



4700 West Lake Avenue
Glenview, IL 60025 - 1485
847-375-4731 Phone
info@painmed.org

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www.painmed.org

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Contact Information
Susan M. Thompson
Director, Communications
American Academy of Pain Medicine
847-375-3686 office
sthompson@painmed.org

Novel Spinal Neuromodulation Device Delivers Significant Pain Relief to Low Back Pain Patients

March 25, 2011, National Harbor, MD—Results from an ongoing prospective study report that a novel spinal [neuromodulation](#) device changes the paradigm for patients suffering with low back pain who have not found relief through conventional [spinal cord stimulation](#) (SCS). The single-centered results from this ongoing, multi-centered study were presented today at the American Academy of Pain Medicine's 27th Annual Meeting.

The results of the study were presented by Adnan Al-Kaisy MB ChB FRCA, Clinical Lead of the Pain Management & Neuromodulation Centre, Guy's & St Thomas' Hospital, London, UK. Dr. Al-Kaisy and his colleagues conducted the study in the United Kingdom with 30 patients (with and without previous spine surgery) who had an average back pain Visual Analog Score (VAS) of 8 (out of 10) and an average leg pain VAS score of 6 (out of ten). Following approval from an ethics committee and the completion of a successful trial, dual octapolar, percutaneous leads were placed sequentially near the anatomic midline, between T8-T11 (the thoracic area of the spinal column). The Nevro system device was then connected to a rechargeable IPG (Implantable Pulse Generator) capable of delivering waveforms with frequencies up to 10 kHz (kilohertz).

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At three months, the average VAS score for back pain fell to 2.9 (p-value < 0.05) and the average VAS score for leg pain fell to 2.2 (p-value < 0.05). At six months the average back and leg pain VAS scores fell to 1.6 respectively. The study also used the Oswestry Disability Index (ODI) to measure how the back pain affected the patients' everyday life. The ODI decreased from 61 (p-value < 0.001) to 44 (p-value < 0.001).

The device proved to deliver significant pain relief at six months for both back and leg pain, without producing paresthesia. There was also no need for intra-operative paresthesia mapping with the improved ease of implantation of the device. The device improved patient function without movement-induced shocking and when the system was used overnight, the subjects reported improved sleep.

According to Dr. Al-Kaisy, ever since the first implant of Spinal Cord Stimulation in 1967 by Sheely, a Neuromodulator has struggled to find a solution, using different techniques of Electrical Neuromodulation, to manage the lower back pain. "To date there is no evidence that any of these techniques provide persistent long term pain relief at the lower back. Nevro Spinal Cord Stimulation is the cutting edge in implant technology which certainly is going to make a major difference in the management of persistent lower back pain," comments Dr. Al-Kaisy. "Using unique super high frequency stimulation, it suppresses the sparse fibers of the lower back, at the spinal cord level. Moreover, the frequency is so high the patient does not feel 'the tingling sensation' which some patients find extremely uncomfortable and distressing," Dr. Al-Kaisy concludes.

The goal of spinal neuromodulation is to achieve paresthesia, which alters the pain sensation into a "pins and needles" or tingling sensation through stimulation of certain pain pathways. Although SCS is the preferred treatment for patients suffering with failed back syndrome surgery (FBSS), providing paresthetic coverage of the low back is difficult and clinical results are poor. Seventy-one percent of SCS users also report uncomfortable stimulation.¹

1. Reference*: Kuechmann, et al. Could automatic position adaptive stimulation be useful in spinal cord stimulation? 6th Congress of the European Federation of IASP Chapters 2009 and www.restoresensor.eu

For more information: www.painmed.org/press

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