weight, Dong-A Co., Korea) was used for the locking and unlocking of the knee joint. The solenoid unlocks the joint during toe-off and locks it just before heel contact. During the swing phase, the joint is unlocked by the solenoid, and the flexion occurs by the inertia created during the swing phase (Fig.1), as applied by Edward [18].

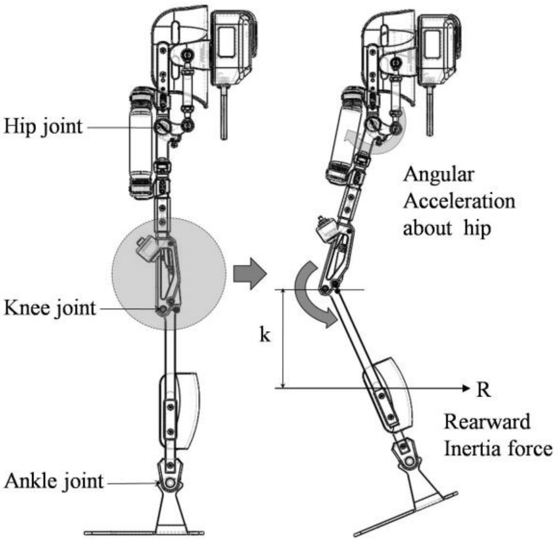


Fig. 1. The moveable knee mechanism: R, rearward inertia force; k, length of action. Shown at the mid swing position, the moment acting to bend the knee is equal to R x k.

A gas spring cylinder (70g weight, 15mm outer diameter, 130mm length, 30mm stroke, Sangyun Co., Korea) was used for an extension aid for the stance phase. The repulsion forces of the cylinder were 45N, 60N and 75N. This was to set the repulsion rate according to the body weight.

The knee joint in the stance phase is unable to flex due to the metal locking device attached to the solenoid, and when in swing phase, the locking device is unlocked by the solenoid, and the joint is naturally wound by cancelling the repulsion force of the spring cylinder with the rear inertia exerted by the leg weight (Fig.2).

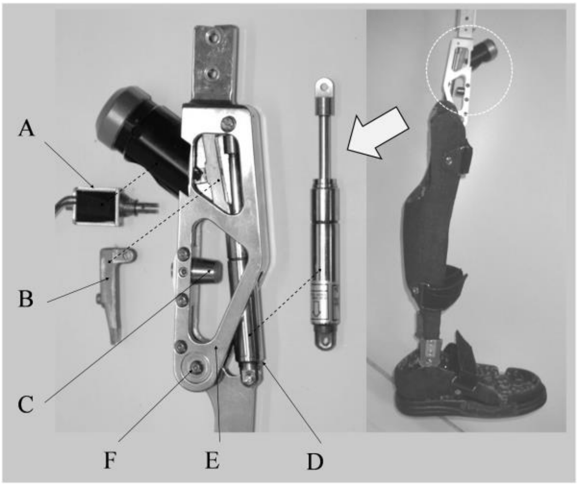


Fig. 2. Photographs of the moveable knee joint: A, Solenoid; B, Locker; C, Stopper; D, Gas spring cylinder; E, Knee body (TiAl6V4); F, Knee joint.

During the swing phase, the gas spring cylinder helps extension by the expansion of the compressed air. When the joint is fully extended, the solenoid locks the joint and maintains stability at stance phase. The maximum flexion angle of the joint was designed not to exceed 40° in consideration of walking stability.

In order to decide the amount of repulsion of the gas spring cylinder, the flexion moment of the knee joint generated during swing phase by the body weight is calculated [19]. The repulsion force of the gas spring cylinder at this moment is smaller than the maximum flexion moment, enabling the flexion. In this research, the size of the repulsion force was set at 60% of the maximum flexion moment. ADAMS (Automatic Dynamic Analysis of Mechanical Systems) was used to calculate the repulsion force of the gas spring cylinder.

3. Powered Gait Orthosis

3.1. Hip joint powered by compressed-air

The PGO developed for this study adopted an Isocentric RGO (IRGO) structure in order to insure the stability of the balancing posture.

The structure of the PGO was modified to accommodate air muscles as developed by Kang and Kim et al. [16] and was made in titanium alloy for rigidity [20]. The air muscle is a power device devised to use air pressure to function similarly to biological muscles, and its strength lies in its relatively large power compared to weight [21]. Air muscles (20mm diameter, 210mm length, Shadow Robot Co., U.K.) were installed from the points above and below the rotating axes of the hip joint to enable flexion (Fig.3).

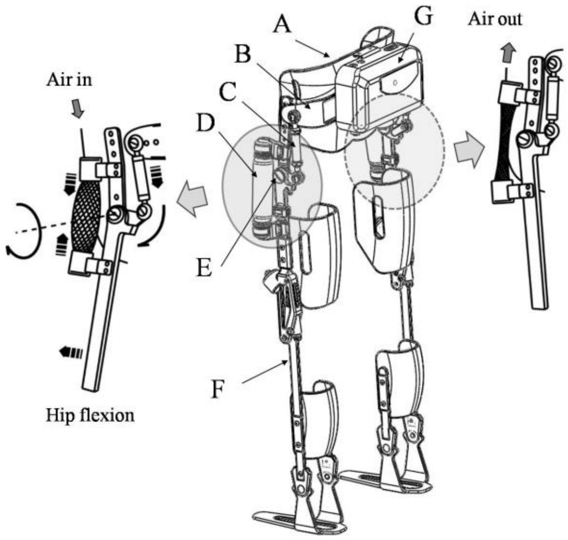


Fig. 3. The air-compression powered hip joint: A, Spinal orthosis; B, Pelvic band; C, Ball joint link; D, Air-muscle; E, Hip joint (TiAl6V4); F, Up-right bar (TiAl6V4); G, Driving system.

Each air muscle complements the rotation of the body that rotates the pelvic band which brings corresponding leg forward alternately through a link mechanism. Therefore the patient consumes less energy.

3.2. Driving system

The control system is composed of a solenoid valve (LCP35A, MAC Valve Inc., USA), air pump (DC24V, 2.5kg/cm^2 max, 805g weight, Korea Pneumatics Co., Korea), battery (Li-ion, 4400mmAh 11.1V, 450g weight, Samsung Co. Ltd., Korea), and real-time controller. The real-time controller has a high operational speed and uses a microprocessor with built-in features such as various input/output ports, AD conversion, direct communication, and PWM output function. The signals for gait are an EMG signal emitted from the electromyography sensor attached to both arms, and signal from foot sensors at the insoles of both foot. Signals from one side are used to move the corresponding leg.

4. Subjects

In order to analyze the kinematic and clinical effects of the paraplegic wearing a PGO under study, three participants were selected (Table 1). The participants were composed of two males and a female.

Table 1. Details of subjects included in the study

Subject	Sex	Injury level	Age	Time since injury (years)	Walking Aid
A	M	T4	34	6	Parallel bar
B	F	T4	21	3	Parallel bar
C	M	T6	25	2	Parallel bar

Fig. 4. Gait training of the powered orthosis

All participants had no previous experiences with PGO’s. They went through a minimum one week of parallel bar training for acclimation of the PGO-aided walk. In order to have full effects of gait training, all participants were allowed for 2 hours every day, five times a week for 16 weeks. The PGO provided were manufactured according to the plaster molds lifted from each participant to fit their body shape (Fig.4).

5. Equipment and Methods

5.1. Motion Analysis

Vicon 370 (Oxford Metrics, UK) was used as the data processing device in order to understand the kinematic traits of the participants, along with 6 infra-red light motion capture camera (Oxford Metrics, UK), four strength measuring pads (Kistler, Switzerland), and a 25mm reflective marker.

For the experiment, the participants put on the PGO at the parallel bars beforehand and did trial walks for more than 10 minutes, and when the heartbeat rate stabilized after a 20-minute rest, five repetitions of gait analysis were carried out wearing the PGO.

5.2. Clinical Evaluation

In order to measure the clinical effects from the gait training, an evaluation protocol was drafted. The protocol selected items from which clinical effects are expected. The changes in heart rate and body weight from the training effects are recorded, and the changes in body fat mass and BMI (body mass index) values according to changed body weight were measured. The changes in the BMD (Bone Mineral Density) rate from the flexion exercise during PGO gait were also measured. A T-score value (comparison against the average BMD of young adults) was used for the BMD results, and the measured regions were lumbar spine and femur, where joints have lots of movements during gait exercise. The changes in bladder function were also measured for the effects, and were measured by VCUG (Voiding Cystourethrography).

6. Results

6.1. Gait Analysis

Walking ability for paraplegics is a necessary element in everyday life for functional independence. In order to achieve it, the patient’s ability must be improved with continuous gait training. The kinematic improvement effect of continuous training using gait orthosis has already been well known [22-25]. In this study, parameters measured for the analysis were the gait speed, number of steps per minute, and the length of each step for Group (subjects A,B, and C). The measurements were done at the onset of, two months after and four months after the gait training.

The number of steps for each participant was different, but it can be seen that they were all improved as the training sessions continued (Fig.5A). Subject B especially, showed improvement of about 59% at the end of training. Subject A showed improvement of by about 26%, and Subject C by about 56%.

The gait speed also showed improvements over the course of training (Fig.5B). Subject A was confirmed with about 82% improvement at the end of training compared to the initial stage. In the case of Subject C, there was no significant difference in the gait speed during the two months of training. These differences show that the training effects could vary according to personal traits such as age, physical condition or activeness.

The lengths of each step showed an increase among the participants as training progressed (Fig.5C). Subject A improved by about 54% at the end, and Subject C by about 35%. On the other hand, while Subject B showed no big difference up to the two-month period, the numbers increased by about 20% after four months.

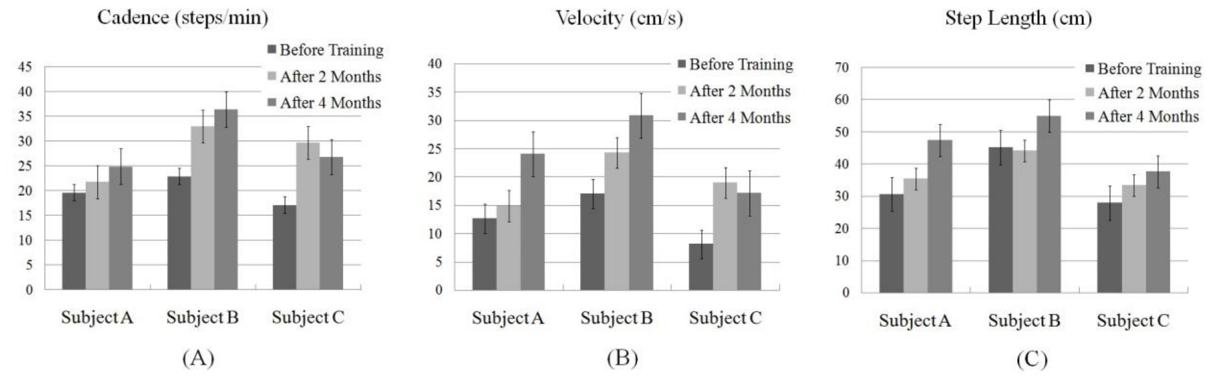
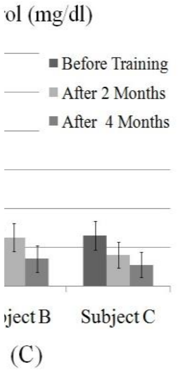


Fig. 5. Comparison of gait parameters change in moveable joint knee for PGO: (A) Cadence (steps/min), (B) Velocity (cm/s), (C) Step length (cm).



lass, (C) Cholesterol.

6.2. Clinical Evaluation

Rehabilitation training for paraplegics is required to prevent various complications that could be caused by paralysis. Rehabilitation training methods such as FES induced muscular activities are reported to be effective for clinical improvements [26, 27], and the clinical effects on heart functions and muscular power improvement can be confirmed in long use of orthosis in gait [28]. The improvements in autonomic nerves and bladder function are also reported to be very important for paraplegics [29, 30].

In this research, a PGO with a movable knee joint (Fig.3) was used to measure the clinical effects of improvement for patients. The changes in bodily constituents and BMD over the training period were measured, and the changes in heartbeat rate (HR) and bladder capacity were measured at the beginning, two months in, and four months in.

In measurement of bodily constituents, all subjects showed a decrease in the BMI, which indicates the level of obesity (Fig. 6A). Especially in the case of subject B, the numbers decreased by about 32% after two months, and the BMI value did not change much after that. Body fat and cholesterol all showed decreases in the first two months. This shows that the gait training effectively reduced the body fat. They maintained similar levels after four months, however (Fig.6B, 6C).

Body weight showed a decrease in accordance with the length of training period (Table 2). Subjects A and C showed about 5% difference, however, subject B showed a 27.5% decrease in body weight. The BMD rates were measured at lumbar spine and femur, where the density was expected to change according to the body movements from gait training. The participants showed an increase in the BMD rate in both regions over the course of the training (Table 2). In the BMD test, T-score mark values over -1 were considered normal. Subject B, especially, showed a low BMD rate in the femur region before training, but showed a large increase afterward.

Table 2. Bone mineral density & Body weight

			Before Training	After 2 Months	After 4 Months
BMD (T-score)	L-spine	Subject A	2.7	2.9	3.2
		Subject B	-1.7	-1.5	-1.4
		Subject C	2.0	2.0	2.1
	Femur	Subject A	-1.7	-1.4	-1.6
		Subject B	-4.2	-4.0	-1.4
		Subject C	-0.9	1.2	1.2
Body Weight(kg)		Subject A	85	83	82
		Subject B	51	40	40
		Subject C	85	81	80

Changes in the resting HR of the patients according to the training period were measured (Fig. 7). There were changes in HR from training, but they were all in the range of a standard adult HR, 60~80(beats/min). Therefore, the test showed no increase or decrease in the normal heartbeat rate from gait training. Changes in the bladder function due to the training were also measured. VCUG (Voiding Cystourethrography) was used for the measuring (Fig. 8B). The majority of paraplegics have, as a complication, a weakening or contraction of bladder functions due to abnormalities in the autonomic nerves. Subjects B and C showed no changes in bladder contraction or capacity after the training, and subject A displayed an increase in bladder capacity by about 11.5% after two months of training (Fig.8A).

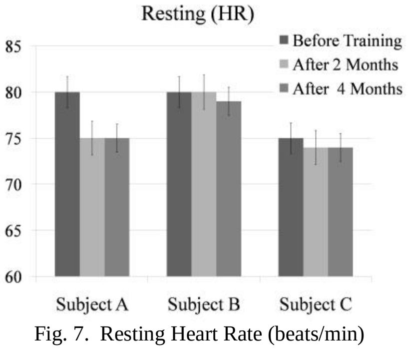


Fig. 7. Resting Heart Rate (beats/min)

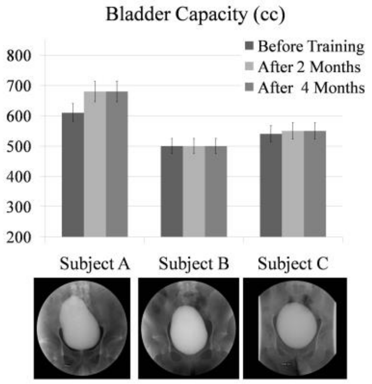


Fig. 8. Comparison of bladder capacity and photograph of VCUG

7. Conclusions

In this study, to validate the effect of gait training from sustained functional training after training to acclimate to it, a PGO developed by Kang, Kim et al.[16] was modified to incorporate a moveable knee joint for more natural gait.

By analyzing the kinematic and clinical improvement effects in accordance with the period of the training from the experiments, the following conclusions were made.

A PGO with a moveable knee joint for paraplegics has greater kinematic effects than with a fixed knee, and showed improvements in gait speed, cadence, and step length after a long training period.

The continuous gait training using moveable knee joint PGO decreased the BMI and also reduced the level of body fat and cholesterol to affect bodily constituents. The changes in body weight of the participants showed a decrease over the training period, and the BMD at the lumbar spine and femur increased, bringing it up to a normal BMD level. The paraplegics with normal heartbeat rates showed no significant changes in HR during the gait training using PGO with moveable knee joints. Gait training using a PGO with moveable knee joints also improved the bladder capacity.

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