New Bipedal Locomotion Option for Individuals with Thoracic Level Motor Complete Spinal Cord Injury

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Until now, wheelchair propulsion has been the most common mode of locomotion for individuals with a motor complete thoracic level spinal cord injury (SCI).[1] Using a wheelchair, individuals are often able to navigate around a properly modified home and workplace environment, perform many activities of daily living, and engage in some social and recreational activities. However, wheelchair seating posture reduces the opportunity for eye to eye social interaction with able bodied adults, does not load the legs in a normal manner, can promote joint contractures, lead to pressure sores, and increase the risk of shoulder overuse.

Other modes of locomotion such as knee-ankle-foot orthoses (KAFOs) have come up far short of even the standard set by the wheelchair. Difficulty donning/doffing, high energy consumption and potential for increased upper limb overuse can all be identified as causes for KAFOs' limited use only as a therapeutic intervention.

Functional Electric Stimulation (FES) systems may enable patients to ambulate for very limited distances. This technique also has many limitations including requiring functioning lower motor neurons (LMNs) for neuromuscular excitability and complete sensory loss to tolerate the significant electrical stimulus needed to achieve muscular contraction. In addition, electrical stimulation differs greatly from the physiological nerve impulse because in FES all motor units in a muscle group are stimulated simultaneously. This rapidly induces muscle fatigue and results in high-energy consumption. The functional performances of all these methods remain quite modest in comparison to normal gait due to very low walking speed and high-energy utilization.

An alternative here described is the use of an externally powered orthosis that facilitates independent walking and in some cases stair climbing.

Description of the ReWalk™ Exoskeleton Suit[2,3]

The ReWalk is a lower extremity, battery powered exoskeleton that allows individuals with thoracic or lower level motor complete SCI to walk independently. ReWalk contains independently computer-controlled bilateral hip and knee joint motors, rechargeable batteries, and a computerized control system carried in a backpack. ReWalk users fully control their walking through subtle trunk motion and changes in center of gravity positions. A sensor registers these changes, determines the angle of the torso, and generates a preset hip and knee displacement (angle and time) that results in stepping. The ankles are supported using simple double action orthotic joints that have limited motion and spring assisted dorsiflexion, adjustable through screw tension. ReWalk currently exists in two versions, ReWalk I for use in institutional set up and ReWalk P for use at home and in the community. ReWalk I is easily adjustable in height and width, has padded interfaces for calves and thighs, and a rigid pelvic frame linking the limbs. Padded

The ReWalk suit enables ambulation for those with thoracic level motor complete spinal cord injury. *Image courtesy of Argo Medical Technologies.*

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Velcro closures, shoes, and a waist belt are used to secure the user in the exoskeleton. ReWalk P is available in 4 sizes and multiple colors and is fitted by the manufacturer to match the patient anatomy. The same system, as previously described for ReWalk I, is also used to secure the user in the ReWalk P exoskeleton. Crutches provide standing stability, and the subject can interact remotely with the computer system handling a user-operated wrist pad controller that can command sit to stand, stand to sit, and walk activation.

Currently, there are two other commercial systems following on the tracks of ReWalk, but the unique manner in which the user is actively involved in controlling walking is only available in the ReWalk system. The specially designed software algorithm interprets a signal from the torso placed sensor and generates alternating limb coordinated motion to produce bipedal walking. As a safety feature, the system prevents two sequential steps of the same leg. During training, joint angle displacements for the knee and hip can be adjusted using an external computer to optimize the walking characteristics of the user. A manual training mode can be used to trigger steps bypassing the tilt sensor. The same mode of operation can be used to trigger sit-stand-sit transfers.

ReWalk is suitable for adults who have preserved bilateral upper extremity function after sustaining a SCI. Because the system is battery powered, completely untethered, and individuals are fully in control of when they step, ReWalk offers a real option to improve upon the current ambulation standard for individuals with thoracic level motor complete SCI. Moreover, because walking in ReWalk emulates upright bipedal walking, it may offer the potential to overcome some of the physical and psychosocial problems caused by the loss of natural walking. (Figure 1)

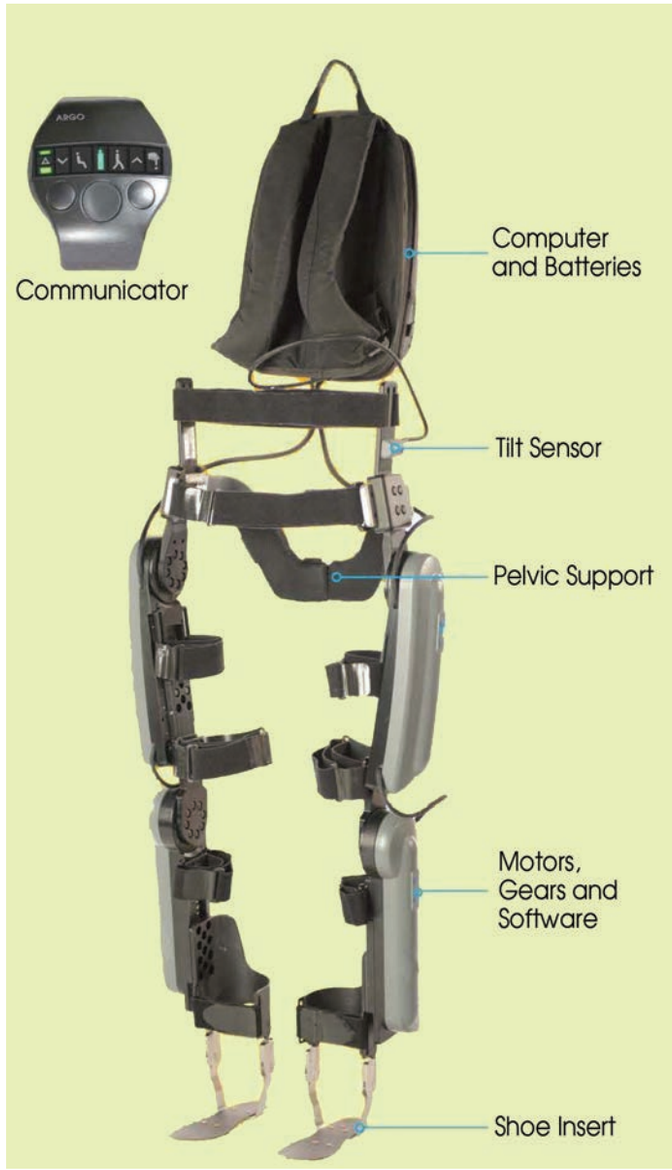

Figure 1. Components of Argo's ReWalk system. *Image courtesy of Argo Medical Technologies.*

Impact of the Loss of Walking for the SCI Population

Lack of standing, ambulation, muscle activity, weight bearing, and neuro-endocrine changes, all contribute to rapid and marked alteration in body composition. Individuals with SCI experience declines in muscle mass and bone density, as well as increases in adipose tissue. Additional complications, such as muscle atrophy, joint contractures, pressure sores, osteoporosis, increased spasticity, pain, edema, urinary and intestinal stasis, and carbohydrate, lipid and protein metabolism abnormalities may also be present.[4,5]

Non-recreational walking accounts for a significant fraction of activity for the average non-disabled adult. Lower physical activity levels have been observed after SCI resulting from lost motor function, lack of training during acute rehabilitation, decreased access to exercise facilities with adequate adaptive fitness equipment, limited time, and psychological factors. The physical de-conditioning resulting from largely sedentary lives of individuals with thoracic or higher level SCI is well documented.[5,6] Exercise has been shown to be an effective contributor to overall health maintenance, bone density, a proper level of muscle tone, cardiovascular fitness, regular bowel and bladder function, reduced risk for obesity, heart disease, and reduction of Type II diabetes for patients with SCI. Therapeutic exercise for individuals with SCI have several limitations. For example, they may have difficulty in exercise execution, insufficient cardiovascular stimulus, greater potential for injury, and they need specialized equipment. Individuals with thoracic level SCI who rely on wheelchair propulsion for locomotion and their arms for transfers may increase the likelihood of overuse of already taxed upper limb joints when performing upper body exercises including hand ergometry or weight lifting. Reduced work and leisure time after a SCI has been reported to reduce adherence to an exercise routine that is separate from, rather than a part of, the activities of daily living. Functional walking is an excellent means to accomplish exercise without requiring extra time commitments, but this is a difficult option—particularly for those with motor complete SCI at the thoracic or higher levels. ReWalk facilitates functional independent walking and may have a positive impact on many of the detrimental effects of spinal cord injury. In two recent publications, we have demonstrated the safety and tolerability of the device and some of the effects of training. Additional trials needed to demonstrate its impact on other physiological parameters are in the development stage.

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