The NTI Appliance for TMD and Headache Therapy

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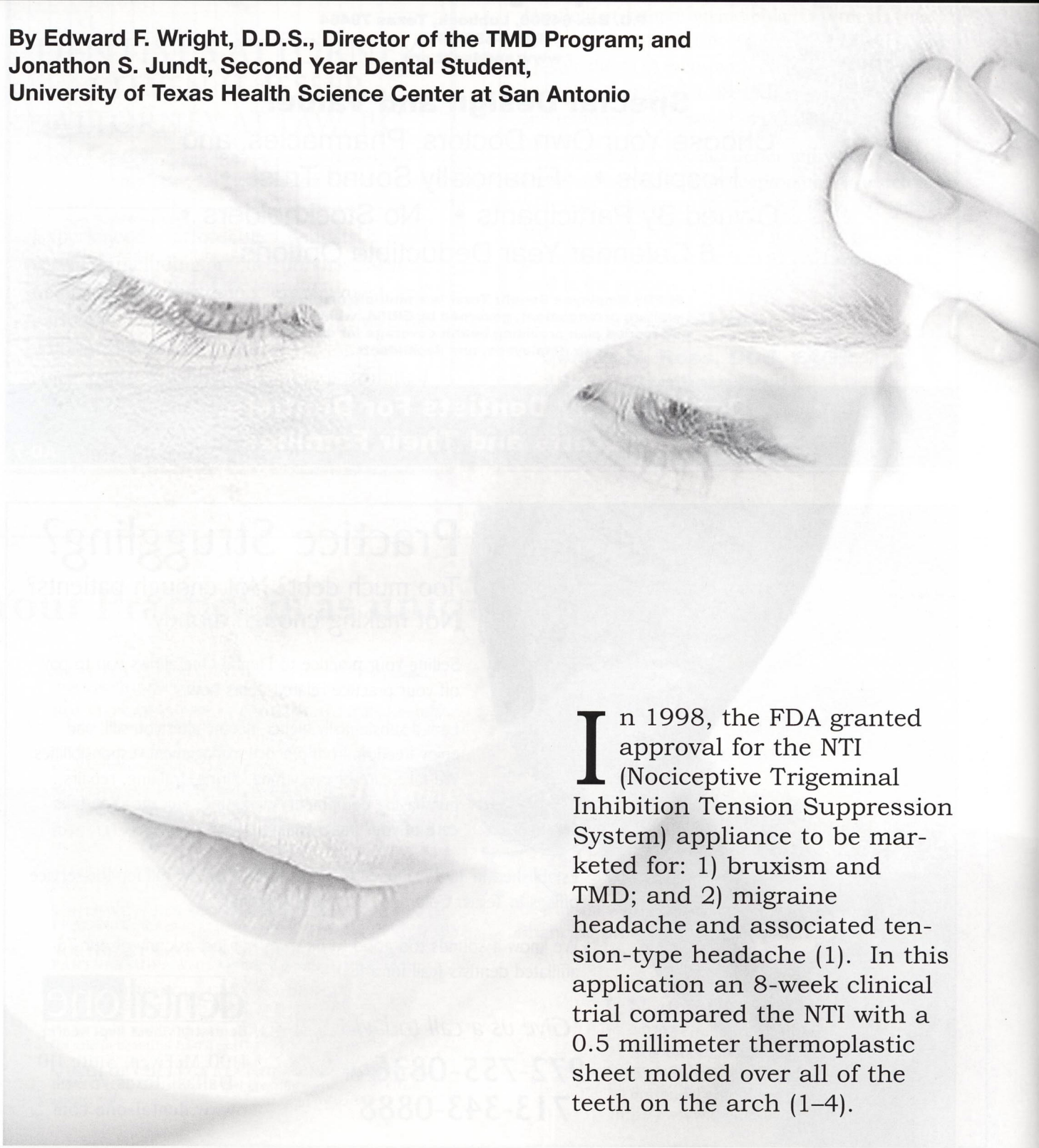

In 1998, the FDA granted approval for the NTI (Nociceptive Trigeminal Inhibition Tension Suppression System) appliance to be marketed for: 1) bruxism and TMD; and 2) migraine headache and associated tension-type headache (1). In this application an 8-week clinical trial compared the NTI with a 0.5 millimeter thermoplastic sheet molded over all of the teeth on the arch (1–4).

The NTI is a preformed plastic mold that is filled with autopolymerizing acrylic, placed over the two maxillary central incisor teeth (occasionally extends over a portion of the lateral incisors), removed after 2 minutes, and trimmed. The incisal portion of the appliance has a protrusion that is customized to form a single point contact preferably over the incisal embrasure of the mandibular central incisors (Figure 1) (1–4). Recently, the NTI has also been provided as a prefabricated mandibular partial anterior-coverage appliance that is similarly adjusted against the maxillary teeth.

Due to the NTI's small size, both clinical and legal concerns have arisen regarding accidental aspiration or ingestion. At the U.S. Food and Drug Administration's Medical Device Reporting website, three reports have been made of NTI appliance aspiration in the United States and one in Norway (5).

Devices similar to the NTI (e.g., Lucia jig, leaf gauge, cotton roll, etc.) have been used for decades to temporarily deprogram the masticatory muscles (6). Care must be taken with these devices, because they tend to compress TMJ structures and can cause pain if there is pre-existing TMJ inflammation (6–8). This may be the reason patients with TMJ inflammation were excluded from the study accompanying the FDA application (2, 3).

The literature suggests that full coverage appliances (those that cover all of the teeth in the arch) are more effective than partial coverage appliances and reduce the probability of tooth movement. Continuous long-term use of any partial coverage appliance may cause intrusion of the covered teeth and extrusion of the uncovered teeth (9). Some patients who wear a partial coverage appliance 24 hours a day

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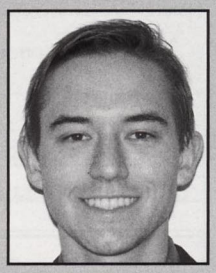

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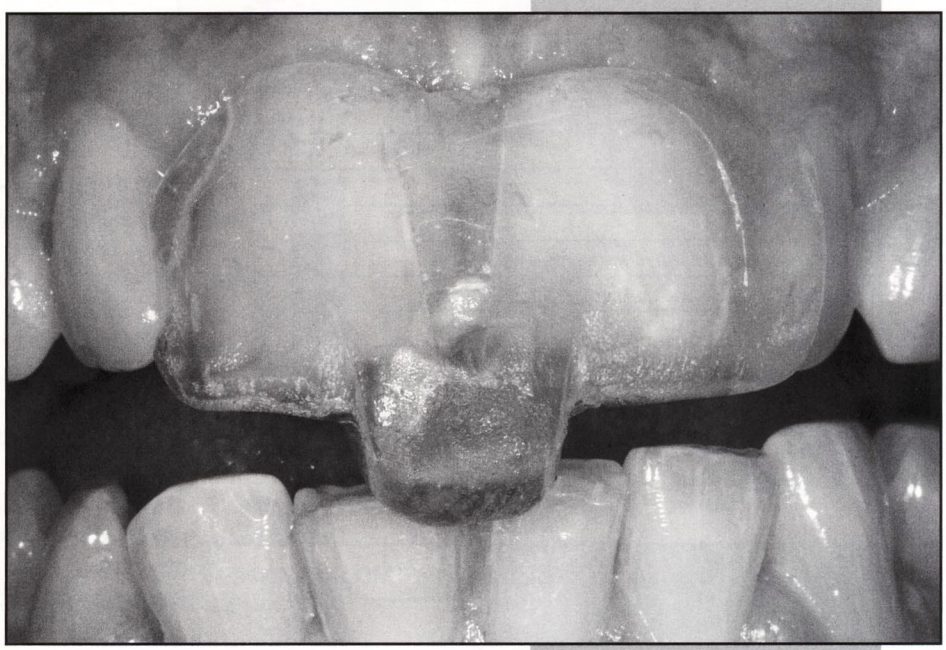
Figure 1. The NTI Appliance.



experience occlusal changes to the degree that when they remove the appliance, the only teeth that occlude are those not covered by the appliance (7). There is a case report of a patient provided an appliance that did not cover his erupted third molars. After wearing this appliance 24 hours a day for 5 weeks, the patient had developed an open-bite where only his super-erupted third molars would occlude when the appliance is removed (10).

Despite instructions to wear the appliance only at night, some patients experiment and find that daytime wear also benefits their symptoms, so they wear their appliances more than they were instructed. Therefore patients using a partial coverage appliance should be closely followed for occlusal changes (6, 9).

Due to the associated problems, 1) many practitioners do not provide their patients with partial coverage appliances; 2) partial coverage appliances are only recommended for judicious short-term use; and 3) if a partial coverage appliance is provided, it is recommended the practitioner warn the patient about potential occlusal changes and closely monitor the patient to detect any changes early (5, 6, 11).

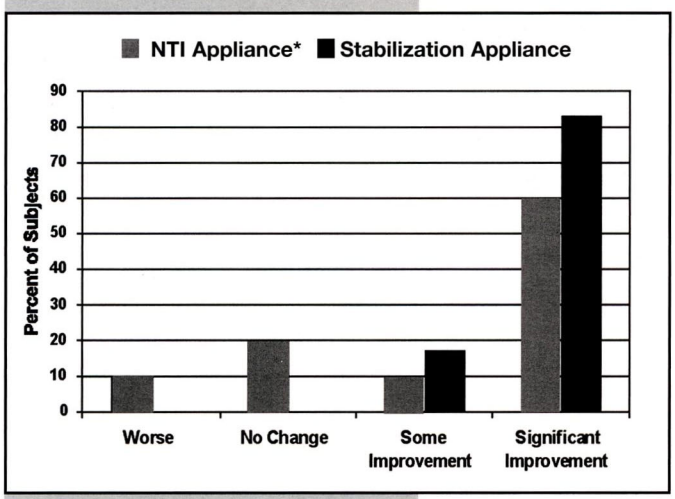


Figure 2. Change in TMD Symptoms at 6-month follow-up (11).
* An additional four subjects previously dropped out of the NTI group because their symptoms got worse or did not improve.

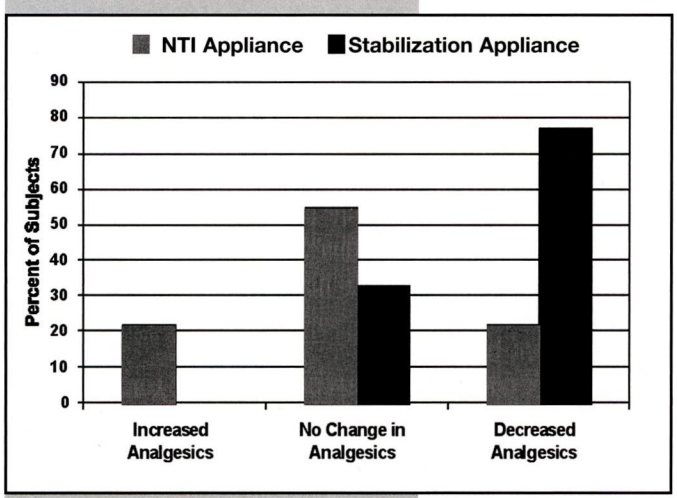


Figure 3. Change in Analgesic Intake for TMD Symptoms at 6-month follow-up (11).

The NTI Appliance for TMD Therapy

Recently two randomized clinical trials compared the NTI with the traditional stabilization (flat-plane) appliance for changes in TMD symptoms (5, 11). The first study followed their subjects for 6 months, and at the 3-month follow-up appointment, subjects who had not obtained improvement were given the option to switch appliances. Of the 14 subjects in the NTI group, four requested to switch to the stabilization appliance, while none of the 14 stabilization appliance subjects requested to switch. Also at the 3-month follow-up, five NTI appliance subjects reported tenderness of their teeth compared to three subjects in the stabilization appliance group (11).

At the 6-month follow-up, among the remaining 10 subjects in the NTI group, one reported TMD symptoms were worse, two reported no change, one reported some improvement, and six reported significant improvement. While among the 14 stabilization appliance group subjects, two reported some improvement and 12 reported significant improvement (Figure 2) (11).

Prior to the study, 9 of the 10 subjects in the NTI group consumed analgesics for their TMD symptoms and 13 of the 14 subjects in the stabilization appliance group consumed analgesics for their TMD symptoms. At the 6-month follow-up, 2 of the 9 NTI group subjects reported a decrease and 2 reported an increase in analgesic intake, while 10 of the 13 subjects in the stabilization appliance group reported a decrease and none reported an increase in analgesic intake for their TMD symptoms (Figure 3) (11).

The occlusion was evaluated for changes at the 3- and 6-month follow-up appointments; only one subject had a significant change in occlusion. This subject was among the 10 subjects in the NTI group, the occlusal change was not apparent at the 3-month follow-up, but at the 6-month follow-up, the vertical overlap had decreased by 1 millimeter and the number of occluding tooth pairs had decreased from 10 to 5 (11).

Among the seven subjects initially in the NTI group who did not obtain symptom improvement and were offered a stabilization appliance (at the 3- or 6-month follow-ups), six accepted the offer; one of those judged the NTI appliance as more pleasant and five stated the stabilization appliance was more comfortable (11).

The other randomized clinical trial which compared the NTI with the traditional stabilization appliance had groups that were significantly different ($p=0.02$) in regard to generalized body pain (5). Seven of the eighteen subjects in the NTI group and 17 of the 20 subjects in the stabilization appliance group had generalized body pain. It has been shown that TMD patients with generalized body pain do not respond as well to TMD therapies as those without generalized body pain (7, 12–14).

In spite of the large number of subjects in the stabilization appliance group with generalized body pain, both groups had similar significant ($p<0.05$) improvements over 3 months. Unfortunately this study only followed their subjects for 3 months and did not evaluate for occlusal changes (5).

Practitioners treating TMD patients with the NTI appliance have reported exacerbation of TMJ inflammation, as well as one report of a patient with a susceptible TMJ developing a close-lock (acute TMJ disc displacement without reduction); this can also occur from overloading the TMJ (6, 7).

The NTI Appliance for Headache Therapy

TMD has been associated with migraine with aura, migraine without aura, tension headache, and combinations of these headaches (15–18). Numerous studies have demonstrated that TMD appliances may reduce headache symptoms (2, 19–25).

In one study, 20 patients with chronic severe headaches received a stabilization appliance and self-management therapies after a no-treatment control period. The pretreatment and 5-week follow-up values revealed the mean Headache Disability Inventory (HDI) score had decreased by 17 percent ($p<0.003$), headache medication consumption dropped by 18 percent ($p<0.0001$), and headache symptoms decreased by 19 percent ($p<0.002$) (19).

At the 5-week follow-up, some subjects chose to continue using their appliances, and those underwent an evaluation 3 months later. Comparing the pretreatment and 3-month values, the mean HDI score decreased by 23 percent ($p<0.003$), headache medication consumption decreased by 46 percent ($p<0.001$), and headache symptoms decreased by 39 percent ($p<0.001$), (Figure 4A and B) (19).

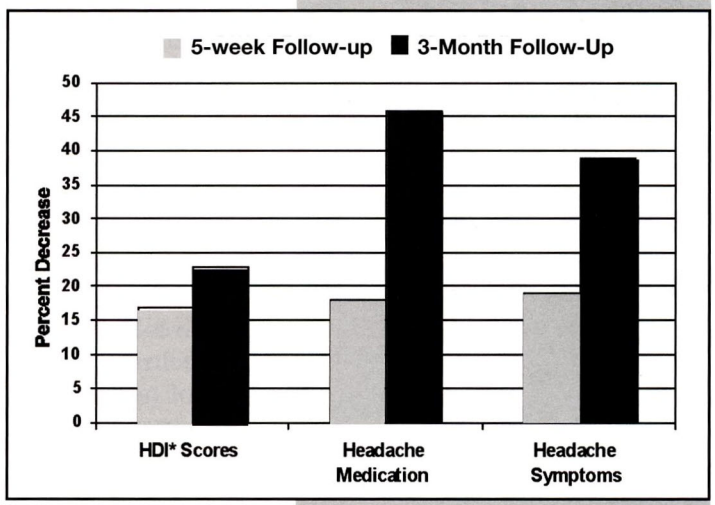


Figure 4A. Reductions from Stabilization Appliance and Self-management Therapies (19).
* HDI: Headache Disability Inventory score

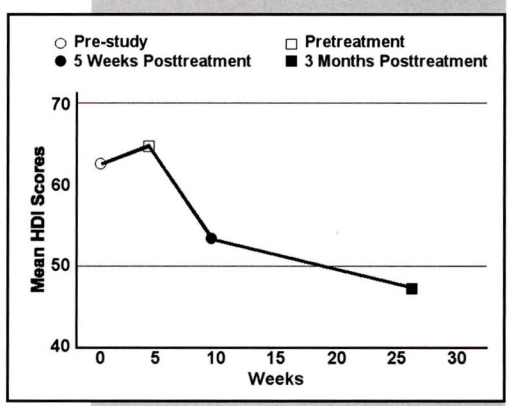


Figure 4B.

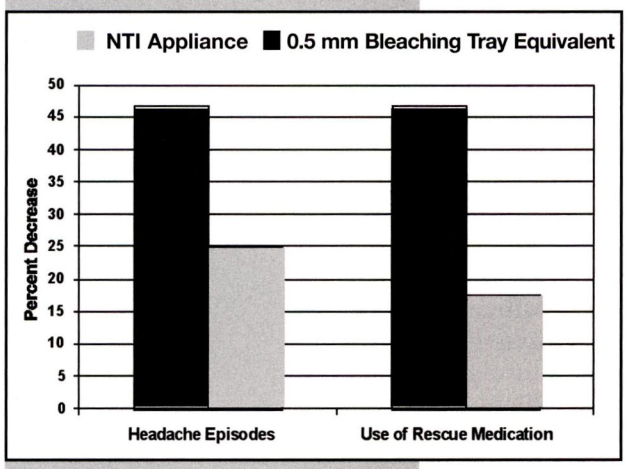


Figure 5. Reductions at 8-week follow-up (3).

The authors also found there was no correlation between response and headache type (p=0.722), suggesting appliance and self-management therapies can be beneficial for many chronic severe headache patients, regardless of the headache type (tension-type, migraine without aura, and migraine with aura) (19).

In another study, headache patients with classic migraine symptoms upon awakening were provided stabilization appliances, and they reported considerable reduction in headache frequency and severity. Some of the subjects were asked to discontinue wearing their appliance for 1 month and they found their headache symptoms returned, suggesting the improvement experienced with the appliance was probably not due to the placebo effect and that the appliance must be worn to maintain this improvement (25).

Among 100 consecutive chronic headache (migraine, tension, and combination) patients referred to a neurologist, 55 were found to have TMD with severity considered worthy of treatment. These 55 patients were randomly divided into two groups, one treated by a neurologist and the other almost solely by a stabilization appliance. More patients treated with the appliance reported a decrease in headache intensity ($P<0.025$) or a reduction in medication ($P<0.05$). Changes in headache frequency ($P<0.025$) were also reported more often in the group treated with the appliance (23).

Two-and-a-half-year and five-year follow-ups of chronic headache subjects treated with TMD appliances suggest headache improvements obtained from this therapy are sustained for most individuals (2, 20).

In the NTI's FDA application, an 8-week clinical trial compared the NTI with a 0.5 millimeter thermoplastic sheet molded over all of the teeth on the arch. The molded appliance was similar to a bleaching tray and provided no "additional determinates of occlusion." The subjects were evaluated for changes with number of headache episodes, associated symptoms, and headache rescue medication consumption (Figure 5) (2, 3). It was reported that five of the 43 subjects in the NTI group, had a slight degree of mobility (less than 1 mm) of their mandibular incisors (1, 4).

Recommendations

Based on the current literature, the NTI appliance is not as effective as a full-occlusal coverage appliance, has the propensity for causing occlusal changes and possibly mobile teeth, and there is a concern of possible ingestion or aspiration of the appliance due to its small size. Therefore, the principal author does not provide an NTI appliance for TMD or headache patients.

Some dentists use an NTI appliance to provide immediate therapy for a patient until a full-occlusal coverage appliance can be fabricated by the laboratory. The authors feel this is reasonable as long as the patient falls within the qualifying criteria listed in the next paragraph. There is concern that a small percentage of patients provided this temporary therapy may obtain satisfactory symptom improvement, not return for their full-occlusal coverage appliance, and wear the NTI appliance long-term. For immediate therapeutic intervention, the authors prefer using

medications and/or an adjusted soft thermoplastic full-occlusal coverage appliance (7, 27).

It is recommended that, if an NTI appliance is used, it only be used short-term for patients who are without TMJ inflammation, without TMJ noise, without a history of TMJ close-lock (acute TMJ disc displacement without reduction), without periodontally involved or mobile anterior teeth, and who can clench on the appliance without discomfort.

If a patient insists on using the appliance long-term, he or she should be informed of possible resulting occlusal changes and that anterior teeth that occlude on the appliance could become mobile. The patient should then be closely monitored for these changes (6, 9). Patients should be monitored for occlusal changes by 1) following which maxillary teeth are able to hold shim stock against their opposing teeth, while the patient bites in maximum intercuspation and 2) following potential changes of the anterior teeth by comparing the patient's anterior teeth with dental casts made prior to the NTI appliance wear, observing for changes in the vertical overlap and tooth position.

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