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Design and Evaluation of a Hybrid Passive and Active Gravity Neutral Orthosis (GNO)

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Abstract— **Neuromuscular diseases (NMD), including Spinal Muscular Atrophy (SMA) and Duchenne Muscular Dystrophy (DMD), result in progressive muscular weakness that often leaves patients functionally dependent on caregivers for many activities of daily living (ADL) such as eating, bathing, grooming (touching the face and head), reaching (grabbing for objects), and dressing. In severe cases, patients are unable to perform even the simplest of activities from exploring their 3D space to touching their own face. The ability to move and initiate age appropriate tasks, such as playing and exploration, are considered to be of vital importance to both their physical and cognitive development. Therefore, to improve quality of life and reduce dependence on caregivers in children and young adults with NMD, we designed, built and evaluated an assistive, active orthosis to support arm function. The goal of this project is the development and evaluation of a mechanical arm orthosis to both encourage and assist functional arm movement while providing the user a sense of independence and control over one's own body.**

I. Introduction

Spinal Muscular Atrophy (SMA) is a genetically determined motor neuron disease that often presents in infancy or childhood. The most severe form of the disease, occurring in infancy, remains the leading genetic cause of infant death today [1]. SMA is an autosomal recessive disorder that affects motor neurons and the motor units associated with them, causing muscle atrophy and weakness. [2]. A clinical classification of SMA is used to help describe the different phenotypes, with the most severe form, SMA type 1, beginning in early infancy and the least severe form, SMA type 3, later in childhood and adulthood [3].

Duchenne muscular dystrophy (DMD) is an X-chromosome inherited neuromuscular disease that results in progressive loss of function due to muscle fiber deterioration and is usually diagnosed between 2 and 6 years of age. DMD is the most common of the childhood muscular dystrophies with an incidence of 1:3300 male births. Progressive muscle weakness eventually results in the inability to walk and perform ADL [4], [5]. Both SMA and DMD affect proximal or shoulder muscles more than distal muscles. This results in impairments in motions that involve moving one's arms against gravity leading to losses in range of motion and functional movement.

Currently available assistive devices do not adequately address the wide range of muscle weakness in children with NMD. Passive, or non-powered, orthosis devices may be favored because they have a simple design, are cost-effective, and allow for free 3D movement of the arms for certain patients [6], [7]. One example of a commercially available device is the Wilmington Robotic Exoskeleton (WREX) [8]. Passive orthosis devices, such as the WREX, normally use the elastic energy of rubber bands or springs to achieve anti-gravity motions. However, an inherent limitation is that the user must possess some minimum muscle strength to overcome friction and balancing forces. A previous study in patients with NMD suggested that users in Brooke Scale categories 3 to 5 (i.e. those with moderate weakness) prefer a passive orthosis [9]. This suggests some amount of anti-gravity movement is necessary to use passive devices.

For patients who are too weak to perform anti-gravity motions, the development of an active, or powered, orthosis is necessary [8], [9]. A powered orthosis uses a motorized component to assist in anti-gravity movement. The development of such a device, which is both practical and clinically relevant, has proven to be difficult. In addition, patients tend to look less favorably upon active orthosis devices that have complex designs and bulky appearances [10]. Though a few design concepts and models have been developed (Motorized Upper Limb Orthotic System (MULOS) [11], Golden arm [12]) most are not commercially available [13].

The current study reports on a hybrid gravity neutral orthosis (GNO) that provides both passive and active assistance to the patient's own ability to move their arms. A simple and cost-effective hybrid design was implemented with an intuitive control system to operate the active components. To target a wider range of disease severity, the GNO control system can be tailored to a patient's muscle strength. Mounted on a wheelchair, the GNO supports and counters the weight of the patient's arms to create a sense of weightlessness. Horizontal movement is aided by a passive system while vertical (anti-gravity) movement is assisted via

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an active, motorized component. The feasibility and effectiveness of the GNO device was evaluated by a multi-disciplinary team consisting of neurologists, physiatrists, physical therapists, and biomedical engineers.

II. Methods

A. Gravity Neutral Orthosis

Fig. 1 shows a schematic of the different components of the GNO. Each component is described in further detail.

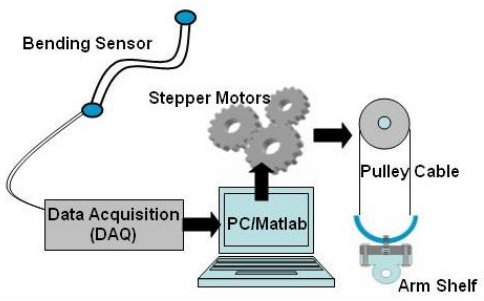

Fig. 1. GNO components schematic.

1) Bi-Directional Flexible Bending Sensors: Developed by Images Scientific Instruments, Inc., these sensors are variable resistors that change in resistance when they are bent or flexed in either direction. The sensors at rest (unbent) have a nominal resistance that increases when bent in one direction and decreases in the other, providing a simple and intuitive control mechanism to operate the motor-assisting anti-gravity movements. Strapped to the dorsal surface of the hand and wrist, the sensor bends with wrist motion to raise and lower the arm. For significantly weaker patients with poor wrist control, the sensor can be attached to the finger.

2) Data Acquisition (DAQ)/Matlab: A DAQ (National Instruments Corporation) was used in conjunction with Matlab (The MathWorks, Inc.) to acquire and process sensor data and drive the motors. Through Matlab, the sensitivity of the bending sensor can be adjusted for each individual patient. For Patient 1, who had better wrist control, a lower sensitivity was used requiring greater wrist flexion or extension to trigger the motor. A higher sensitivity was used for Patient 2 allowing him to initiate motor response with smaller wrist movements.

3) GeckoDrive/Stepper Motors: The output signal from the DAQ/Matlab communicates with the motor controller (GeckoDrive) which then controls the stepper motors (Vexta). The motor is connected to a pulley that moves the front of the arm shelf up and down. The motorized assist is installed to allow flexion and extension at the elbow in patients who cannot overcome the effects of gravity by retracting and extending a cord in a marionette-style configuration.

4) Frame and Arm Shelf: The frame and arm shelves were designed and built at the Biomedical Engineering Machine Shop at Columbia University. A polycarbonate brace supports the forearm from the elbow to the wrist. The brace was attached to a frame that provides low friction motion in a fixed plane which may be adjusted. The frame consists of a vertically adjustable aluminum base that supports a linkage consisting of two steel arms and three joints, each with one degree of freedom in the horizontal plane. The joints incorporate plain bearings for radial loads and thrust bearings for axial loads.

B. Participants

Two patients with DMD were enrolled in the study (Table I). Both patients were diagnosed with DMD at a young age, are non-ambulatory, and use a power wheelchair. All patients were recruited through the Pediatric Neuromuscular Clinic at Columbia University Medical Center. After being given the details of the research study, patients signed informed consents, approved by the Columbia University IRB.

TABLE I
Patient Data

Patient	1		2	
Age (years)	18		15	
MMT Strength	**R**	**L**	**R**	**L**
Shoulder Abduction (Deltoids)	0/5	0/5	0/5	0/5
Elbow Flexion (Biceps)	2/5	2/5	2/5	1/5
Elbow Extension (Triceps)	2/5	2/5	2/5	1/5
Wrist Flexion	3/5	3/5	3/5	3/5
Wrist Extension	3+/5	4-/5	3-/5	3-/5
Finger Flexion	4/5	5/5	3+/5	3/5
Finger Extension	4+/5	5/5	3-/5	3-/5
Finger Abduction	3/5	3-/5	3/5	2/5

Manual muscle testing (MMT) and range of motion (ROM) assessments of both arms were performed at the beginning of the study. MMT evaluates the strength of muscle groups responsible for a particular limb motion. The grading scale established by the Medical Research Council (MRC) was used. Muscle weakness can cause imbalances between agonist and antagonist muscle groups resulting in joint contractures and muscle tightness which further impair function. ROM assessments identify limitations to passive motion. The results of the MMT are listed in Table 1.

Both patients had significant arm weakness resulting in limitations in performing ADL, such as bringing their hands to the mouth for feeding. Patient 1 had greater distal muscle strength of the wrist and fingers than Patient 2. Patients also had significant limitations in elbow and forearm ROM and as a result could not extend or rotate their arms fully.

C. Experimental Procedure

Patients with a proximal arm weakness of less than 3 out of 5 on the MRC scale were recruited from the Columbia University Pediatric Neuromuscular Clinic. A minimal amount of active wrist or finger motion was required to control the bending sensors.

In clinic, the frame was securely mounted to the back of their wheelchair, and the operation of the GNO was explained, followed by an approximate 30 minute acclimation period. The motor speed was initially set very low and increased as patients became accustomed to the device. The evaluation of motor function and movement was then performed with and without the GNO. A physical therapist observed the feasibility and ease of getting into the GNO and the movements facilitated by the orthosis.

The Jebsen Taylor Hand Function Timed Test is a standardized assessment that evaluates functional activities of the arm. Time taken to write a 3rd grade level sentence with 24 words, flip over five 3"x5" index cards, and place small objects (two paper clips, two bottle caps, and two pennies) into a metal can, with their dominant hand was recorded with and without the GNO.

III. Results

The frame was successfully mounted onto the back of both patients' wheelchairs (Fig. 2a). The height and length of the device was adjusted so neutral, erect spinal alignment was maintained and so that the shoulder was not elevated or depressed. The support that the device provided the arm enabled both patients a greater active range of motion in the horizontal plane (Fig. 2b).

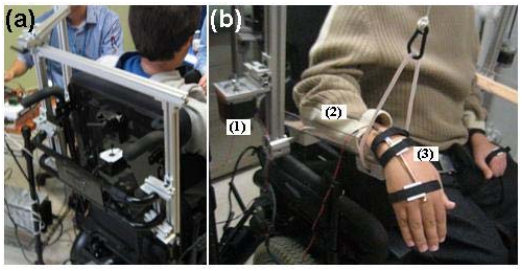

Fig. 2. (a) Frame properly mounted on Patient 1's wheelchair (b) Patient 2 in GNO – motor (1), arm shelf (2), bending sensors (3).

After verbal instruction and a few practice trials, patients demonstrated good control of the motor-assisted vertical motion by extending and flexing their wrists. Though Patient 1 could extend his wrist above neutral Patient 2 could not and therefore, the control system and sensitivity had to be adjusted to accommodate for this weakness. Fig. 3 demonstrates the three positions Patient 2 used to control the motor: lowered (Fig. 3a), resting (Fig. 3b), and raised position (Fig. 3c). In the lowered position the motor responded by lowering the arm, and in the raised position the motor responded by raising the arm. At resting or neutral position, the motor did not move, as designed.

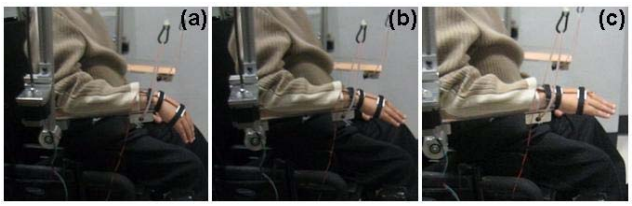

Fig. 3. (a) Lowered position, (b) Resting position, (c) Raised position.

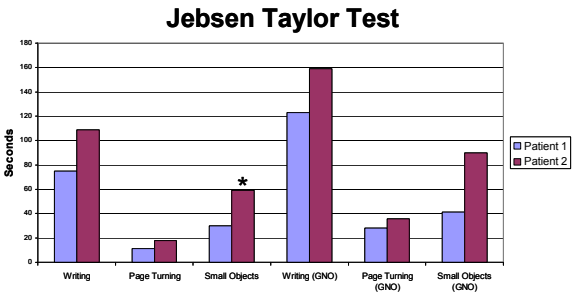

Fig. 4. Jebsen Taylor Tests for Patient 1 and 2 with and without GNO. *Patient 2 used both hands to complete this task without the GNO.

For each of the Jebsen tasks, the time to completion increased for both patients when attempting the tasks inside the GNO (Fig. 4). Overall, Patient 1 took less time than Patient 2 to complete each task with and without the device.

Patient 2 could not complete the small objects tasks using one hand. Instead, he propped up his left hand to the rim of the can using his right hand and transferred the items from one hand to the other (Fig. 5a). Within the device however, he was able to complete the task with one hand even though it took him longer (Fig. 5b).

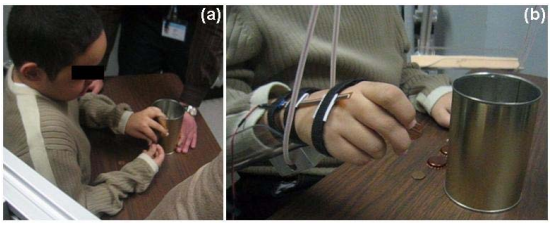

Fig. 5. (a) Patient 2 lifting a paper clip using both hands without GNO and (b) a penny using one hand with GNO.

Patient feedback on how to improve the GNO was recorded and discussed within multi-disciplinary team meetings. Patients recommended a more efficient mounting configuration, and a smaller, less conspicuous frame design. A second modified GNO version 2 was then designed and built (Fig. 6). Although the working mechanisms remain similar, the frame was redesigned to address their concerns. The new GNO frame no longer mounts to the back of the wheelchair, hanging over the shoulder. Instead, it replaces the wheelchair's existing arm rest. In addition, a new brushless DC motor was used instead of a stepper motor for its higher torque. The motor generates motion directly at the elbow through a worm gear transmission that has the benefit of preventing the patient from unintentionally moving the arm shelf.

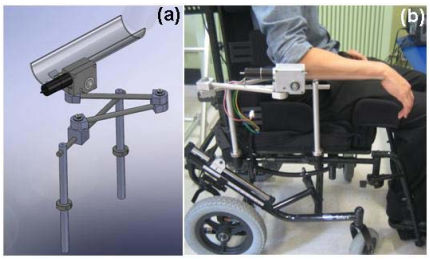

Fig. 6. (a) New model design GNO version 2 (b) New GNO mounted on a wheelchair.

IV. Discussion

Feedback from patients was generally positive and both expressed interest in continuing to test the second generation GNO device that was recently developed. The GNO enabled patients to have greater active ROM in the horizontal plane. However, this did not translate to immediate and measurable improvements in functional movements, which may be due to lack of a learning period with the device. A 30 minute acclimation period was insufficient and given more time, we predict that patients would have become better acclimated with the device, thereby improving their ability to perform functional activities. Physical limitations of the device also impeded functional movements. The positioning of the arm shelf in the first prototype did not fully allow for hand-to-face activities, which will be possible with the next generation prototype. Patients also stated that the control system for anti-gravity movement felt physiologic and was easy to use. It has been reported that a simple control system is critical for a successful power orthosis [13].

Using the GNO, each task of the Jebsen Test (Fig. 4) took longer to complete. It was observed that both patients had developed adequate compensatory mechanisms for losses in function. For example, Patient 1 was able to bring a cracker to his mouth by using the momentum of his upper body and trunk to swing his arm across his body. Although patients demonstrated good motor control using the GNO, they performed better on the Jebsen Test using their well adapted compensatory mechanisms. More practice time to adjust to the GNO may improve scores in the future.

Patients were unable to reach midline when inside the GNO, limiting their free horizontal movement. The frame configuration did not allow sufficient arm extension and the bulkiness of the frame and arm-shelf interfered with wheelchair components, such as the torso support pads. Horizontal arm motion across midline was necessary to perform the Jebsen tasks efficiently. For instance, in Fig. 7,

Fig. 7. Patient 1 placing a paper clip into a metal can (Jebsen Test).

Patient 1 had to use his left hand to slide the items along the table for his right hand to pick them up, thus increasing the time required for the task.

For the writing and page turning tasks of the Jebsen Test, the hands hovered slightly over the table which made precise hand control difficult. This type of interference was also seen in trials using the WREX [8]. When picking up small objects, completion times could have improved if the speed of the motor was set higher.

Although patients were faster on the Jebsen Test with their compensatory mechanisms, the impact of the GNO on endurance activities needs to be explored. Strategies utilized by patients to compensate for weakness require increased energy expenditure. Therefore, while the patients performed each of the tasks faster outside of the device it is predicted that, if endurance was quantified, the GNO would have increased endurance.

V. Conclusion

A practical and potentially beneficial mechanical arm orthosis that encourages and assists functional arm movement has been developed. The GNO allowed for weaker patients with neuromuscular disease greater ROM and improved motor control. The unique control mechanism can be tailored and adapted to an individual's strength and active range of motion. Modest improvements in the quality of movement were noted, but functional movements were limited by the initial GNO design.

A new design has been implemented and will be tested in the near future. The new device will not only address many of the issues previously mentioned to improve Jebsen scores, but also increase both horizontal and vertical ROM, thereby providing more meaningful functional motions.

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