Case Report

Walking with a hybrid orthosis system

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Objective: The purpose of this case study was to determine the functional effectiveness of the hybrid orthosis system (HOS) for sit-to-stand and walking compared with the reciprocal gait orthosis (RGO) alone in a subject with significant orthopedic abnormalities.

Design: A subject with complete T7 paraplegia and a 13 cm leg length discrepancy was implanted with 14 intramuscular electrodes and fitted with a custom isocentric RGO. The subject was instructed in the use of the HOS and a two wheeled walker in the home and community settings.

Main outcome measures: Using the Functional Independence Measure (FIM), and the Borg exertion scale the subject's level of independence and his perceived exertion was determined as well as the safety and efficacy of system use in the community.

Results: Results show that the HOS provided safe, independent ambulation with a two wheeled walker and met established criteria for limited community use. Walking in the RGO alone was feasible, however, the addition of functional electrical stimulation (FES) allowed this subject to walk farther and with less perceived exertion.

Conclusion: This case study suggests that a hybrid orthosis system can be an effective clinical option for individuals with significant orthopedic complications that might otherwise contraindicate the prescription of either conventional braces or FES alone.

Keywords: spinal cord injury; functional electrical stimulation; reciprocal gait orthosis

Introduction

Researchers have been developing FES systems for restoring lower extremity function in persons with paraplegia for many years. FES provides supportive forces for standing and propulsive forces for walking by exciting the intact peripheral nerves causing paralyzed muscles to contract. Stimulation systems using surface or implanted muscular electrodes are capable of restoring mobility in the form of back and side stepping, walking and stair climbing.^{1–3} FES employs the synchronous stimulation of motor units at frequencies above normal physiological values, but this leads to rapid muscle fatigue affecting the duration over which FES can be used.^{4,5} Destabilization of the joints due to muscular fatigue limits the functional use of FES to short durations or distances, prohibiting extended standing tasks or community ambulation.

The reciprocal gait orthosis (RGO) is among the most widely used orthotic devices for the restoration of standing and walking in persons with paraplegia.^{6–8}

This sophisticated mechanical orthosis provides a rigid exoskeleton which stabilizes both the trunk and lower extremities and permits reciprocal gait through mechanical linkages. Functionally, the RGO allows the user to stand for extended periods of time at minimal metabolic cost for the performance of single or dual handed activities.^{6,7} The RGO has limited use in the adult population due to difficulty with the sit-to-stand task and excessive energy cost and stress on the arms during ambulation.⁸

To provide prolonged standing and ambulation with minimal metabolic energy consumption and upper extremity exertion, researchers have endeavored to combine the best qualities of an orthosis with FES.^{8–10} This combination is termed a hybrid orthosis system (HOS). HOS's combine the stability and antigravity support of an orthosis such as an RGO with the propulsive forces provided by FES. The inherent trunk support of the RGO combined with the extension locking mechanism of the knee joints allows the user unlimited standing periods without stimulation. The addition of FES allows the user to stand up in a fluid and controlled manner with reduced upper

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extremity exertion. Recent research in application of various types of HOS's supports the idea that subjects are able to ambulate greater distances with less energy consumption than with the RGO alone.⁹⁻¹¹

The purpose of this case study was to determine the functional effectiveness of the HOS compared with the RGO alone for a subject with a T7 level SCI and complicating orthopedic problems. Utilizing the Functional Independence Measure (FIM) and the Borg exertion scale, the tasks of sit-to-stand and ambulation were rated. The use of forearm crutches *versus* a two wheeled walker was also investigated. In addition, the distance ambulated with the HOS to produce fatigue was looked at in an effort to determine system use for community ambulation.

Methods

Case history

The subject is a 36-year-old male who sustained a T7 complete SCI in a sledding accident in 1976. The upper extremities had normal strength, range of motion and function. Spasticity in the lower extremities was mild to moderate and did not interfere with functional activities. Both hips were fractured in separate traumatic events in 1987 requiring open reduction and internal fixation. Due to poor healing of the right hip, the subject incurred a 13 cm leg length shortening on the right. Prior to acceptance into the project, the subject underwent physical therapy for conventional brace walking using an Isocentric [Center for Orthotics Design Inc., Redwood City, CA, USA] RGO and at the end of 13 months was able to walk up to 10 m with close supervision using a standard walker.

Methods

Muscles implanted included: quadriceps femoris, gluteus maximus, gluteus medius, tensor fasciae latae, iliopsoas, sartorius and gracilis. All muscles were implanted bilaterally except that absence of the right femoral head, neck and proximal femur made implantation of the iliopsoas and gluteal muscles ineffective on that side. Electrical stimulation patterns for sit-to-stand and ambulation were developed using PC based software (Figures 2 and 3). The subject was provided with a custom fit RGO with a 13 cm shoe lift and hip joints capable of abduction to make transfers easier. The total weight of the brace was 16 lbs (Figure 1).

The subject was trained in sit-to-stand and ambulation with the HOS and a two wheeled walker and crutches on various surfaces including: linoleum, carpet, concrete sidewalks, gravel and grass, ramps and curb cutouts. He was instructed in donning and doffing the system on a bed and in his wheelchair.

The FIM was used to compare the functionality of the HOS with the RGO without stimulation for ambulation and sit-to-stand. The Borg Scale, a category-ratio perceived exertion scale, has been

Figure 1 Subject standing in RGO with right shoe lift

widely used to study perception of exertion during exercise in laboratory, occupational and clinical settings.¹² This test was chosen in an attempt to determine system usability from the subject's perspective and for its ease of administration and familiarity in the clinical setting.

Distance and velocity measurements were taken to assess the feasibility of using the hybrid system in the community. In a study performed in Los Angeles County, it was found that distances to access frequently used community sites such as physician's offices, drug stores, banks and restaurants were found to be an average of 332 meters.¹³ It was further reported in the study that street crossing signals permitted an average of 20.5 s to walk from curb to curb, which required a walking velocity of 1.32 m/s. A distance of 300 m was chosen to represent moderate community walking distances.

Data collection

Data for the FIM and rate of perceived exertion (RPE) were collected in the laboratory during five separate test sessions over the course of 2 weeks. Data were

collected both with FES and without, for ambulation with forearm crutches and with a two wheeled walker. The subject was asked to give his RPE immediately after standing to rate exertion with standing and immediately after sitting down to rate his exertion with walking.

The actual test trials consisted of asking the subject to rise from his wheelchair, walk at a self chosen pace for 6 m, turn and walk back to his chair and sit down. The subject was supervised by the same person at every trial who was asked to give as much assistance as he felt was needed.

RPE and FIM scores were recorded for the four tests on each of the 5 days. The mean and standard deviation were calculated and a student *t*-test used to determine the significant difference between walking with the RGO alone and the HOS with walker or crutches for support.

Data collection for distance and velocity measurements was taken on 12 separate days (3 days for each of the four distances). The subject was asked to walk either 30, 50, 100 or 300 m as many times as possible before complete fatigue per subjective report. He was given a 5 min rest between each measured walk. This was performed while leaning against a wall with the FES shut off. The subject chose to use forearm crutches stating he could walk fastest with this device. A Kruskal-Wallis one-way analysis of variance was used to determine significant difference in total distance between walking short (30 m and 50 m) distances and long (100 m and 300 m) distances.

Results

The subject had a FIM score of 6 (modified independence) for sit-to-stand and ambulation using a two wheeled walker and an average score of $4.4 \pm .3$ (occasional contact assist) for the same activities with crutches. These results were consistent whether FES was used or not.

Results of the RPE indicated the subject found sit-to-stand with FES or without to be in the 'very light'

Table 1 Average total distance and velocity of three sessions for each trial distance using HOS

<i>Trial distance</i>	<i>Average total distance</i>	<i>Average total velocity</i>
30 m	430 ± 76	$0.42 \text{ m/s} \pm 0.02$
50 m	417 ± 76	$0.36 \text{ m/s} \pm 0.05$
100 m	300 ± 0	$0.36 \text{ m/s} \pm 0.03$
300 m	290 ± 17	$0.29 \text{ m/s} \pm 0.02$

exertion range. Walking was perceived to be significantly easier ($P=0.05$) in the 'fairly light' ($\text{RPE} = 10.4 \pm 1.5$ $n=5$) range with FES *versus* 'somewhat hard' ($\text{RPE} = 12.8 \pm 0.4$ $n=5$) range without FES when using a walker. When using crutches, walking was perceived to be significantly easier ($P=0.05$) in the 'somewhat hard' (13 ± 1.5 $n=5$) range with FES and 'hard' ($15 \pm .7$ $n=5$) range without FES.

Table 1 shows the total averages of 3 days ambulation distance and velocity for each trial distance. The total average distance walked at short distance trials (30 m and 50 m) with rest stops was significantly ($P=0.003$) farther than during distance trails of 100 m and 300 m, indicating that the subject was able to walk a farther total distance when given 5 min rests more frequently. Additionally, the subject walked faster when walking shorter (30 m) distances between rests.

Discussion

Although not conclusive, the results of this study highlight advantages a HOS can offer a person with paraplegia and a significant skeletal deformity. Functionally, the subject walked independently in his home with a two wheeled walker at a 'fairly light' perceived exertion rating. He was able to walk 30 m up to 14 times given 5 min standing rest periods indicating unlimited household type use is feasible.

Figure 2 FES pattern for standing up. The height of the shaded area represents the pulse width used for each muscle with maximum of 150 microseconds. Due to a Girdlestone procedure on the right hip, the knee joint was locked and stimulation was not provided to the right lower extremity during the sit-to-stand maneuver. Once the subject was standing and the hip and knee joints were locked, the stimulation could be turned off to provide energy efficient standing

Figure 3 FES pattern of one complete gait cycle for walking with RGO. The pattern consists of bursts of pulses of 20 mA in amplitude causing muscles to contract. The frequencies of stimulation ranged from 16 to 33 pps at pulse widths shown by the height of the shaded area with maximum of 150 microseconds. The progression through the pattern was activated by a hand switch at right heel strike (RHS) and left heel strike (LHS). Duration of the gait cycle was 1.65 s plus any delay introduced by the subject pressing the hand switch

The limiting factor for long distance walking reported by the subject was upper extremity and cardiovascular fatigue. Walking speeds of 0.3 m/s fall short of the 1.3 m/s allotted at automated crossing lights but would allow the subject to complete tasks such as going to the post office or restaurants in a reasonable amount of time and with an exertion level acceptable to him.

From the subject's perspective, the most important aspects of the HOS were (1) that he was able to walk for exercise in his home any time he chose and (2) he obtained an independent means of walking using 'fairly light' exertion for household distances. This allowed him to get up from his chair easily and stand to perform tasks in his home. He reported that he does not use the HOS in the community due to the cumbersome nature of the brace which makes transfers in and out of the car difficult. Also, wearing the brace on the outside of his clothing was not acceptable to him.

Redesigning of the brace to decrease the weight, decrease friction in the hip and knee joints for smoother movements, and increase flexibility of the trunk portion would make brace wearing more appealing and functional for the user. Notwithstanding, this hybrid system shows promise and these barriers can be overcome through the improvement of technology and brace modifications.

Conclusion

This case report considers the efficacy of a hybrid orthosis system for a subject with significant ortho-

pedic abnormalities. Traditionally, this subject would have been excluded from the use of FES or RGO alone and never have been given the opportunity to walk, illustrating hybrid intervention may be applicable to a wider population than either FES or bracing alone. With the aid of the HOS, the subject walked farther and perceived walking to be easier than with the RGO alone. He became functionally independent in his home with the system and with supervision was able to ambulate with crutches for community distances of up to 430 m.

This case study illustrates the potential usefulness of the HOS for walking and standing in the home or work environment. A brace which would provide the user with comfortable, all day wearing time would make the HOS an appealing and highly functional adjunct to wheelchair use for persons with paraplegia. Continued efforts should be focused on creation of a safe, easy to use, cost and energy efficient system which provides mobility for ambulation and stability for standing tasks. Further research is needed in the promising area of implantable FES systems and brace design.

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