

Cedars-Sinai first West Coast ALS clinic to implant breathing-assist device under new FDA approval

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Cedars-Sinai Medical Center has become the first West Coast site -- and one of only three nationwide -- to implant a device that stimulates the respiratory muscle in the chest and draws air into the lungs of patients suffering from amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease) under recently approved Food and Drug Administration guidelines.

The progressive disease attacks neurons in the brain and spinal cord that control muscles throughout the body; most patients with ALS die from lung complications and [respiratory failure](#).

"We currently have no cure for ALS, which often causes patients to become completely paralyzed in the later stages, but this respiratory-assist system is one way we can attempt to improve our patients' quality of life, helping them remain comfortable and possibly delaying the need for a ventilator," said Dr. Robert H. Baloh, director of the Neuromuscular Division in the Department of Neurology at Cedars-Sinai Medical Center and a top ALS clinician and research scientist.

The FDA granted approval in September 2011 for the NeuRX [Diaphragm](#) Pacing System (DPS)[®] as a therapy for patients suffering from ALS-related chronic hypoventilation -- the inability to take enough air into the lungs, which reduces oxygen and increases carbon dioxide in the blood.

Cedars-Sinai has treated 13 patients with the device, which consists of four electrodes that stimulate the muscle, a fifth electrode placed under the skin to complete the electrical circuit, a connector holder and an external battery-powered pulse generator. The generator regulates movement of the diaphragm muscle, creating a vacuum-like effect in the chest cavity that pulls air into the lungs. When the contraction eases, air is expelled. The cycle repeats 10 to 14 times per minute.

Dr. Robert McKenna Jr., medical director of Thoracic Surgery and Trauma and surgical director of the Women's Guild Lung Institute, and Dr. Harmik J. Soukiasian, associate director of Thoracic Surgery, implant the devices in a minimally invasive, laparoscopic procedure that typically requires only an overnight hospital stay. After surgery, the pulse generator is programmed to provide an ideal amount of air intake for each patient. The device can be used in a hospital, at a rehabilitation center or at home, and unlike an external ventilator, the system is silent.

Developed by Synapse Biomedical Inc., the diaphragm pacing system first was implanted in March 2000 and received FDA approval for treating those with spinal cord injuries in 2008.

The Amyotrophic Lateral Sclerosis Association estimates there are 30,000 Americans living with the disease. Average age at diagnosis is 55, and 5,600 new cases are diagnosed each year. ALS strikes randomly 90 percent to 95 percent of the time, with only 5 percent to 10 percent of cases having a familial connection.

Baloh, who holds a medical degree and PhD, joined Cedars-Sinai earlier this year to direct the division and create one of the most comprehensive teams in California focusing on ALS and other neurodegenerative and neuromuscular disorders. He joins Dr. Patrick D. Lyden, chair of the Department of Neurology, and Clive Svendsen, PhD, director of Cedars-Sinai's Regenerative Medicine Institute, in the search for molecular

causes and potential cures, stem cell therapies and innovative treatments that will improve patients' lives.

"That Cedars-Sinai was the first multidisciplinary ALS clinic to make this therapy available to patients outside of a research trial was clearly due to the close collaboration between the [thoracic surgery](#) team, the ALS program physicians, and the pulmonology team, and is a strong indication of our commitment to bringing cutting-edge therapies to our patients in the years to come," Baloh said.

Provided by Cedars-Sinai Medical Center

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