

# Intractable Migraine Headache Reduction With a Targeted Approach to Reduce Trigeminal Nerve Activity Using the NTI Tension Suppression System: A Case Study

Andrew Blumenfeld, MD\* and James Boyd, DDS\*

\*The Headache Center of Southern California, Encinitas, California

## ABSTRACT

### OBJECTIVES:

1. Review longitudinal clinical records of a female patient using the NTI dental prosthesis to resolve otherwise intractable migraine headache.
2. Initiate a controlled two-week nocturnal clinical observation of this patient when using, and when not using the NTI device.
3. Obtain nocturnal electromyographic recordings from this patient both with and without the NTI device during sleep.
4. Elicit subjective quantitative assessments of headache pain on awakening from monitored sleep.

### BACKGROUND:

In 2001 the Nociceptive Trigeminal Inhibition Tension Suppression System (NTI) was approved by the FDA for the prophylactic treatment of medically-diagnosed migraine and tension-type headaches. The NTI prosthesis reduces the intensity of parafunctional pericranial trigeminal activity and thereby limits noxious afferent sensitization of the 5th nerve. The NTI has shown strong clinical promise as a non-invasive, non-pharmacologic prophylaxis for intractable headache. This case study involved a patient with intractable chronic daily headache with frequent migraine (~6/month). The NTI device was initially adjusted to the patient's individual requirements and placed on her dentition for nightly use. There was a marked reduction in headache within days. The NTI had been worn nightly by this patient with no relapse for >2 years at the time the present study was initiated.

### METHODS:

A female migraineur, chronically using the NTI was monitored for a total of 13 consecutive nights with EMG recordings of pericranial muscular activity obtained from adhesive surface electrodes. On the first five nights the patient used the NTI prosthesis. The device was removed during the next four nights and then replaced on the concluding four nights. Upon awakening, the patient was asked to assess her "morning headache pain" on a scale of 1-10 and assign it a quantitative rating. EMG recordings were compared across successive days.

### RESULTS:

There was a significant increase in net EMG activity on nights when the NTI device was not worn, (nights 6-9) vs. nights when it was worn (nights 1-5 and 10-13). There was also a significant correlation between the reduction in nocturnal electromyographic activity and reports of headache-associated pain on awakening.

### CONCLUSION:

Parafunctional motor hyperactivity, or jaw-clenching, can contribute significantly to dysfunctions of sensory input modulation to trigeminal centers leading to migraine. Since migraine etiology often includes an abnormally decreased threshold for morning headache, the present results suggest that continual nocturnal reduction of parafunctional motor activity with the NTI device can reduce the frequency of morning headache, diminish associated pain, and therapeutically limit a patient's susceptibility to other migraine triggers.

## BACKGROUND Theory and Practice

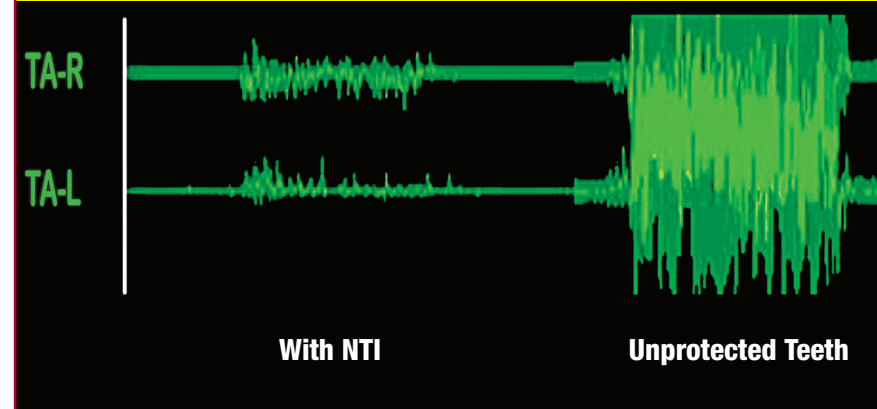
Nocturnal trigeminal motor hyperactivity, or jaw-clenching, can contribute significantly to modulatory dysfunctions of sensory input to trigeminal centers leading to migraine.

In migraine, the trigeminal nucleus may become hypersensitized to otherwise normal stimuli. Under these circumstances, migraine "triggers" can result in chemical secretions (primarily CGRP) that irritate arteries surrounding the brain (resulting in migraine) and within the sinuses (resulting in sinus headache).

The Nociceptive Trigeminal Inhibition Tension Suppression System (NTI) was approved by the FDA in 2001 for prophylactic treatment of migraine and tension-type headaches by reducing the intensity of trigeminally innervated muscular activity and limiting noxious afferent sensitization of the 5th nerve (see Fig. 1).

**Figure 1. Trigeminal Motor Activity With and Without the NTI Device**

Maximum trigeminal motor activity of the temporalis (clenching)



## BACKGROUND Clinical Experience

The NTI device has been used successfully for a number of years, but to date there has been little data documenting how such patients respond following the removal of the device.

The case study shown here involved a patient with intractable chronic daily headache with frequent migraine (~6/month). The NTI device was initially adjusted to the patient's individual dental requirements and emplaced for nightly use.

Significantly, the NTI had been worn nightly by this patient with no relapse for >2 years at the time this study was initiated. When the device was removed in line with the aims of this study, the patient immediately relapsed. When the NTI device was returned, headache intensity and frequency was reduced within days.

## METHODS

Surface electrode EMG recordings of pericranial muscular activity were obtained from a female migraineur, chronically using the NTI, on 13 consecutive nights.

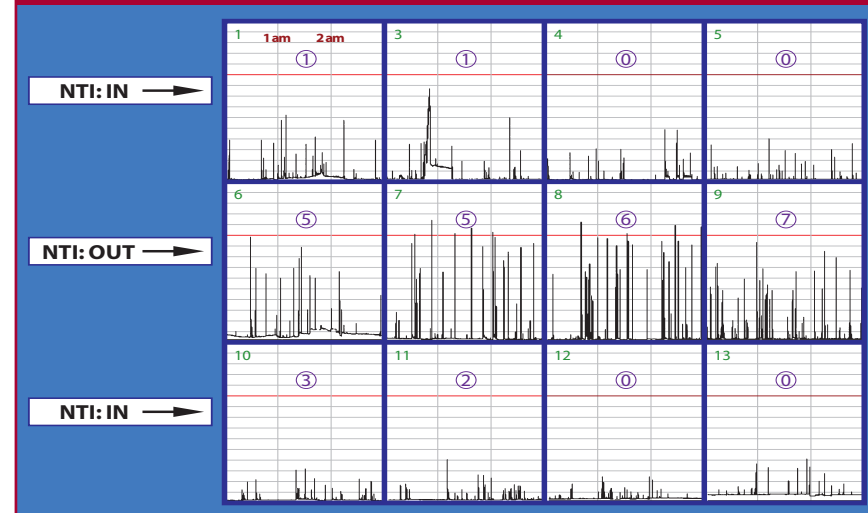
On the first five nights, the patient used the NTI prosthesis. The device was removed during the next four nights and then replaced on the concluding four nights. Upon awakening, the patient was asked to assess her "morning headache pain" on a scale of 1-10 and assign it a quantitative rating.

EMG recordings were compared with pain assessments across successive days.

## RESULTS 1

As shown in the chart records below (Fig. 2), net EMG activity increased significantly on nights when the NTI device was not worn, (nights 6-9) vs. nights when it was worn (nights 1-5, 10-13).

**Figure 2. Nocturnal Sleep EMGs Showing Clenching Intensity With and Without the NTI Device**



There was also a significant correlation between the reduction in nocturnal electromyographic activity and reports of headache pain (circled numbers) on awakening.

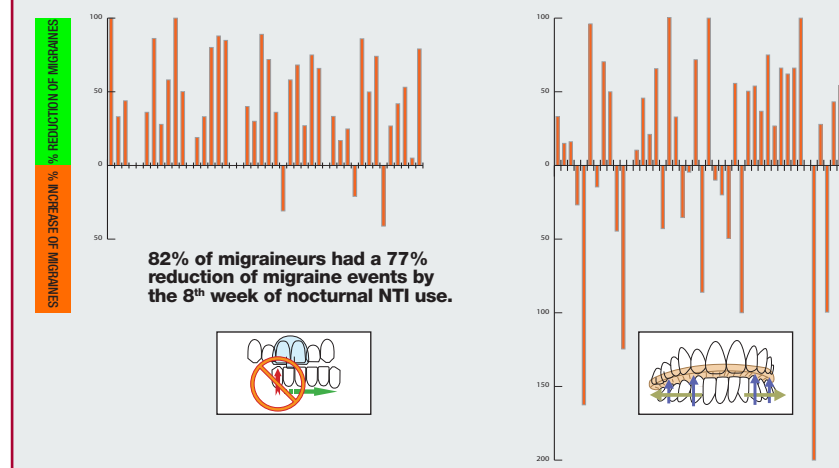
## RESULTS 2

As shown in the figure below (Fig. 3), data obtained from a clinical trial showed net migraine activity overwhelmingly reduced in chronic migraineurs using the NTI device during an 8-week period.

**Figure 3. % Reduction vs. % Increase in Migraines With the NTI Device**

Example of data from one of the clinical trial sites:

Each red bar represents an individual migraineur. Spaces where no bar is present represents a migraineur who had no change in their migraine attack frequency.



The inset depicts the incisor teeth in contact with the NTI device during treatment. There is a single anterior point contact with the mandibular anterior teeth, and cuspids cannot occlude. Overall, the device stops canine and posterior contacts preventing high-intensity trigeminal motor hyperactivity.

## CONCLUSION

Nocturnal trigeminal motor hyperactivity, or jaw-clenching, can contribute significantly to dysfunctions of sensory input modulation to trigeminal centers leading to migraine.

Migraine etiology often includes an abnormally decreased threshold for morning headache. The present results suggest that continual nocturnal reduction of parafunctional trigeminal motor activity with the NTI device can:

1. Reduce the frequency of morning headache
2. Diminish associated pain
3. Therapeutically limit a patient's susceptibility to other migraine triggers

## REFERENCES

1. Lamey PJ, Burnett CA, Fartash L, Clifford TJ, McGovern JM. Migraine and masticatory muscle volume, bite force, and craniofacial morphology. *Headache*. 2001;41(1):49-56.
2. Burnett CA, Fartash L, Murray B, Lamey PJ. Masseter and temporalis muscle EMG levels and bite force in migraineurs. *Headache*. 2000;40(10):813-817.
3. Buzzi MG, Bonamini M, Moskowitz MA. Neurogenic model of migraine. *Cephalgia*. 1995;15(4):277-280.
4. Goadsby PJ, Hoskin KL. Serotonin inhibits trigeminal nucleus evoked by craniovascular stimulation through a 5HT1B/1D receptor: a central action in migraine? *Ann Neurol*. 1998;43:711-718.
5. Lous I, Olesen J. Evaluation of pericranial tenderness and oral function in patients with common migraine, muscle contraction headache, and 'combination headache'. *Pain*. 1982;12:385-393.
6. Shankland WE. Migraine and tension-type headache reduction through pericranial muscular suppression check: a preliminary report. *Cranio*. 2001;19(4):269-278.
7. Organizations and Websites available at: <http://www.nti-tss.com>

## DISCLOSURE

Andrew Blumenfeld, MD is currently in the Speaker's Bureau for Pfizer, Merck, GSK, Ortho McNeil, and Allergan and has received Grant/Research Support from Allergan and Medtronic.

James Boyd, DDS is the developer of the therapeutic protocol for the NTI-TSS and is CEO of NTI-TSS, Inc.

The NTI Device is FDA approved for the prevention of medically diagnosed migraine pain.

This poster was presented at the 48th Annual Scientific Meeting of the American Headache Society, June 23, 2006, Los Angeles, CA.