FDA clears medical device for muscle and joint rehabilitation

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This is the AMES rehabilitation device. Credit: Oregon Health & Science University

The Food and Drug Administration today granted 510(k) clearance to a

muscle and joint rehabilitation medical device developed by OHSU Scientist Dr. Paul Cordo, Ph.D., and AMES Technology, Inc.

AMES is an Oregon Health & Science University spinoff company established to transform Dr. Cordo's OHSU research findings into a rehabilitation medical device for use in hospitals and clinics. Today's FDA clearance allows AMES to market and sell the device. AMES anticipates delivering the device to hospitals and clinics in early 2014. The typical patient population that possibly receive treatment with an AMES Device would include stroke victims and patients with partial injuries to the spinal cord injury patients.

The AMES rehabilitation medical device uses robotic technology to assist a patient in moving the affected limb while vibrating the muscle receptors at the same time. During use, the patient's input effort and other parameters important in therapy are measured and recorded by the AMES Device and displayed to the patient as real-time visual biofeedback. The AMES Device can also perform several diagnostic tests each time a patient is treated by the device to track progress for clinicians and insurance providers.

Dr. Cordo's research at OHSU involved applying muscle vibration to the receptors in the muscle tendon at the same time as the joint is being moved. This is thought to result in an exaggerated perception of movement of the extremity, in the correct direction, at the time movement is made. The central nervous system monitors the sensory output of the muscles and when a signal is detected, the brain senses that movement, thereby helping guide the motion. AMES has invested in the application of these important findings into a commercial medical device. This resulted in a device that is capable of delivering combination therapy through a series of programmed treatment regimens controlled via computer software.

"Taking stroke as an example, if a person survives the initial injury, the probability is about 50 percent that he or she will never recover any functional use of the affected limb," said Dr. Cordo, a professor in the OHSU Department of Biomedical Engineering and Chief Technology Officer for AMES. "Clinicians have few options for the most severely disabled people other than working around their disabilities. How many other types of medical conditions can you think of where we give up on curing the worst affected 50 percent of the affected population? We don't think this is acceptable, so over the last 10 years, we've been working to come up with an alternative that is effective with the severely disabled, or at least able to bring them to the point that other therapies will be effective. The AMES rehabilitation device is the product of that decade of work."

Current research shows that muscle vibration can help the brain "locate" the muscles controlling the joint, to reduce joint tightness, and to enhance sensation at the treated joint or joints. This enhanced sensation is thought to help the brain re-establish communication with the affected muscles.

A series of clinical studies with the AMES Device were conducted at multiple sites across the United States, some with chronic and sub-acute stroke patients and some with chronic spinal cord injury victims. These studies have provided clinical evidence that the AMES approach improves movement and strength in people with injuries to the brain and spinal cord, in some cases restoring the ability to carry out independent activities that were previously unattainable. The studies included treating the arm, hand and the leg. Most of the participants who were enrolled in these studies were considered to be very disabled when they started AMES treatment.

Currently, in the United States alone, there are more than 10 million people whose movement is profoundly limited by diseases of and

injuries to the brain and spinal cord. About half of these people are so disabled that currently available therapies are not effective in restoring normal movement. Recent rehabilitation research suggests that at least some of these severely disabled people can recover functional movement if the therapy focuses on the fundamental problems that prevent movement, as with the AMES Device.

While the device cannot regain movement for certain types of central nervous system injuries and diseases, such as where the spinal cord is completely severed, the device can assist in regaining some movement in a large number of patients.

"We are very excited about the prospect that AMES technology will improve the lives of thousands of injury and stroke victims," said Dr. Tim Stout, M.D., Ph.D., M.B.A., OHSU's Vice President for Technology Transfer and Business Development. "This is revolutionary technology that can change how we treat these patients."

OHSU and Dr. Cordo have a significant financial interest in AMES Technology, Inc., a company that may have a commercial interest in the results of this research and technology. This potential individual and institutional conflict of interest has been reviewed and managed by OHSU.

The AMES device is patented technology and is exclusively licensed worldwide to AMES.

Provided by Oregon Health & Science University