



Published Study Demonstrates Effectiveness of Vitalstim Therapy for Patients Suffering with Dysphagia

Patients Treated with Neuromuscular Electrical Stimulation Show Increased Swallowing Ability with Sustained Improvement After Six-Month Follow Up

ST. PAUL, MN, June 30, 2008 - A recent study published in the April 2008 issue of the *Annals of Otolaryngology & Rhinology* has revealed the positive clinical effect of the adjunctive use of VitalStim® Therapy. A leading brand within the Empi Recovery Sciences line of pain management and rehabilitation products, VitalStim is a non-invasive neuromuscular electrical stimulation (NMES) device for the treatment of dysphagia. Results of the study were also originally presented at the American Association of Speech-Language Pathology Conference in Miami, Fla. in November 2006.

Dysphagia, or difficulty swallowing, is a sorely neglected medical condition which affects 15 million Americans and is generally caused by a neurological disorder or event, such as a stroke, degenerative neurological diseases and head and neck cancer. Without proper management, dysphagia can lead to aspiration, pneumonia, choking, chronic malnutrition, severe life-threatening dehydration, an increased rate of infection, longer hospital stays, long-term institutional care and even death.

VitalStim Therapy is a non-invasive external electrical stimulation therapy that was cleared to market by the FDA in December 2002. VitalStim is a portable, dual-channel electrotherapy system that is used with electrodes specifically designed for application to the muscles of the throat to promote swallowing.

Entitled "Adjunctive Neuromuscular Electrical Stimulation for Treatment-Refractory Dysphagia," the study details the measured clinical effect of the VitalStim program on six patients with chronic, treatment-refractory dysphagia. The study describes a prospective case series using validated outcome measures to represent different domains and a standard program of dysphagia therapy, which includes a consistent application of NMES following VitalStim Therapy protocol.

Patients received an average of 12 treatment sessions throughout the study. Following the treatment, patient measurements demonstrated key findings, including:

- 80 percent of patients reached the defined primary end-point of clinical improvement in swallowing ability, with significant Mann Assessment of Swallowing Ability (MASA) score improvements;
- All patients in the study significantly increased the range and amount of materials consumed orally - 83 percent of the patients increased their Functional Oral Intake (FOIS) score by at least two scale points, with most of the patients progressing from a restricted, single-consistency diet to a full oral diet;
- The average weight gain for the group over the three-week treatment period was two pounds;
- Patients involved in the study perceived significant improvement in their ability to swallow after treatment - no patient rated their post-therapy swallowing ability as lower than their baseline score;
- No patient experienced any swallowing-related medical complication over the treatment period.

The study was led by Giselle D. Carnaby-Mann, MPH, Ph.D., associate research scientist in the Department of Behavioral Science and Community Health at the University of Florida, and Michael A. Crary, Ph.D., professor in the Department of Communicative Disorders at the University of Florida. In addition, both are co-directors of the Swallowing Research Laboratory at the University of Florida.

Six months following completion of the treatment period, four of the patients completing the protocol returned for a medical review. Post-treatment examinations showed no statistically significant changes in clinical outcome measures, showing sustained efficacy after cessation of treatment.

For more information, please visit www.vitalstimtherapy.com/research.

About Empi, Inc.

Headquartered in St. Paul, Minnesota, Empi is a leading manufacturer and provider of non-invasive medical products for pain management and physical rehabilitation. Empi is committed to delivering positive patient outcomes and providing innovative products specifically designed to meet the needs of the patient, medical professional, and payor. For additional information on the company, please visit www.empi.com. Empi is a DJO company.

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