

NSS Products Research

NSS products are for acute and chronic pain. The Patented Technology and Method is the same in all NSS products. Difference between Acute & Chronic technology is in the Duty Cycle (length of time the device is on/off). Method of Action is the same.

A Novel Approach for the Treatment of Refractory Functional Gastrointestinal Disorders in Children: A Randomized, Controlled Trial of Neurostimulation

Dr. Katja Kovacic MD (Presented at Children's World Congress)- Oct. 11 2016

- 92% of all subjects had failed drug therapy.
- 86% of the group with the active device showed clinically significant improvement.
- >30% reduction in chronic pain compared to placebo
- This offers a novel approach for children and adolescents with refractory FGIDS.

A Novel Therapy for Functional Gastrointestinal Disorders in Children: A Randomized, Double Blind, Sham-Controlled Trial of Neurostimulation

Medical College of Wisconsin; Children's Hospital of Wisconsin – Presented at the American Gastroenterology Association – Chicago, IL May 2017

Katja Kovacic, Keri Hainsworth, Manu Sood, Gisela Chemlinski, Rachel Unteutsch, Melodee Nugent, Pippa Simpson, Adrian Miranda– (Presented in Chicago)-May 2017

- Prospective Double Blind, Randomized, Sham-Controlled Trial of 115 patients
- Chronic Pain Study – minimum 2 months' chronic pain
- >70% reduction in chronic pain within 3 weeks
- Majority of patients had failed pharmacological therapies
- > 30% above placebo, exceeding FDA standards
- Overall well-being sustained after 2 months
- > 95% patient satisfaction

Neuromodulation with BRIDGE Device Rapidly and Effectively Improves Signs and Symptoms of Opioid Withdrawal-A Multisite Study –

Adrian Miranda, M.D., Arturo Taca, M.D.; Department of Pediatrics, Division of Gastroenterology and Hepatology; Medical College of Wisconsin – Published 16 Mar 2017: ISSN: 0095-2990; American Journal of Drug and Alcohol Abuse

- Clinical reports show NSS/Bridge treatment significantly dropped the COWS scores by 67.7% in 20 minutes and 84.6% in 60 minutes.
- 5 days post BRIDGE placement, pain was reduced 97%.
- Reports demonstrate 88.8% continued to MAT

Percutaneous Electrical Nerve Field Stimulation Modulates Central Pain Pathways and Attenuates Post-Inflammatory Visceral and Somatic Hyperalgesia in Rats – Published Neuroscience 356 (2017) 11-21

Reji Babygirija, Manu D Sood, Pradeep Kannampalli, Jyoti N Sengupta and Adrian Miranda

- Auricular stimulation with the NSS/Bridge device significantly prevents the development of post-inflammatory visceral and somatic hypersensitivity associated with TNBS colitis. The effect is likely centrally mediated.
- Confirms Method of Action through scientific animal validation.
- Neurostimulation with the NSS/Bridge device significantly decreases the baseline firing of amygdala neurons and attenuates the response to somatic stimulation in just 15 minutes.
- Neurostimulation with the NSS/Bridge device decreases the spontaneous firing and response to somatic stimulation of lumbar spinal neurons suggesting influence on the descending modulatory effect on spinal neurons.
- Confirmed the anti-inflammatory effects of the device on inflamed tissues

Effects of Peri-Auricular Percutaneous Neuro-Modulating Field Stimulation (PENFS) of the Cranial Nerves on the Auto-Regulatory Hemodynamics of Intracranial Circulation in a Single Blind Sham Controlled Cohort -

(Internal Data)

Dr. Art Roberts, DDS, MD

- The results indicated up to 19% increase in mean flow velocity, 11% in PI and RI compared to sham.
- An increase in cerebral perfusion was demonstrated by decreasing resistance (PI and RI) to outflow and an observed significant increase in mean flow velocity.

Report of Minimal Adverse Events Resulting from Implantation of Peri-Auricular Percutaneous Electrical Nerve Field Stimulation:

A Retrospective Cohort Study.

Dr. Art Roberts DDS, MD, et al

Dovepress Journal Oct 12, 2016;

- The FDA, the IRB's for the DVCIPM (Defense and Veterans Center for Integrative Pain Management), and the Medical College of Wisconsin, categorized the device as minimal risk.
- These findings were also supported by Robert's publication in The Pain Practitioner (vol 25, No3). This 6 site retrospective study supports these findings

FDA 510(k) 140530

Additional Publications

Decrease in VAS Score Following Placement of a Percutaneous Peri-Auricular Peripheral Nerve Field Stimulator, Dr. Art Roberts DDS,MD, et al

Published. DOI: 10.5923/j.cmd.20150502.01

- A three site retrospective chart audit report of findings. Average reduction in pre and post treatment VAS pain scores was 67.45%.
- There were also indications of reduction in opioids and an increase in activities and better sleep. There were no reported adverse reactions.

Percutaneous Peri-Auricular Peripheral Nerve Field Stimulation A Novel, Non-Opioid Therapy for Diabetic Neuropathy.

Dr. Art Roberts DDS, MD. et al

The Pain Practitioner vol 25, No 3.

- Initial reports of a three site retrospective chart audit indicates the technology of the NSS is a safe and effective non-narcotic alternative for reducing chronic pain.

Effects of Auricular Stimulation on Pain and Narcotic Use in Adults Post Colorectal Surgery- a Randomized, Double Blind Human Study.

Froedtert Hospital, Milwaukee. – In Process – Expected completion 2017

- Evaluate the effects of auricular stimulation on pain and opioid use, nausea and vomiting, length of hospital stay, improvement of physical function following colorectal surgery

