SUMMARY OF CLINICAL RESEARCH INVOLVING THE ALTERG BIONIC LEG®

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At AlterG, we are committed to proper scientific investigation of the potential clinical and athletic performance benefits of using our devices. We are pleased to have multiple studies in clinically relevant areas currently underway by independent researchers, at highly reputable institutions in the U.S. and Internationally. Out of respect for the integrity of the scientific process, we will not cite specific authors or institutions until the studies have been published in peer-reviewed journals, presented at professional meetings, or until the author gives us permission. In the following sections, I will outline for you our new presentations or publications, previously published or presented research, present in aggregate format findings from studies already completed but not yet published. Additionally, I will outline the other available forms of clinical material, such as Case Reports, Case Series, Clinical Protocols, White Papers, and Clinical Guidelines.

**INTRODUCTION:**
An emerging area of neurorehabilitation is the use of robotic devices to enhance the efficiency and effectiveness of lower extremity physical therapy post-stroke. Many of the robotic devices currently available rely on computer-driven locomotive algorithms combined with partial bodyweight-supported treadmill training that drive reflex stepping with minimal patient intention during therapy. In this case series, we examined the effect of task-oriented mobility training in patients in a post-stroke chronic state using a novel, wearable, mobile, intention-based robotic leg orthosis.

**CASE PRESENTATION:**
Three individuals, all of whom had reached a plateau with conventional bodyweight-supported treadmill training, participated in task-oriented mobility therapy (1.5 hours, two to four times per week for four weeks) with a robotic leg orthosis under supervision by a physical therapist. Participant 1 was a 59-year-old Caucasian man, who had an ischemic left stroke six years previously with resultant right hemiparesis. Participant 2 was a 42-year-old Caucasian woman with left hemiparesis after a right stroke 15 months previously. Participant 3 was a 62-year-old Caucasian woman with a history of a right middle cerebral artery aneurysm with third degree sub-arachnoid hemorrhage 10 years ago. Immediately after training, all participants demonstrated improved gait speed (10 meter walk), stride length, and walking endurance (6 minute walk) compared with baseline measurements. Improvements were maintained one month after training. Timed up and go (TUG) and five times sit-to-stand were maintained for all three participants, with only one individual remaining outside the safety performance norm.

**CONCLUSIONS:**
Lower extremity training integrating an intention-based robotic leg orthosis may improve gait speed, endurance and community levels of participation in select patients in a post-stroke chronic state after plateauing within a bodyweight-supported treadmill training program. The wearable, mobile assistive robotic device safely supplemented supervised physical therapy including mobility and balance skill training.


**BACKGROUND AND AIM:**
Until recently, robotic devices for stroke rehabilitation had multi-joint designs that were often tethered to a treadmill for gait training. A new single-joint wearable robotic knee orthosis (RKO) has been designed that provides patient-initiated powered-assistance in untethered functional mobility. This case-series documents application of the wearable RKO in untethered functional training with stroke survivors.

**TECHNIQUE:**
Three ambulatory adult stroke survivors used a wearable RKO during 18 one-hour sessions within a six-week physical therapy program. Subjects were assessed with a variety of balance, gait, and functional tests including the Berg Balance Scale (BBS); six-minute walk test (6MWT); and Emory Functional Ambulation Profile (EFAP) pre-treatment, post-treatment, one-month and three-month follow-up.

**DISCUSSION:**
All subjects improved balance, gait and functional performances with mean individual improvements of 12.6% for BBS, 12.0% for 6MWT and 16.7% for EFAP post-treatment. No adverse events occurred. These three stroke survivors may have benefited from the task-specific functional training program augmented by RKO use.

**CLINICAL RELEVANCE:**
Physical therapists may find a wearable robotic knee orthosis useful for providing patient-initiated assisted movement for ambulatory chronic stroke survivors during functional task-specific balance and mobility training.

Towards more effective robotic gait training for stroke rehabilitation: a review. *Journal of Neuro-Engineering and Rehabilitation*. 9: 65

**BACKGROUND:**
Stroke is the most common cause of disability in the developed world and can severely degrade walking function. Robot-driven gait therapy can provide
assistance to patients during training and offers a number of advantages over other forms of therapy. These potential benefits do not, however, seem to have been fully realized as of yet in clinical practice.

OBJECTIVES:
This review determines ways in which robot-driven gait technology could be improved in order to achieve better outcomes in gait rehabilitation.

Methods: The literature on gait impairments caused by stroke is reviewed, followed by research detailing the different pathways to recovery. The outcomes of clinical trials investigating robot-driven gait therapy are then examined. Finally, an analysis of the literature focused on the technical features of the robot-based devices is presented. This review thus combines both clinical and technical aspects in order to determine the routes by which robot-driven gait therapy could be further developed.

CONCLUSIONS:
Active subject participation in robot-driven gait therapy is vital to many of the potential recovery pathways and is therefore an important feature of gait training. Higher levels of subject participation and challenge could be promoted through designs with a high emphasis on robotic transparency and sufficient degrees of freedom to allow other aspects of gait such as balance to be incorporated.


ABSTRACT
Recent studies have reported positive outcomes following use of the Tibion Bionic Leg (TBL). Here we investigated EMG changes during overground walking while wearing the TBL. In healthy participants, EMG modulation was reduced and EMG phasing was altered in proximal muscles while EMG amplitude was altered in distal muscles. Responses to the TBL in persons post-stroke were more subtle, but reveal EMG reorganization towards normal. Thus, functional improvements may result from repetitive practice with more appropriate EMG phasing and increased activation.


ABSTRACT
The ability to transfer from sitting to standing (STS) is central to independent mobility and presents a significant, unique challenge to individuals post-stroke with residual unilateral lower-extremity weakness. We examined the effects of a novel, wearable robotic lower extremity orthosis on STS transfer kinetics. The device appears to facilitate symmetry of limb force allocation during STS.

Vose, J., McCarthy, A., Tacdol, E and Horst, R. Modification of Lower Extremity Kinetic Symmetry During Sit-to-Stand Transfers Using a Robotic Leg Orthosis with Individuals Post-Stroke.