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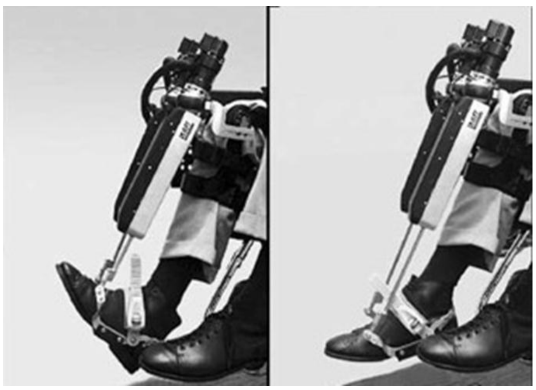
INMOTION ANKLEBOT™

(EXOSKELETAL ROBOTIC ANKLE SYSTEM)

Keywords: stroke rehabilitation, robotic device, impedance-controlled ankle robot

SUMMARY OF TECHNOLOGY



Picture 1: A-dorsiflexion (toe up) B- plantarflexion (toe down)

InMotion AnkleBot™ is a robotic exoskeletons system known as "Robotic Walking Coach" developed by Bionik Laboratories Corp used for lower extremities rehabilitation system for stroke or other neurology disorder (cerebral palsy, multiple sclerosis, spinal cord injury). [1]

The anklebot's proximal attachment is mounted anterior to an orthopaedic knee brace lined with foam pads and cushioned straps to maximize comfort and provide protection from skin irritations. Distal attachments are secured to a modified orthopaedic shoe. Additional protection is provided by pads where subjects indicated sensitivity to pressure. Shoe fit is aided with foam insoles and socks as required.

The procedure involves the patient sitting in a modified Geri chair with adjustable back-leg rest mechanisms affording optimal postural alignment during training, with a knee brace secured to a mounting plate for support and knee immobilization. A seatbelt is secured around the pelvis to limit proximal hip and thigh motion. The paretic lower leg will be positioned at ~45° on a cushioned support, isolating the foot to move freely about the ankle. The patient is then introduced to the video "racer" game that is subsequently used to assess paretic ankle motor control.

It provides actuation in two of the ankle's three degree of freedom (DOF); allows 25° of dorsiflexion, 45° of plantarflexion, 25° of inversion, 20° of eversion, and 15° of internal or external rotation.[1]

The frequency of training using the anklebot is three times per week for one hour therapy sessions for six weeks duration.

InMotion AnkleBot is currently available in multiple clinics for research in the U.S. Bionik expects to file for U.S. Food and Drug Administration (FDA) clearance in the third quarter of 2017 with planned market introduction in the first quarter of 2018.

POTENTIAL FOR IMPACT

According to World Health Organization (WHO), cerebrovascular accidents (stroke) are the second leading cause of death and the third leading cause of disability.[2]

Early rehabilitation is crucial to help the stroke survivors to improve function and gain as much independence as possible. In majority of hemiparetic stroke patients, gait is the main problem.

There are several methods for gait rehabilitation technique which include classical gait rehabilitation techniques (neurophysiological and motor learning approaches), functional electrical stimulation (FES), robotic devices, and brain-computer interfaces (BCI). [3]

Many of the proposed technology-based gait intervention strategies place high physical demands on therapist. The appeal of powered robotic exoskeletons in post-stroke rehabilitation is that it provides substantially higher repetitions for walking practice without placing strain on the therapist.[4]

There were only three retrievable evidence found regarding the related treatment.

A randomised controlled trial was conducted in Maryland involving 34 patients who suffered from stroke with residual hemiparesis (ankle manual muscle test grade 1/5 to 4/5 and with at least trace muscle activation in plantar- or dorsiflexion). Eighteen subjects from the robot group received anklebot training with an assist-as-needed approach during >200 volitional targeted paretic ankle movements, with difficulty adjusted to active range of motion and success rate. The control group received stretching >200 daily mobilisations in these same ranges. In this study, the patient and the assessors were not blinded. The result indicated that the comparisons of mean percent changes in step time ratios of paretic-to-nonparetic sides proved that robot group making greater progress toward 1:1 temporal symmetry by reduction of 25% ($p = 0.032$). The robot group also demonstrated greater improvements in percent change of steps length ratio of paretic-to-non-paretic sides which reflect toward greater interlimb symmetry ($p=0.038$) with longer nonparetic step lengths in the robot (133%) compared to stretching (31%) groups. In absolute terms this amounts to a mean 13.2 cm gain in the nonparetic step length with robotics training, compared to only 6.2 cm for controls. Paretic ankle control improved in the robot group, with increased peak angular velocity by greater gains of 106% ($p \leq 0.001$) compared to stretching group. The mean angular velocity showed gains of 141%($p \leq 0.01$) in the robot groups compared to 25% in the control group. There were also increased movement smoothness by decreased normalized jerk by 24% ($p \leq 0.01$) compared to stretching group who were essentially unchanged (+4%, $p = 0.688$). There were no adverse events noted in the study.[5]

A single-arm pilot study involving eight stroke survivors with chronic hemiparetic gait had undergone 6-week visually guided, impedance controlled, ankle robotics intervention to assess the effectiveness of treatment on the paretic motor control and gait function. Subjects were trained in dorsiflexion plantarflexion by playing video games with the robot during three 1-hour training sessions weekly, totaling 560 repetitions per session. The results showed that improvement of paretic ankle motor control was seen as increased target success, along with faster and smoother movements. Walking velocity increased significantly from 51.4cm/s to 61.7 cm/s ($p=0.032$), whereas durations of paretic single support increased from 21.1% ± 2.4 to 24.2% ± 2.4 ($p= 0.033$) and double support decreased from 46.6% ± 4.6 to 40.3 ± 4.0 ($p= 0.01$).[6]

Another randomised controlled study conducted in Maryland with the duration of three weeks, randomised ten people with chronic hemiparetic stroke to impedance-controlled ankle robot (anklebot) training under either high reward (HR) or low reward conditions. The 1-hour training sessions involving the patient playing a seated video game by moving the paretic ankle to hit moving onscreen targets with the anklebot only providing assistance as needed. Assessments included paretic ankle motor control, learning curves, electroencephalograpy (EEG) coherence and spectral power during unassisted trials, and gait function. While both groups exhibited changes in EEG, the HR group had smoother movements with significantly reduced jerk as a function of time ($t(4) = 3.05$, $p = 0.04$), whereas the LR group was relatively unchanged. It also reduced contralesional-frontoparietal coherence by a significant decrease in low beta and theta coherence between the left frontal region and bilateral parietal regions ($p < 0.01$). Additionally, it also reduced left-temporal spectral power by significant decrease in left temporal gamma power in posttraining relative to baseline ($t(1,4) = 2.73$, $p = 0.05$). Gait analyses revealed an increase in nonparetic step length ($t(7) = 2.69$, $p = 0.05$) in the HR group only. These results suggest that combining explicit rewards with novel anklebot training may accelerate motor learning for restoring mobility.[7]

Those studies indicate better response on improvement of paretic ankle motor control and movement smoothness. With extra encouragement with high reward system in the later study mentioned, it may accelerate motor learning to improve mobility. However more high-quality evidence is required to support the effectiveness, safety and cost-effectiveness of the treatment.

EVIDENCE

Forrester LW, Roy A, Krebs HI et al. Ankle Training With A Robotic Device Improves Hemiparetic Gait After A Stroke. Neurorehabil Neural Repair. 2011; 25(4): 369-377

Forrester LW, Roy A, Krywonis A et al. Modular Ankle Robotics Training In Early Sub-Acute Stroke: A Randomized Controlled Pilot Study. Neurorehabil Neural Repair. 2014; 28(7): 678-687.

Goodman RN, Rietschel JC, Roy A et al. Increased Reward In Ankle Robotics Training Enhances Motor Control And Cortical Efficiency In Stroke. J Rehabil Res Dev. 2014; 51(2): 213-228

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6. Forrester LW, Roy A, Krebs HI et al. Ankle Training With A Robotic Device Improves Hemiparetic Gait After A Stroke. Neurorehabil Neural Repair. 2011; 25(4): 369-377
7. Goodman RN, Rietschel JC, Roy A et al. Increased Reward In Ankle Robotics Training Enhances Motor Control And Cortical Efficiency In Stroke. J Rehabil Res Dev. 2014; 51(2): 213-228

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