

The Latest Facts about the Diaphragm Pacing Stimulation (DPS) System

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Most of us who use ventilators are aware that the late Christopher Reeve had some kind of experimental diaphragmatic stimulator implanted in 2003 to help decrease his dependence on his ventilator. Many folks may think this technology is only available for the rich and famous. Not true!

It is true, though, that Reeve was one of Dr. Raymond P. Onders's first success stories. Having completed 38 of these procedures to date – 27 in people with spinal cord injury (SCI), 11 in people with ALS – Dr. Onders is now performing one or two every month with a 96% success rate in people with SCI (an intact phrenic nerve is key), enabling them to breathe with an adequate tidal volume without a ventilator. He has performed the procedure both soon after an injury and up to 25 years post-injury.



*The clinical trial is currently recruiting patients at the University Hospitals of Cleveland and the Shepherd Center in Atlanta. A third site is planned for the West coast. Detailed information is online at www.clinicaltrials.gov/ct/show.

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For about two decades, Onders and his colleagues, Anthony DiMarco, MD, and J. Thomas Mortimer, PhD, pondered the issue of some kind of implanted device to improve the quality of life for ventilator users. Today, as the Director of Minimally Invasive Surgery at University Hospitals of Cleveland in Ohio and Associate Professor of Surgery at Case Western Reserve University, Dr. Onders is making this dream a reality.

The device is called the NeuRx Diaphragm Pacing Stimulation (DPS) System. Its goal is to free a person's dependence on a ventilator over time by stimulating the diaphragm with intermittent electric impulses. They cause the diaphragm, the primary muscle for breathing in, to contract, thus enabling air to enter the lungs as in normal respiration. The impulse

sensation has been described as similar to a flick of the finger.

In a two-hour outpatient procedure, electrodes are placed directly on the diaphragm near the phrenic nerves using a laparoscope. The wires from the electrodes are attached to an external battery pack about the size of a remote control and set at a determined rate, usually 10 to 14 discharges per minute. Because the procedure is still considered investigational by the FDA, potential candidates* and dedicated caregivers must follow precise post-operative instructions and return for all scheduled follow-up appointments.

Full FDA approval is expected in about one year for people with SCI to receive the DPS System. Its protocol has been designated "category B" by the FDA, making it eligible for Medicare billing.

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Synapse Biomedical Inc. is the company that Drs. Onders and DiMarco formed to manufacture the DPS System.
www.snyapsebiomedical.com

All the people who have had the procedure so far were covered by Medicare, Medicaid or private insurance with the usual copay. For non-US citizens paying cash, the bill includes device cost, surgery, anesthesia, professional fees and x-rays for a total cost of approximately \$20,000. Transportation costs are the patient's responsibility.

I had an opportunity to ask Dr. Onders and Nurse Practitioner Elmo questions about this important work.

Q: How do you measure success?

A: In our ongoing studies, 27 SCI patients using mechanical ventilation via tracheostomy were implanted with the DPS System. All procedures were performed on an outpatient basis with no intra-operative complications. One patient had a false positive preoperative phrenic nerve conduction study, and therefore was never able to pace. The remaining 26 patients (96%) achieved greater than their predicted tidal volume during stimulation; 24 patients underwent weaning from the ventilator at home by capping the trach while the DPS

System stimulated their diaphragm. Fifteen patients now use the device fulltime, and eight use it 12-24 hours a day resulting in more than 40 years of cumulative active implantation time. The home-based weaning protocol allows patients to maintain caregiver support, work and significantly lower expenses.

Q: How does this work for people with ALS?

A: The objective of our study in people with ALS was to use diaphragm pacing technology to maintain respiratory muscle function. If successful, at least two significant benefits may occur. Life threatening respiratory muscle dysfunction may be significantly delayed. And, diaphragm pacing may be effective in ventilatory support of patients with ALS, either decreasing or obviating the need for assisted mechanical ventilation.

We have now implanted 11 ALS patients with the DPS System. These patients had a forced vital capacity (FVC) of at least 50% at the initial screening and had not yet required invasive mechanical ventilation. The first four patients have used the system for more than one year. The results to date have confirmed that there is a sound scientific rationale for electrical stimulation of the diaphragm in ALS, especially in this group of patients whose FVC at implantation was 53% or lower.

In our first four patients who have surpassed the one-year mark, we have shown a 65% decrease in the rate of respiratory decline. The pre-implant rate of decline was 4.1% per month, while the post-implant rate after conditioning with DPS was 1.4% per month. This corresponds to more

Diaphragm or Phrenic Nerve Pacers

Diaphragm pacing via phrenic nerve stimulation is not new. William Dobelle, of the Dobelle Institute (now Avery Biomedical Devices, Inc.), began developing it in 1971. The current Avery model is the Mark IV Breathing Pacemaker and the only phrenic nerve pacing system that has full FDA approval for implantation in the USA. The Avery system requires surgical, rather than laparoscopic, implantation of electrodes directly on the phrenic nerve and utilizes an antenna.
www.breathingpacemakers.com

A Finnish company, Atrotech Ltd., uses a quadripolar electrode system for their device, the Atrostim® Phrenic Nerve Stimulator V2.0, which must be surgically implanted. Like the DPS System, it is classified as only an investigational device by the FDA for use in the USA.
www.atrotech.com

than an additional 20 months of survival without a ventilator.

Q: What is the goal of DPS?

A: Our goal with people with SCI is to replace the ventilator. The longest-term patient was implanted March 6, 2000 and has been using the DPS System as his sole means of respiratory support for more than six years. With the ALS population, we are evaluating whether electrical stimulation of the diaphragm will slow the rate of progression and delay the need for a ventilator.

Q: Is the DPS System less expensive than a ventilator?

A: Economically, when balanced against the long-term costs of ventilator equipment, supplies and care, the DPS System is far less costly. After the cost of the procedure itself, there are minor costs for battery and external cable replacements. Our data show that savings for one patient who uses the DPS System fulltime are \$13,000 per month for Ohio Medicaid.

Q: Are there other benefits to using DPS?

A: Physically, individuals with the DPS System are able to smell, eat and talk more “normally.” They also report less need for suctioning and fewer hospitalizations.

During hurricanes and other natural disasters, the widespread loss of electricity can cause significant and life-threatening problems for anyone who uses a ventilator more than a few hours per day. Ventilator batteries last from only one to eight hours before requiring electricity for recharging. The DPS System uses a standard disposable 12V external battery that lasts 500 hours, and patients are



Laszlo Nagy (laszlon@adelphia.net) became a C3 quadriplegic as a result of a motorcycle accident in June 2002. Nagy says, “I was implanted with the DPS System exactly one year later. Seven weeks after the surgery, I was ventilator free for 24 hours a day, seven days a week. Since then, I have never needed to use a ventilator, and I have been infection free. I have also developed the ability to breathe on my own for up to several hours, turning off the DPS System. I use this as my ‘backup,’ although I keep an Ambu bag on my wheelchair.”

Nagy retained his tracheostomy for suctioning, usually only once a day. He continues, “I am able to live in my own home. On August 12, I got married. The DPS System allows me to travel and to leave my home virtually worry free. It has made my life much easier.”



Tom Davis (tomdavisfl@cox.net), a C1/C2 quadriplegic, had the DPS System procedure in May 2004. One month later he was completely “freed from the ventilator” and remains so. Davis says, “The DPS System has revolutionized my lifestyle. I no longer have to lug around that heavy ventilator on the back of my chair. Instead, I have a small box that is tucked in the waistband of my pants. Without the ventilator, the length of my wheelchair has been shortened by nearly two feet and has given me much more maneuverability in tight spaces.

“When they turned the pacer on for the first time, I could smell everything in the room. This of course has made food taste much better, which has caused me to gain a little weight. The procedure has cut in half the amount of times I need suctioning.

“Also, I no longer have those long pauses between breaths from the ventilator. When people talk to me on the phone, they have no idea that I use an assisted breathing device. I love it!”

supplied with a stock of batteries. The DPS System improves the quality of life during these events by decreasing anxiety, easing evacuation if necessary, and simplifying temporary housing until power is restored.

Q: Who are other potential candidates for DPS?

A: We expect to branch into the muscular dystrophies, post-polio and hypoventilation syndromes, such as CCHS, within a year. ▲

References

DiMarco AF, Onders RP, Ignagni A, Kowalski KE. Inspiratory muscle pacing in spinal cord injury: case report and clinical commentary. *Journal of Spinal Cord Medicine* 2006; 29(2): 95-108.
Office of Public Affairs. Christopher Reeve Receives New Implantable Breathing Device Developed by Faculty. School of Medicine Case Western Reserve University.
Passon S. Breathing Easier. *Spinal Column*, the magazine of Shepherd Center. Spring 2006; 16-17.