ABSTRACT

Background: During the gait cycle, power generated during the push-off stage by individuals with Cerebral Palsy (CP) is deficient. Associated with this power is a deficient moment about the ankle. Current ankle and foot orthotics (AFO) can restrain abnormal joint motion, improve the kinematics, and stabilize gait and posture but cannot provide augmented moment and power during push-off phase. Thus gait of CP patients is not improved during push-off by traditional orthotics.

Methods: In this study, a new powered orthotic that will supply the deficient power and control foot drop was developed. Fundamental principles and analysis of fluid flow were applied in the design. A design using a Pneumatic Artificial Muscle (PAM) was developed. A dynamic model was established which uses the patient’s measured clinical gait motion and is able to predict the amount of foot drop and deficient power. This model was coupled with a control system to provide proper sequencing in the activation and deactivation of the powered device. The device is designed so that it may be “tuned” to each patient based on the patient’s weight, foot size and dynamics of gait. The device is designed for CP children 6-9 years of age.

Results: For a specific patient, the chosen PAM was tested in the laboratory and the kinetics and kinematics of the device were established. It was found that the displacement (stroke) changes nonlinearly with time and the displacement reaches its maximum value which is 1.55 in (0.039 m) at about 0.2 sec. On the other hand, the force output of the PAM varies linearly with displacement, and it takes about 0.3 sec to reach the maximum value of the force which is 32 lbf (142.3 N). For a specific patient, with a specific foot size, this generates a moment about the ankle equal to 7.73 N·m (68.4 lbf·in) This moment at 4.786 rad/s produces augmented power about the ankle equal to the deficient power in the CP patient. Simulations using the established dynamic model were found to accurately predict the deficient amount of power for the CP patient. Also, it was found that the model was able to predict the time during the gait cycle when the PAM should be activated to provide augmented power.

Conclusions: The new powered orthotic device provides supplemental power to augment for the patient’s deficient power and further improves the quality of the second ground reaction force peak (GRF2) at push-off. Compared to traditional orthotic designs, the new powered design has the potential to increase power at the third rocker despite the CP patient’s reduced muscle strength and increased spasticity.
Background
Cerebral Palsy (CP) is a group of neurological disorders, which appear in infancy [1]. People with CP frequently experience sporadic reflexes and rigidity of the limbs hindering coordinated movements like walking and other skills requiring fine motor control [2]. The causes of CP are still to be determined but are most likely attributed to maldeveloped regions of the prefrontal cortex.

During the gait cycle, power is generated during the toe-off (push-off) stage about the ankle to propel the body forward. Contact of the foot with the ground creates a force known as the Ground Reaction Force (GRF). People with normal gait cycles are able to generate sufficient GRFs to overcome their own body weight as well as the additional force to propel them forward. It is common that children with CP are able to generate enough GRF to overcome their body weight but are unable to generate the additional GRF to effectively propel them [1, 2]. This is illustrated in Figure 1.

![Figure 1: Vertical Ground Reaction Force at Heel-Strike, Mid-Stance and Toe-Off stages of the gait cycle. The GRF for a CP child is reduced compared to that of a typically developing child (TD GRF2).](image)

The deficient force for children with CP is shown in Figure 1. The second upper peak is from a normal gait cycle and the second lower peak represents what children with CP are capable of producing. It can be seen that children with CP are able to produce enough force to overcome their own body weight but lack the additional force to propel them forward. This is not to say people with CP are unable to perform the motor skill associated with walking, it is simply they are unable to generate a sufficient moment about the ankle during their dorsiflexion and plantarflexion stage of their gait cycle commonly referred to as push-off. A general sign of insufficient moment about the ankle while walking is foot dragging and leg drop.

Moreover, a correlation has been detected and examined between plantarflexion moment and muscle strength in six of the eight muscles groups. A similar observation was accomplished on the subject of muscle strength and producing ankle power [2].

Current ankle and foot orthotics (AFO) are able to correct abnormal joint motion, improve the gross motor function, and balance gait and posture [1, 3]. These conventional orthotics reduce plantarflexion in the course of the stance phase and prevent foot drop throughout the swing phase. Nevertheless, CP children create inadequate power at the third rocker by way of reduced muscle strength along with increased spasticity [4, 5, 6]. Associated with this reduced power is a deficient moment about the ankle joint (0.28 N·m/kg, range: 0.12-0.51 N·m/kg) which is considerably less in the CP than in typically developing children. Therefore, passive orthotic designs are restricted in their qualification to enhance the gait of CP children.

Previous powered orthotic designs have made use of foot switches despite the fact that using EMG to obtain the triceps surge recruitment produced ankle kinematics closer to normal than the foot switch. However, in devices using EMG, the control was too variable because of physical impairments due neuromuscular diseases to make such devices practical [7].

In addition, current powered orthotic designs are based on position control of the foot [7, 8, 9]. So, these have concentrated on the gross motion of the lower extremity although current power assisted AFO designs advance gait mechanics [7]. But, this approach may not influence the kinetics of the ankle and foot. Some devices have been developed which impact kinetics but these do not appear to be designed so as to provide supplemental power at push-off [10].

Thus, these existing orthotics do not reform efficiency and power for the time of toe-off (GRF2) [5]. The objective of this research was in the development of an advanced powered orthotic design which is able to provide the deficient power and control foot drop.

In the development of the new design, several approaches were investigated. These included implementation of actuators and Nitinol wires. While both these approaches provided sufficient position control neither was able to provide a sufficient moment about ankle joint. However, Pneumatic Artificial Muscles (PAM) have high mechanical output to weight ratio which makes them ideal for powered orthotics [11]. PAM's are powered by
pneumatic pressure and contract when pressurized. The materials used for the construction of PAMs consist of a flexible membrane, a reinforced woven sheath, and air tight plumbing fixtures. The flexible membrane is located inside the woven sheath and air tight plumbing fixtures are located on either end. When the PAM is pressurized, the flexible membrane inside the sheath expands and by effect contracts the overall length of the PAM, thereby generating an axial force. Because the response of the device is nonlinear contraction occurs in a nonlinear fashion. Typically, any size PAM may reach a 25% maximum contraction.

**MATERIALS AND METHOD**

**Device Design**

The design shown in Figure 2 is based on analysis of fluid pressure and fluid flow. Not shown in the figure is a torsional spring which is used to return the foot to neutral position for the swing phase and heel strike. The stiffness of the spring is obtained by “tuning” the spring to the patient’s specific ankle stiffness.

A constant volume analysis was used to determine the necessary PAM [12]. In particular, its length diameter and service pressure was found so that moment was generated about the ankle in the sagittal plane equal to the value of the deficient moment. For this study, data from a 7.5 year old patient weighing 29 kg (63.9 lbf) was used. For this child, the deficient moment would be 7.73 N·m (68.4 lbf·in), if the device were placed 0.076 m (3 in) posterior to the ankle joint. The necessary force output of the PAM would then be 101.4 N (22.8 lbf) operating at 55 psi (379.2 kPa). A Festo 534202 Pneumatic Artificial Muscle (PAM) was found to generate this force by using MuscleSim software (Festo USA, Hauppauge, NY).

A supply of pressurized air is needed to activate the PAM. Stevens et al., showed that only 5% of the active time of a child with CP is spent in the high activity range, and 67% and 28% of the time is spent in the low and moderate activity [13] such as walking. Comparison of the time it takes to pressurize, activate and deactivate the PAM suggests that the moderate activity range (16 to 40 steps per minute) may be achieved. The device was designed with a targeted range of 20 steps per minute which results in a minimum flow rate of 4.81 LPM of air needed to be supplied by the mini-pump. Thus a GTA-20RNS mini-pump (Pacific Air Engineering, Lake Forest, CA) was selected running on 24VDC power. Besides be able to supply the needed flow rate, this pump is relatively quiet with a rating of 45 dB (equivalent to a computer). Furthermore, it is lightweight (1.76 lbf).

In order to deliver the necessary flow rate, an air reservoir is necessary. By employing standard fluid flow analysis, a reservoir of $2.406 \times 10^{-4} \text{ m}^3 (0.085 \text{ ft}^3)$ was found to be necessary. Of this reservoir volume, $4.813 \times 10^{-4} \text{ m}^3 (0.017 \text{ ft}^3)$ is required to actually activate the PAM.

**PAM Design Validation**

A special test fixture was designed and built for the purpose of ascertaining the clinical response of the PAM (Figure 3). This response is nonlinear and the force created reaches a maximum at an initial contraction but drops to zero when the PAM reaches its maximum contraction [8]. To acquire this response, an accelerometer was attached to the moving end of the PAM. With the moving end pushing against a compression spring of known stiffness, and the accelerometer measuring the acceleration of the moving end, the force output of the PAM was readily determined.
Device Dynamic Modeling

The dynamic response of the PAM driven orthotic is needed for proper control of the device. In particular, the PAM must be activated and deactivated at the appropriate portion of the gait cycle. Thus, a control system to track motion of the foot is needed. In order to establish the algorithm for this control system, a model that will predict the motion of the foot is needed so that the deviation of the motion from normal may be established.

The foot model (Figure 4) is a two degree of freedom system in the sagittal plane modeled as rigid body links with frictionless joints [9]. This model will simulate motion of the foot and predict the deviation from normal for the patient. A similar model but which includes the weight of the PHAFO (3.77 lbf) is used during actual clinical use of the device, though the weight of the PHAFO is not significant compared to the weight of the leg and foot.

In the model, K and A are respectively, the center of the knee and ankle joint. For each link i = {K,A}: \( l_i \) is the length of the link, \( C_i \) the center of mass of link \( i \), \( r_i \) the distance from joint \( i \) to \( C_i \), \( \theta_i \) is the joint angle, \{ \( \hat{e}_1 \) and \( \hat{e}_2 \) \} are body coordinate frames for link \( i \) and \{ \( \hat{x}_w \) and \( \hat{y}_w \) \} are an inertial world coordinate frame. The variables \{\( d_x, d_y \)\} represent the distance from the inertial coordinate axis to the knee joint and the constants \( h_1 \) and \( h_2 \) are distances relating to the foot as shown in the figure.

By applying fundamental kinematics to the link one obtains in the body frame equations,

\[
\ddot{P}_{k,e_k} = R_{w,k}^T \ddot{d}_{w,k} + \left( \Omega_k^2 + \dot{\Omega}_k \right) \mathbf{r}_k \\
\ddot{P}_{A,e_A} = R_{k,A}^T \ddot{d}_{w,k} + R_{k,A}^T \left[ \left( \Omega_k + \dot{\Omega}_k \right) \left( \mathbf{I}_k + R_{k,A} \dot{R}_{k,A} \right) + 2 \Omega_k \mathbf{R}_{k,A} \Omega_d \mathbf{R}_{k,A} + R_{k,A} \left( \dot{\Omega}_d + \Omega_d^2 \right) \right] \mathbf{r}_d
\]

where \( \ddot{P}_{k,e_k} \) and \( \ddot{P}_{A,e_A} \) denote the acceleration of the center of mass of link \( k \) and link \( A \) in the frames \( k \) and \( A \), respectively. Accelerometers attached to the tibia (link \( k \)) and foot (link \( A \)) will measure accelerations \( \ddot{P}_{k,e_k} \) and \( \ddot{P}_{A,e_A} \). Gyrosopes will measure \( \Omega_k = R_{w,k}^T \dot{R}_{w,k} \) and \( \Omega_d = R_{k,A}^T \dot{R}_{k,A} \) [15]. These quantities are transfor-
Information matrices involving the orientation (angles) and angular velocities of the limb segments.

Patient data from the Center for Motion Analysis at Orthopaedics, Medical College of Wisconsin (MCW) for normal gait and gait of a child with CP, was used to validate the dynamic model given by equation set (1).

RESULTS AND DISCUSSION

PAM Design Validation

Plots of the acceleration, velocity, and displacement (stroke) of the moving end of the PAM were acquired (Figure 5) under applied pressure. Unpressurized the PAM returns to its nominal length in less than 1 sec which matches the temporal requirement to reactivate the PAM at the proper point in the gait cycle. A maximum displacement of 1.55 in (0.0406 m) is attained in 0.22 sec, while a maximum velocity of 15 in/s (0.381 m/s) is achieved in 0.1 sec. The maximum acceleration of 400 in/s$^2$ (10.16 m/s$^2$) is attained in 0.005 sec.

![Displacement](image1.png) ![Velocity](image2.png) ![Acceleration](image3.png)

Figure 5: Dynamic response of the PAM: (a) displacement, (b) velocity and (c) acceleration.

The measured displacement was applied to numerically determine the force created by the PAM. The correlation between the force and stroke from testing of the PAM is shown in Figure 6. The force response is linear, and 32 lb (142.3 N) is the greatest force at 1.55 (0.039 m) in stroke. It takes about 0.3 sec to reach the maximum force.
Device Dynamic Modeling

Figure 7 shows the output of equation set (1) using patient data from the Center for Motion Analysis at Orthopaedics, Medical College of Wisconsin (MCW) for normal gait (top) and gait of a child with CP (bottom). At push-off (57-66% of gait), plantarflexion is reduced for the CP patient by 9.4% compared to normal (range: 0.283 ft to 0.375 ft).

Designing a powered orthotic device which can provide supplemental power to make up for the defective power and improve the GRF2 peak is highly possible according to the correlation of the displacement and the stroke in Figure 5a and the relation between the force and the stroke in Figure 6.

Nonlinear analysis of the curve in Figure 5 and linear analysis of the curve in Figure 6 point out that the maximum force of 32 lb (142.3 N) was achieved by the PAM in the design at the pressure of 55 psi (379.2 kPa) in 0.3 sec with a stroke of 1.55 (0.039 m). Based on the testing, the maximum force is higher than the design force (28 lbf), so the PAM need not be pressurized to 100% capacity.

By considering the volume of the air reservoir and mass flow rate it can be shown that filling the tank to the required air volume for PAM activation takes about 6 sec. But, the time to activate the PAM is 0.3 sec, so the time required to activate the PAM is available in the gait cycle. Therefore, filling the tank and activating the PAM in the time needed to match the gait cycle is possible.

The results in Figure 7 indicate that it is practical to model the motion of the powered orthotic using dynamic analysis with gait data measured in the clinic as input to the model. The dynamic model will predict the reduced push-off in the CP gait. Coupling of this model with a feedback control system facilitates active control of the device, so that the PAM is activated and deactivated at the proper time in the gait cycle thereby providing the deficient power necessary for a normal gait.

Conclusions

The goal of the study was to develop a new powered orthotic that is capable of generating additional power to assist gait in CP children. This supplemental power will make up for deficient power needed to improve the gait at push-off. A pneumatic device was implemented. The output of this device is nonlinear and its behavior was
validated in the laboratory. As traditional orthotics are not capable of generating augmented power at push-off, the design has tremendous potential to impact gait at the third rocker despite the CP patient’s reduced muscle strength and increased spasticity. The device is currently being tested in the clinical setting.

Limitations
The response of the PAM was obtained in the laboratory in a controlled environment. Furthermore, a simple linear control system was used for the design, by simply opening a valve and activating the PAM. However, kinematic and kinetic response is nonlinear and a non-linear controller should be implemented. The PAM as well as the rest of the system should be validated in a clinical setting. At present, this validation is proceeding with a much larger patient population and a nonlinear controller.

Author’s Contributions
All the authors contributed to the writing of the manuscript. Drs. Rizza and Luo developed the design of the device. Dr. Rodriguez developed the dynamic model and performed the numerical simulations. Drs. Liu and Wang reviewed and analyzed clinical data. Mr. Yang assembled the device and performed the various tests.

References