

Gastroparesis and Dysmotilities Association
GPDA
www.gpda.net

Press Release

For immediate release: May 5, 2004

**Jeanne Keith-Ferris, RN, BScN President and Founder, GPDA
Calgary, AB**

Are you “wired up” for your next meal? Now, hope is on the horizon for those who are suffering from digestive motility diseases.

Canadian researchers continue to make shocking news! For over 40 years now, medical devices used to directly stimulate human tissues with weak electrical currents have been implanted in patients to treat a variety of nerve or muscle disorders. The first and best known of these “shocking devices” is the cardiac pacemaker, pioneered by Canadian researcher, John Hopps.

John Hopps was an electrical engineer from the University of Manitoba. In 1941, while conducting research into hypothermia at the National Research Council, Hopps inadvertently discovered that a non-beating heart could be restarted with a direct electrical stimulus. This discovery led him on a new track of research and development into the world’s first external cardiac pacemaker. www.inventors.about.com

This cumbersome and awkward device would have continued to be the pacesetter for cardiac patients for many more years had it not been for another researcher, Wilson Greatbatch. In the late 1950s, Greatbatch’s work in the recording of heart sounds led him to stumble upon the concept of a small electrical device that could regulate the human heart. After two years of intense research, Greatbatch fashioned the first implantable heart pacemaker. This revolutionary treatment, using a compact electromuscular stimulation device, opened the door for research inquiry into an array of implantable, stimulating systems. www.inventors.about.com

Today, these devices are used to treat, via electrical stimulation, a variety of symptoms and disorders. Leads, implanted onto either nervous tissue or muscle tissue, are connected to a battery-driven power source that can apply multiple programmable stimulation frequencies and pulse duration variables. The common devices in use now are sacral nerve stimulation, spinal cord stimulation, deep brain stimulation, and gastric electrical stimulation.

Building upon the applications of gastric electrical stimulation has led Canadian researcher Martin P. Mintchev, Ph.D., P.Eng. (Professor, Department of Electrical and

Computer Engineering, University of Calgary; Adjunct Professor of Surgery, University of Alberta) to extend this area into the realm of induced peristalsis as a means to treating patients with digestive motility diseases. Dr. Mintchev's research will have applications for various segments of the digestive tract, but his initial device is targeted to treat gastroparesis, or what is also known as delayed gastric emptying.

This new device would benefit a group of patients who are long on suffering and short on treatments. Gastroparesis literally means "weak stomach." The severely affected patients are very ill due to non-stop nausea and vomiting. Unable to keep food down, their partially paralyzed stomachs have lost the ability to process a meal and pump it along (peristalsis). Those most commonly affected are women in the prime of life who have no known cause for their debilitating stomach disorder.

Diabetics, too, can develop this problem; thought to result from damage to the autonomic nervous system, the branch of the nervous system responsible for digestive processes as well as other organ regulations of the heart, bladder and sexual function.

In order to reverse these debilitating symptoms and help the stomach to empty its contents normally, Dr. Mintchev envisions the powering-up of the stomach with multiple channel leads, connected to an implantable microsystem and driven by a high-energy source.

Other researchers have attempted this with very simplistic designs. One restricting factor has been the need for high energy hooked to an external power source. Power packs were awkward, and wires that exited from the abdomen meant that patients were exposed to potential infections.

Present implantable electrical devices need only a low-power source to tweak their effect on tissues—so a small battery can be placed inside the person's body—as with a heart pacemaker.

Getting around these high-energy needs has been but one challenge for Dr. Mintchev. To solve the problem, he is designing a completely enclosed system that will respond to an external energy source delivered via a light-weight power pack that slides around the abdomen like a belt. The energy is sent by the belt battery pack, through the skin, and onto the implanted system.

This device, known as neural electrical gastric stimulation (NEGS), represents the new generation of gastric electrical stimulation approaches to treat delayed gastric emptying. Another challenge faced by Dr. Mintchev and his research team was how to sequentially control the motor action of the stomach in order to mimic normal emptying. What Dr. Mintchev has come up with is a microprocessor-controlled method to synchronize the stomach's peristaltic action.

Furthermore, the microprocessor system needs to be coupled with built-in wiring. The wiring consists of four to six sets of electrical wires or leads, evenly spaced and lassoed around the stomach. Coming off from each of the main leads are isolated stimulating

electrode wires, up to six, strung out along the main leads, each with metal tips secured by sutures embedding them into the stomach. The main leads are connected to a multi-channel microsystem, which is implanted just beneath the skin's surface.

The brain of the system is the microprocessor, which dictates synchronized control to the stimulating electrode sets. The once impaired workings of the stomach are now overridden and a more normal wave of peristalsis is electrically reproduced allowing the stomach to empty. Rhythmic waves of muscular activity are now choreographed by the microprocessor system. This system will also be flexible enough to allow for customizing the implant to meet the specific needs of each patient.

Once secured in place, all that the patient needs to do is slip on the belt and power up the system soon after eating to begin processing the food. Several stimulation sessions would be needed to empty the stomach with the microprocessor providing a gentle, normal emptying of the stomach contents downwards to the small intestine.

If all works as it should, then those gastroparetic patients who currently cannot eat and must subsist on tube feedings to bypass their non-working stomachs will have an opportunity to eat once again.

Patients who currently suffer with terrible nausea and vomiting from gastroparesis do have access, in the United States, to an implantable stomach neurostimulator. For many patients, this works very well for controlling their symptoms of nausea and vomiting. However, it does not appreciably empty the stomach of food contents

More treatment options are welcomed by these patients who have so few avenues for symptom relief. Dr. Mintchev's device also holds the promise for other applications, such as the treatment of severe constipation known as colonic inertia, or small intestinal pseudo-obstruction, a very serious digestive disorder wherein the small intestine is paralyzed.

Though this device is not yet available to patients, it brings hope for those who are disabled from these digestive motility diseases. Hope is on the horizon.