

2nd European Headache and Migraine Trust INTERNATIONAL CONGRESS - EHMTIC

**Nice, France
October 28–31, 2010
ABSTRACT BOOK**

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Adverse events related to the NTI splint: report from the headache hope study

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Background Migraine is a prevalent and disabling condition, for which treatment options remain limited. Many patients do not wish to take oral preventive medications. The NTI splint is FDA approved for the treatment of migraine. However, the use of this option amongst headache experts is limited in part due to fear of potential dental, rather than systemic, adverse events.

Objectives This study used a web based questionnaire to collect data from dental providers on the methods of use and observed adverse events of the NTI splint in their practices.

Methods A web-based questionnaire was e mailed to dental providers in the United States.

Respondents were identified from dental laboratory and distributor records of documented NTI splint providers.

Questions on the methods of use of the NTI splint and outcomes were asked.

Analysis of the data is expressed as a percentage of total respondents.

Results Of 6,312 panelists contacted, 567(9%) responded.

Respondents were largely male (506/567: 89%) and had on average prescribed 160 NTI splints each.

The total number of NTI splints provided by this group of dental professionals was 90,720.

512/567 responded to the question regarding changes in occlusion secondary to NTI splint use.

The number of patients reported to develop a clinical observation of abnormality of occlusion with an anterior open bite as a result of NTI splint use was reported at: 1.6% of 78,711 cases.

Only 0.3% of patients reported aspirating the device; however 0% reported documented aspirations on X ray.

The dental providers rated the NTI splint as an effective treatment for headache in the majority (over 90%) of the patients they treated.

Conclusions Headache can be effectively and safely treated with the NTI splint in dental practices.

Sponsor: National Dentex Corporation.

Conflict of interest Dr. Blumenfeld has acted as a consultant, speaker or received research support from Allergan Pharmaceuticals.

ADVERSE EVENTS RELATED TO THE NTI SPLINT: REPORT FROM THE HEADACHE HOPE STUDY

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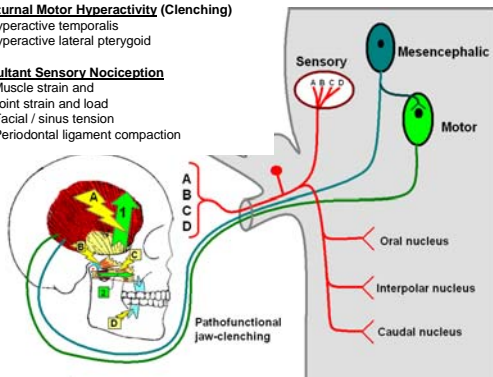
Background – The NTI (Nociceptive Trigeminal Inhibition) intraoral device reduces maximum nocturnal trigeminal motor hyperactivity (jaw clenching), and is hypothesized to therefore reduce resultant noxious afferent activity. The NTI has been FDA approved for the prophylactic treatment of medically diagnosed migraine pain. However, the use of this option amongst headache experts is limited in part due to fear of potential dental, rather than systemic, adverse events.

Nocturnal Motor Hyperactivity (Clenching)

1. Hyperactive temporalis
2. Hyperactive lateral pterygoid

Resultant Sensory Nociception

- A) Muscle strain and
- B) Joint strain and load
- C) Facial / sinus tension
- D) Periodontal ligament compaction



Molar and canine tooth contact allows for pathologic intensity of trigeminal motor hyperactivity (nocturnal jaw clenching)



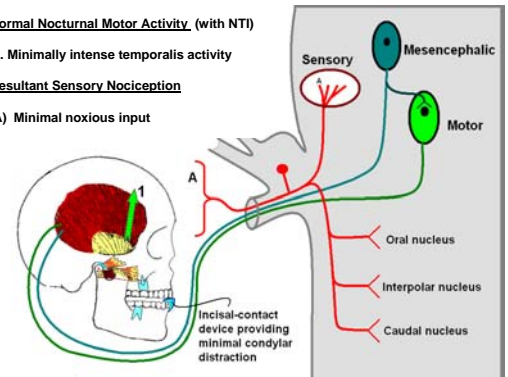
An NTI device is custom made by a dental professional, providing only for incisor-edge contact with minimal jaw-opening (to minimize TMJ strain)

Normal Nocturnal Motor Activity (with NTI)

1. Minimally intense temporalis activity

Resultant Sensory Nociception

- A) Minimal noxious input



Providing for only incisor-edge contact with an NTI device minimizes trigeminal nociception.

Background: Migraine is a prevalent and disabling condition, for which treatment options remain limited. Many patients do not wish to take oral preventive medications. The NTI splint is FDA approved for the treatment of migraine. However, the use of this option amongst headache experts is limited in part due to fear of potential dental, rather than systemic, adverse events.

Objectives: This study used a web based questionnaire to collect data from dental providers on the methods of use and observed adverse events of the NTI splint in their practices.

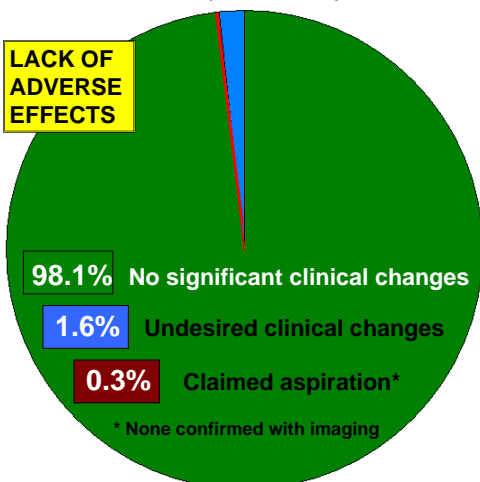
Methods: A web-based questionnaire; Respondents were identified from dental laboratory and distributor records of documented NTI splint providers; Analysis of the data is expressed as a percentage of total respondents.

Results:

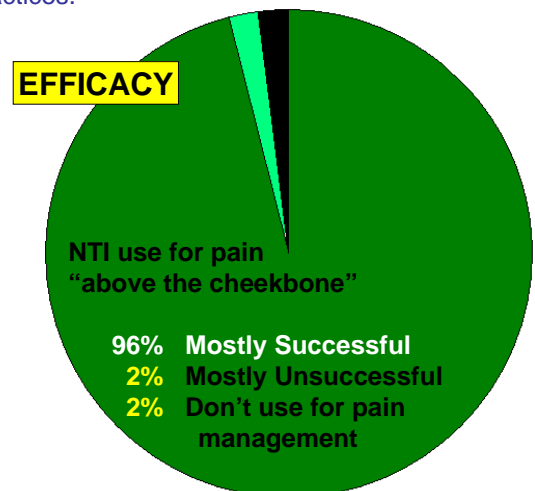
- 6,312 panelists contacted, 567(9%) responded; largely male (506/567: 89%); 160 average NTI splints prescribed; The total number of NTI splints provided by this group of dental professionals was 90,720.
- 1.6% of 78,711 cases reported a developed clinical observation of an anterior open bite.
- 0.3% of patients reported aspirating the device; however 0% reported documented aspirations on X ray.
- The dental providers rated the NTI splint as an effective treatment for headache in the majority (over 90%) of the patients they treated.

Conclusion:

Headache can be effectively and safely treated with the NTI splint in dental practices.



90,720
devices provided



Headache and Migraine Trust International Congress 2008, presentation:

Within two months of nightly NTI use, and then persisting for the nine months of observation, half of the subjects had a significant improvement, while 25% reported that chronic headache *no longer had any impact on their lives*.