

# TRIGEMINOCERVICAL (TCN) AND VAGUS NERVE STIMULATION (VNS) IS A TREATMENT FOR DIABETIC PERIPHERAL NEUROPATHIC PAIN (DPN) AND GLUCOSE CONTROL IN PATIENTS WITH MODERATE TO SEVERE DIABETES:

Observational Trial offering a Statistical Analysis of 83\* NATIVE AMERICAN Patients for an average of 227 Days

Within 90 days Primary NRS Pain and EAG Glucose Endpoints:

- Showed A Drastic Pain Reduction 7.92 -->1.04 and
- A Normalization of Mean Glucose From 209 --> 121
- Both Endpoints Were Maintained for 7.85 months
- \*From a subset of 45 Patients, 36 patients (80%) Reported Stopping ALL Pain and Diabetes Medication

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## OBJECTIVE

Explore the efficacy of minimally invasive combined TCN and VNS auricular peripheral nerve stimulation in managing DPN and glucose levels.

### DIABETES MELLITUS

- Affects more than 422 million people worldwide
- Incurs significant healthcare costs, especially related to pain of Diabetic Peripheral Neuropathy (DPN)
- Most cases are Type 2, a form linked to poor diet, aging, and genetic predisposition

### NATIVE AMERICANS

- 2.3 times more likely to die from diabetes compared to general American population

### STIMULATION TREATMENT

- Vagus nerve stimulation has been shown to affect the balance between insulin secretion and glucose metabolism
- Trigemino-cervical stimulation, a cervical peripheral and cranial nerve stimulation technique, used to treat headaches and neuropathies

## STUDY DESIGN

- 83 Native American patients had device implanted in distal auricular branches of the C2 and C3 nerve roots and Cranial Nerves 5 and 10 (auricular temporal branch of the Trigeminal, and the auricular branch of the Vagus)
- Patients used device for 19 days and were followed for 227 days following treatment
- Patients returned every 30, 60, and 90 days for glucose and pain measurement

## KEY TAKEAWAYS

This study utilized combined TCN and VNS auricular peripheral nerve stimulation to decrease pain and glucose levels. Statistical t-tests reveal profound improvements for this type of treatment. Further studies controlling the placebo effect, diet, and exercise are warranted.

## RESULTS

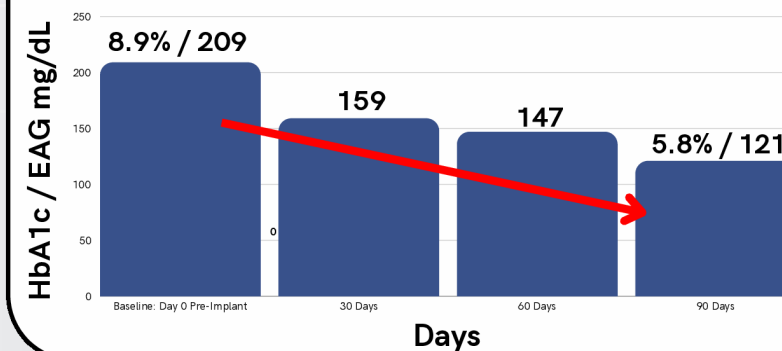
Primary outcome measures in this study were pain scores and glucose levels and percentage improvements from baseline to 30, 60, and 90 days post-treatment.

NRS Pain Score Values - 87% Reduction in 90 Days



Average pain reduced from 7.92 on day 0 to 1.04 on day 90.

Blood Glucose Level - 37% Reduction in 90 Days



By 90 days, blood glucose mean was 5.8% / 121 mg/dL.

The ability to regulate insulin production through neural pathways provides a promising alternative to traditional pharmacological approaches, especially for patients who have not responded adequately to medication.