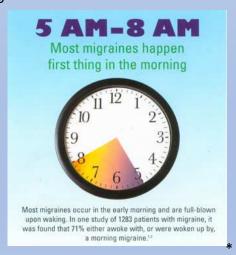


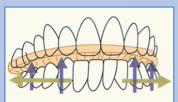
When you wake up, Do You Feel Fabulous? For the person who doesn't suffer from headaches, migraines, or jaw problems, that seems like an unusual question. But for many, waking with some degree of discomfort, from a slight headache and/or jaw soreness, to a full-blown migraine, is not unusual.

When visiting their physician, the migraine patient is typically asked when their worst migraines occur, or what seems to trigger them. Rarely are they asked about how they feel upon waking *each morning*.

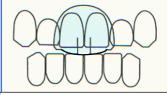


"Teeth grinding" was once thought to be a contributing cause of migraine (which typically occurs in the very early morning hours), but medical research rejected the concept as patients simply clenched harder on their traditional protective mouthpieces than if they didn't have one, resulting in either no change or a worsening of their symptoms.

A new patented design of a mouthpiece, called an *NTI*, has been FDA cleared for the prevention of migraine pain and jaw disorders. Unlike the traditional "full coverage" mouthpieces that allow for >100% of jaw-clenching intensity, the *NTI* provides front incisor teeth contact only when biting down, thereby limiting clenching intensity to 30% while preventing TMJ strain.



Traditional device allows >100% clenching intensity.



NTI limits intensity to 30%, Prevents TMJ strain

Published studies have shown the *NTI*'s proficiency at preventing migraine pain as well as TMJ disorders. In this latest breakthrough study (back), using the HIT-6 questionnaire to evaluate efficacy, the *NTI* has now been shown to be the most effective FDA cleared treatment modality at reducing migraine pain and improving the lives of sufferers.

If you or someone you know experiences frequent headaches or migraine pain, or unresolved jaw disorders, complete a HIT-6 questionnaire (HIT-6.com) and then have an *NTI* provided by a knowledgeable dentist to confirm (or rule-out) if nocturnal jaw-clenching might be playing an influential role in causing frequent headache, migraine pain, or jaw disorders.

*Headache and sleep: examination of sleep patterns and complaints in a large clinical sample of migraineurs. Headache. 2005 Jul-Aug;45(7):904-10

Boston Medical Journal of Neurology:

Adjunctive treatment of chronic migraine using an oral dental device: overview and results of a randomized placebo-controlled crossover study.

https://pubmed.ncbi.nlm.nih.gov/35246048/

Andrew Blumenfeld, MD, Director, The Headache Center of Southern California.

Background: The *NTI* is an FDA approved intraoral device for the prevention of medically diagnosed migraine pain, hypothesized to reduce trigeminal nocioception through reduction of jaw-clenching intensity and associated complications. The *Headache Impact Test* (HIT-6) provides an accurate picture of a patient's level of suffering by asking the patient to rank the extent to which migraine interrupts daily life's activities on a scale from one to five. For the Chronic Migraine patient, preventative treatment that produces a positive shift to a lesser pain category of disability is considered highly significant.

Methods: 25 consecutive intractable Chronic Migraine (CM) patients were diagnosed at a Neurology Headache Center. Patients had been non-responsive to all prior therapies and were considered "unmanageable". Upon completing a baseline HIT-6 questionnaire (the initial average baseline HIT-6 was: "**Severe impact, disabling pain**"), patients were treated every night with either an **NTI** device or a placebo intraoral device that had no influence on nocturnal jaw clenching muscle activity. After 30 days, patients completed another HIT-6, then fitted with the alternate device. After 30 days, patients completed another HIT-6. 19 completed the trial.



NTI device provides incisor contact only, limits clenching intensity to 30%, minimizes TMJ strain/load.

The pain categories of HIT-6 scores:

- Severe impact, disabling pain
- Substantial impact, severe pain
- Some impact, considerable pain
- None to little impact



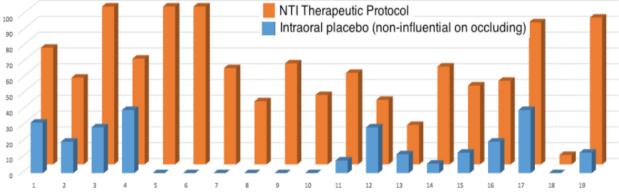
James P. Boyd, DDS

Placebo allowing full arch maximum clenching, no prevention of TMJ strain/load.

RESULTS:

HIT-6 Score Improvement	NTI	Placebo
≥1 category positive shift	89%	16%
2 category positive shift	47%	0%
% improvement in numerical score	62%	14%

Percent improvement of Quality of Life of Chronic Migraineurs when using an NTI device



Percent improvement is determined by calculating the change from initial baseline HIT-6 score to a score of 49 (49 is the highest score in the category of "Little to No Impact")

Conclusion: With nearly half experiencing a profound 2-catagory positive shift, the significant improvement of the majority of patients produced by the **NTI** device suggests that Chronic Migraine sufferers may have intense nocturnal jaw clenching as a contributing factor, which typically goes unnoticed and undetected by both physician and dentist. An **NTI** device and its therapeutic protocol should be provided by a knowledgeable dental practitioner to rule-out intense jaw-clenching and provide adjunct therapy for the Chronic Migraine sufferer.