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ORIGINAL ARTICLE

Clinical comparison between two different splint designs for temporomandibular disorder therapy

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Abstract

Objective. To compare splint therapy in temporomandibular disorder (TMD) patients using two splint designs. ***Material and Methods.*** In a double-blind randomized parallel trial, 40 consenting patients were selected from the dental faculty pool of TMD patients. Two splint designs were produced: an ordinary stabilization (Michigan type) and a NTI (Nociceptiv trigeminal inhibition). The differences in splint design were not described to the patients. All patients were treated by one operator. A separate, blinded, examiner assessed joint and muscle tenderness by palpation and jaw opening prior to splint therapy, and after 2 and 6 weeks' and 3 months' splint use during night-time. The patients reported headache and TMD-related pain on a visual analog scale before and after splint use, and were asked to describe the comfort of the splint and invited to comment. ***Results.*** Thirty-eight patients with mainly myogenic problems were observed over 3 months. A reduction of muscle tenderness upon palpation and self-reported TMD-related pain and headache and an improved jaw opening was seen in both splint groups ($p < 0.05$; paired t-test and Wilcoxon signed-ranks tests). There were no changes for TM joint tenderness upon palpation. No differences were noted between the two splint designs after 3 months for the chosen criteria of treatment efficacy ($p > 0.05$; Mann-Whitney U-test). ***Conclusion.*** No differences in treatment efficacy were noted between the Michigan and the NTI splint types when compared over 3 months.

Key Words: *Craniomandibular disorders, random allocation, temporomandibular dysfunction, temporomandibular joint disorders*

Introduction

Patients with signs and symptoms of temporomandibular disorders (TMD) are commonly treated with occlusal splint therapy [1], although the efficacy remains uncertain and the actual mechanism of action remains debatable [2–4]. Most occlusal splints are relatively simple to make, i.e. chairside, in the clinic using a vacuum pressure method, or by a dental technician following impressions and a registration of the jaw relationship. The most commonly used occlusal splint is the stabilization type [5,6], which appears not to cause any irreversible occlusal changes, even after prolonged use. Other splint designs, in contrast, are designed to deliberately change the occlusion. These were previously recommended for patients with anterior disk displacement, followed by extensive occlusal rehabilitation. The procedure is seldom recommended now because it is irreversible, the intervention is biologically invasive as well as expensive, and the treatment outcome is not always predictable [5,6]. However, it can also be questioned whether the splint design in itself is of major significance, because it has been demonstrated that splints without an occlusal coverage will also give rise to effects for patients with TMD [7–11] or decreased nocturnal masticatory muscle activity [12].

A new splint design has recently been introduced, named the NTI–tss splint (*Nociceptive Trigeminal Inhibition–tension suppression system*). It is being aggressively marketed worldwide, e.g. in Australia, Canada, The Netherlands, Scandinavia, and the USA. Anecdotal surveys report that many dentists in Sweden and Norway favor this type of splint for patients with TMD [13] despite practically non-existent scientific documentation. As late as in October 2003, the Swedish Health Authorities issued the following official counsel to the Swedish Dental Association: "*the*

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NTI splint cannot currently be valued as lege-artis" [14]. Moreover, a very recent report based on a randomized clinical trial (RCT) from Sweden even casts doubt on the efficacy of this new splint type [15]. This contrasts with the positive therapeutic effects of stabilization splint use demonstrated in other recent RCTs from Malmö, Sweden [16,17].

In view of the current growing use of the NTI-tss splint among practitioners, it is important to assess its efficacy. The current clinical trial aimed to compare the outcome of splint therapy over 3 months in a random group of patients with different TMD diagnoses using the conventional stabilization (Michigan type) splint and the NTI-tss splint designs. Our hypothesis was that the treatment outcomes would be comparable, but that the patients would perhaps prefer the NTI-tss splint because of its smaller dimensions.

Materials and methods

Subjects

The present study protocol was endorsed by the Regional Committee for Medical Research Ethics in south Norway (REK-Sør) and was approved by the Norwegian patient information privacy ombudsman.

Patients were referred to or applied for treatment due to TMD problems at the Department of Prosthetic Dentistry and Stomatognathic Physiology, Faculty of Dentistry, University of Oslo, Norway. Adults who had experienced common symptoms of TMD [18] (i.e. impaired range of movement, impaired TM-joint function, muscle pain, TM-joint pain, and/or pain on movement of the mandible) that had lasted for at least 6 months were targeted for participation in this trial. At the first visit, one of the authors (A.M.) collected the patients' anamnestic data and case histories, including questions about pain related to the TM and neck region, use of medication, and general musculoskeletal pain elsewhere. No attempts were made to evaluate qualitatively the patients' headache or general musculoskeletal pain for further differential-diagnostic purposes. Finally, a functional examination of the masticatory system and diagnoses of the patients were made according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [19].

Verbal counselling was given in accordance with the diagnosis. The patients who were considered would benefit from splint therapy were given an oral and written invitation to participate in an evaluation trial for research purposes. The exclusion criteria were the presence of complete or removable partial prostheses with distal extensions or other treatments for TMD during the study, and individuals with recent facial or cervical trauma. The patients were not provided any specific details about the two splint designs to be compared, nor particular design differences. The participants were invited to change splint type during the course of the trial if they were unhappy with the treatment outcome or splint assignment. Patient recruitment continued until 40 patients had agreed to participate. In total, 45 patients were invited to participate, but 5 declined and were consequently offered conventional stabilization splint (Michigan type) therapy. These patients are not included in this report. The recruitment period was from September 2002 to October 2003.

Randomization

The study sample comprised 40 individuals (35 F and M), their ages ranging from 1 to 62 years (mean 37 years). The RDC/TMD diagnoses were: myofascial pain ($n=20$), myofascial pain + disk displacement ($n=19$), and disk displacement ($n=1$). Twenty patients were each allocated an ordinary stabilization splint (Michigan type) and 20 a NTI. The allocation was randomized and done consecutively by someone using a random number list. This person was independent of the trial and unaware of the patient names or diagnoses, and was not involved at any stage in the clinical treatment phase. An allocation list kept by this person was used at the completion of the trial to verify that the patients had been correctly assigned into the allocated splint group. One dentist (A.M.) provided all the treatments throughout the full clinical trial period, and was the only individual who knew the splint type–patient codes.

Interventions

Impressions (Alginoplast; Kulzer GmbH, Hanau, Germany) and an intraoral centric relation record in wax (Aluwax; Aluwax Dental Co., Allendale, USA) were taken of all patients. The stabilization splints were made in heat-cured acrylics by one commercial dental laboratory. The NTI splints were made chairside by the dentist. The stabilization splints were constructed to provide separation of the posterior teeth during protrusion and a canine rise during lateral excursions. Before use, these splints were adjusted to freedom in centric and to include multiple bilateral occlusal contacts in the retruded contact position. The NTI splints were made according to the manufacturer's instructions [20] and adjusted chairside before delivery. Briefly, this was done by selecting a standard acrylic matrix form that fitted passively over the maxillary incisors and by filling this with an acrylic for temporary crowns, which was then left to polymerize intraorally. The finished splint has a "discluding element" which contacts the two lower centrals upon closure and is supposedly an essential element of the NTI splint's alleged beneficial effects (Figure 1). All participants were instructed to wear their splint during night-time.

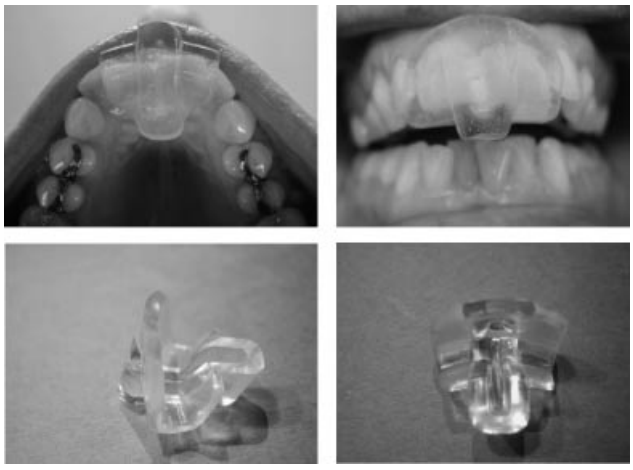

Figure 1. NTI splint. Upper row shows correct intraoral placement over the upper four incisors with a "discluding element" contacting the two lower central incisors. The lower row shows the matrix as it is delivered from the manufacturer.

Outcomes and examinations

At the time of splint delivery, the patients reported their suffering due to headache and TMD-related pain on a 0 to 10 cm visual analog scale (VAS). The two anchor words on a horizontal scale were the Norwegian words "Ingen" and "Uutholdelig", which can be interpreted as "None" and "Intolerable". An experienced physical therapist (B.S.K.) assessed the interincisal distance at unassisted jaw opening, as well as tenderness by palpation of the TM joints and the masticatory, neck, and shoulder muscles. The maximal unassisted jaw opening was assessed using a millimeter ruler. The TM joints were palpated laterally to the condyles under initial jaw opening movement. The masticatory muscles described in the RDC/TMD were palpated, i.e. m. temporalis anterior, m. temporalis posterior, m. masseter superior division, m. masseter profundus. In addition, neck and shoulder muscles were palpated to assess whether the *condition could possibly be related to inadequate breathing and/or poor posture*. These were m. temporalis insert, m. sternocleidomastoideus, m. trapezius, and the neck muscles at the C4 level.

Joint and muscle tenderness was graded into three categories: slight tenderness, moderate tenderness, and severe tenderness represented by a withdrawal reflex. The physical therapist has previously participated in calibration courses with other physical therapists [21], in addition to repeated calibration of the finger pressure using a bite force recorder [22]. In order to obtain a general impression of the state of muscle tenderness, a total score for tenderness was calculated from the sum of the palpation scores of the individual muscles. A simple multiplicative factor of 2 was used for moderate tenderness and 4 for severe tenderness. Thus, the total score for muscle tenderness was calculated as: the number of muscles with slight tenderness $\times 1 +$ the number of muscles with moderate tenderness $\times 2 +$ the number of muscles with severe tenderness $\times 4$.

The patients who had comorbid general musculoskeletal symptoms were not provided with any additional treatment beyond general counseling. Moreover, they were instructed not to begin with new medications during the 3-month trial, and those already receiving medication were asked not to change their prescription.

The same process was also carried out after 2 and 6 weeks and 3 months by the same examiners. All participants obtained the same type of adjunctive treatment (counseling and muscle relaxation exercises) in the course of the visits, and the splint was adjusted if required by the patient or as deemed necessary by the clinician. In addition, the patients reported on a 0 to 10 cm VAS how comfortable they found the splint use and they were invited to submit comments on experiences in connection with the splint therapy. The anchor words on a horizontal VAS were the Norwegian terms "Behagelig" and "Ikke behagelig", translated as "Comfortable" and "Uncomfortable". The same physical therapist (BSK) carried out all the muscle examinations throughout the study and the patients' group allocation remained unknown to this examiner throughout the trial period.

Data analysis

The characteristics of the participants in the two study arms at baseline were compared using three statistical tests. Proportions were compared using the Fisher exact test. Student's *t*-test was applied for comparing continuous variables and the Mann-Whitney U-test for comparing ordinal variables. Assessment of the statistical significance of changes of subjectively reported symptoms according to VAS scores between the baseline and 3-month examination was made using Wilcoxon signed-ranks tests with two-tailed significance. The changes of maximum jaw opening between the baseline and the 3-month examination were measured using paired *t*-tests. Differences between the two treatment groups after 3 months' splint therapy were assessed using the Mann-Whitney U-test with two-tailed significance. All statistical tests were carried out by one of the authors (A.J.) unaware of the splint type codes at the time of the statistical analyses.

Results

The proportion of patients reporting comorbid general pain, headache, and use of medications was high (Table I). The randomized allocations seemed to generate groups at baseline that did not differ with regard to patient characteristics (Table II). The two patient groups differed slightly regarding prevalence of TMJ pain upon palpation (Mann-Whitney U-test, $p = 0.03$) and proportion of patients with general pain

Table I. Self-reported general musculoskeletal pain, descriptor of headache, and regular usage of medicines

General body pain	Wake up with headache	Regular medicine
NTI splint ($n=18$)		
Yes	Yes	None
Yes	None	None
Yes	Yes	Fluoxetin (Psychoanaleptica)
Yes	Yes	Cetirizin (Antihistamine)
Yes	Yes	Paracetamol (Analgetic)
Yes	Yes	Codeine (Analgetic)
Yes	Increase during day	Codeine (Analgetic)
No	Yes	None
No	Yes	None
No	Yes	None
No	Yes	Diclofenac (Antimigrene)
No	Yes	Piroxikam (Antirheumatic)
No	Varies	None
No	Varies	Paracetamol (Analgetic)
No	None	None
No	Increase during day	Cetirizin + Bricanyl (Antihistamine + asthmamed)
No	Increase during day	Cetirizin (Antihistamine)
No	Increase during day	None
Stabilization splint ($n=20$)		
Yes	Yes	None
Yes	Yes	None
Yes	Yes	None
Yes	Yes	None
Yes	Yes	None
Yes	Yes	None
Yes	Yes	None
Yes	Yes	Bricanyl + Viox (Asthmamed + Antirheumatic)
Yes	Yes	Paracetamol + Ibuprofen (Analgetic + Anti-inflammatory)
Yes	Varies	None
Yes	Varies	None
Yes	Varies	Amitriptylin (Psychoanaleptica)
Yes	Varies	Methotrexate (Immune suppressive)
Yes	Varies	Venlafaxin (Psychoanaleptica)
Yes	Increase during day	Bricanyl (Asthmamedicine)
Yes	Increase during day	Klonazepam (Antiepileptica)
Yes	Constant	Karisoprodol + Codeine (muscle relaxant + analgetic)
No	None	Fenemal (Antiepileptica)
No	Increase during day	None
No	Varies	Ibuprofen (Anti-inflammatory)

(Fischer exact test, $p=0.02$), while no other differences were detected.

During the observation period, one patient dropped out of the study as a result of disinterest, and one patient was excluded owing to subsequent diagnosis of trigeminus neuralgia. The groups therefore consisted of 20 patients allocated to the stabilization splint group and 18 to the NTI splint group. All 38 participants attended all the clinical controls during the 3 months' observation period and none of the participants chose to change their splint type during the course of the trial.

The average jaw opening increased gradually in both splint groups during the observation period. The difference between the baseline and the measurements at 3 months was more statistically significant for both the stabilization type splint (paired *t*-test, mean difference 3.1 mm, $t=4.4$, d.f. $=19$, $p<0.001$) and the NTI splint (1.8 mm, $t=2.1$, d.f. $=17$, $p=0.05$). No statistical differences were recorded between the two splint type groups at the 3-month observation (*t*-test, mean difference 2.7 mm, $p=0.29$).

The VAS scores for the self-reported headache (Figure 2) decreased on average between baseline and the 3-month examination in both splint type groups (Wilcoxon signed ranks tests, $p=0.002$ and $p=0.01$). This was also the case for the TMD-related pain (Figure 3) (Wilcoxon signed ranks tests, $p<0.001$ and $p<0.001$). No statistical differences between the two splint groups were recorded for these two outcomes at the 3-month observation (Mann-Whitney U-test, $p=0.70$ and 0.14).

The jaw muscle tenderness decreased between baseline and the 3-month examination for both splint type groups. For instance, the average number of muscles with severe tenderness upon palpation decreased from 5.7 to 1.7 in the NTI splint group and

Table II. Patient characteristics for the two splint groups at baseline prior to splint therapy

	Stabilization splint (mean–median) ($n=20$)	NTI splint (mean–median) ($n=18$)	Statistical difference (p)
Patient gender (female)	17	16	ns*
Average patient age (years)	34–33	39–41	ns†
Maximum jaw opening (mm)	42–44	40–41	ns†
Patients with myofascial pain (RDC/TMD)	9	10	ns*
Patients with myofascial pain + disk displacement (RDC/TMD)	11	7	ns*
Patients with disk displacement (RDC/TMD)	0	1	ns*
Patients with general musculoskeletal pain	16	7	0.02*
Patients with general headache	18	16	ns*
Headache (VAS score, 0–10)	5.4–6	5.7–7	ns‡
Subjective pain (VAS score, 0–10)	6.8–7	6.8–6	ns‡
Average number of TM joints with slight tenderness upon palpation	2.5–2	1.4–1‡	0.02‡
Average number of TM joints with tenderness upon palpation	0.2–0	0.6–0	0.04‡
Average number of muscles with tenderness upon palpation	3.6–3	3.2–3	ns‡
Average number of muscles with moderate tenderness upon palpation	3.8–4	3.3–4	ns‡
Average number of muscles with severe tenderness upon palpation	5.7–6	5.7–5	ns‡
Average "muscle tenderness score" based on palpation	34–34	33–33	ns‡

*Fisher exact test.
†Student's t-test.
‡Mann-Whitney U-test.

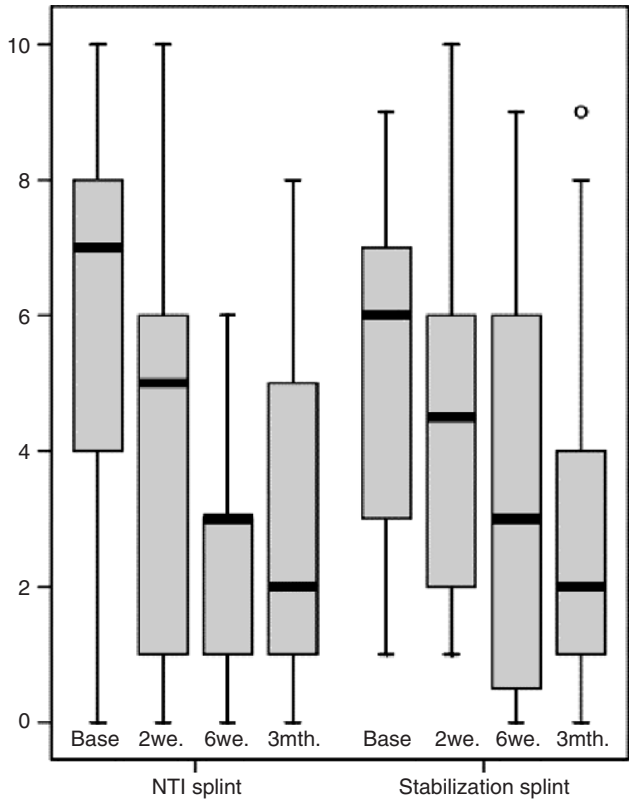

Figure 2. Headache reported by the participants according to VAS scores at baseline, and after 2 and 6 weeks and 3 months. Each box shows the median, quartiles, and extreme VAS scores on a scale between 0 and 10. A low VAS score signifies less headache.

from 5.7 to 1.9 in the stabilization splint group (Wilcoxon signed ranks tests, $p<0.001$). In addition, the average total muscle tenderness following palpation decreased significantly in both splint groups (Figure 4) (Wilcoxon signed ranks tests, $p<0.001$). No statistical differences were recorded between the two splint type groups at the 3-month observation (Mann-Whitney U-tests, $p=0.39$).

It was noted that the palpation tenderness in the neck and the shoulder muscles did not improve in either of the two groups.

The comfort of splint use appeared to be similar for the two groups according to the VAS scores at each control examination (Mann-Whitney U-tests, $p>0.05$), although a trend for higher comfort was reported for the NTI splint (Figure 5). The reported user comfort ranged throughout the full spectrum of the VAS scale, i.e. 1 to 10 for both splints, but the negative feedback differed slightly in nature for the two splint types. The most common complaint about the stabilization splints was that they were too tight ($n=6$), which in most cases was corrected; a feeling of the splint being too big and/or a palatinal over-extension ($n=3$); and two patients reported discomfort in not being able to close the mouth ($n=2$). The most common complaints associated with the NTI splint were dryness in the mouth while sleeping ($n=6$) due to a forced open mouth caused by the splint design, the NTI splint falling out or being taken out unconsciously

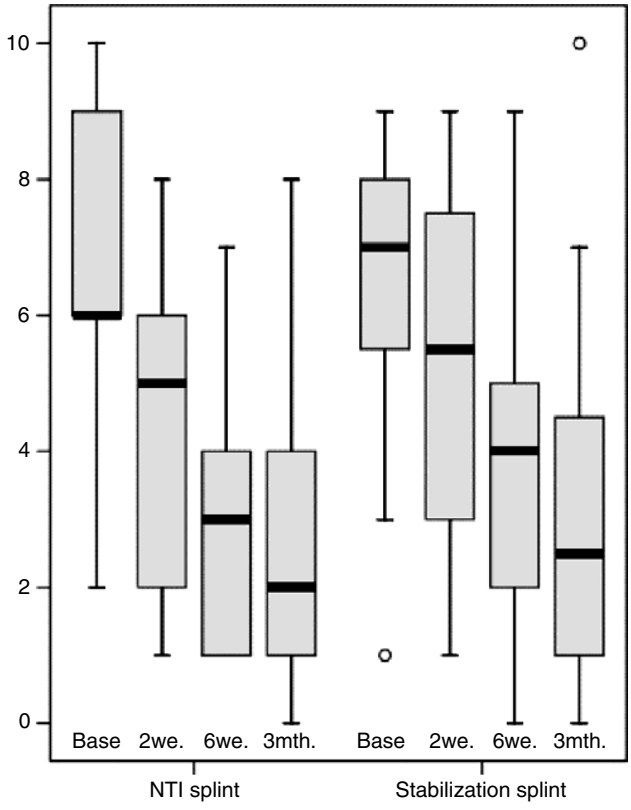

Figure 3. TMD-related pain reported by the participants according to VAS scores at baseline, and after 2 and 6 weeks and 3 months. Each box shows the median, quartiles, and extreme VAS scores on a scale between 0 and 10. A low VAS score signifies less pain.

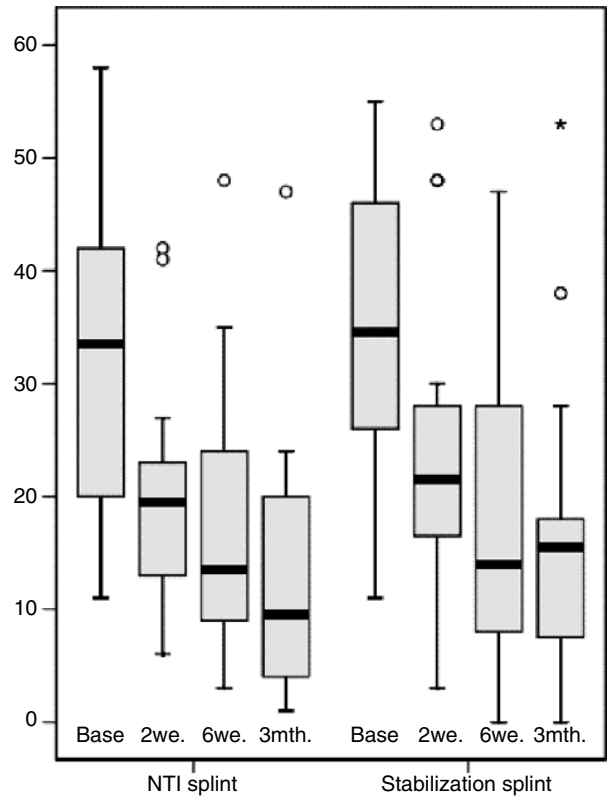

Figure 4. The average total muscle tenderness following palpation measured at baseline, and after 2 and 6 weeks and 3 months. The "pain index" on the vertical axis is the sum of the number of jaw muscles with slight tenderness $\times 1$ + muscles with moderate tenderness $\times 2$ + muscles with severe tenderness $\times 4$. A low pain index value signifies less pain.

while sleeping ($n=2$), and swallowing difficulties ($n=2$). One patient found the protruding tip of the NTI splint very annoying and another complained about sensitive lower front teeth.

Discussion

Within the confines of this clinical study, splint treatment using the stabilization type and the NTI splint types did not differ over 3 months. However, it has to be taken into consideration that the small sample size in the study may have caused a statistical type-2 error. This trial was conducted with a limited number of participants in order to balance between exposing a minimum number of patients to a potential risk of non-active treatment or even unpredictable adverse effects versus a meaningful sample size. Further and bigger randomized controlled trials need to be conducted to verify the findings.

A slightly higher proportion of the participants allocated to the stabilization splint group reported general musculoskeletal pain. Since the randomization process was followed rigidly, this phenomenon seems to be purely statistical. However, it is known that TMD patients with general muscle problems are less likely to benefit from TMD treatment [10]. It could therefore

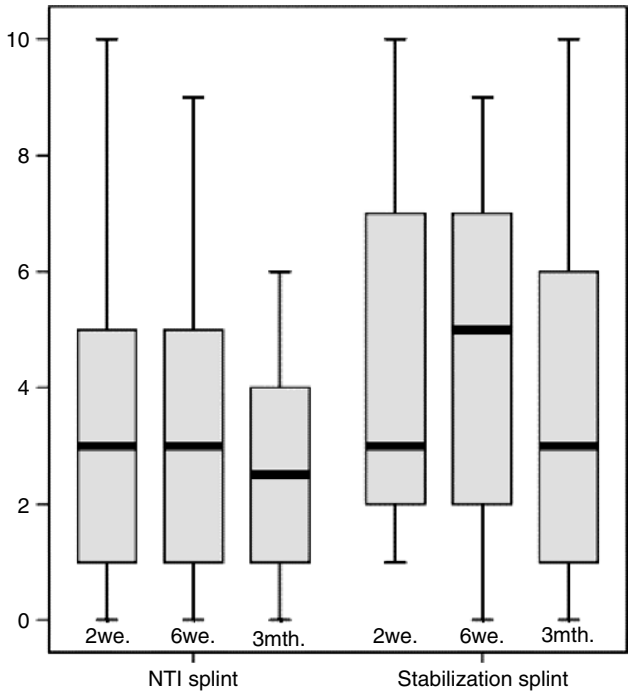

Figure 5. Comfort of splint use reported by the participants according to VAS scores after 2 and 6 weeks and 3 months. Each box shows the median, quartiles, and extreme VAS scores on a scale between 0 and 10. A low VAS score signifies good comfort.

be argued that the stabilization splint patients as a group were less likely to improve following the splint therapy compared to the NTI group.

In general, dentists and investigators are divided in opinion on whether splint therapy is an effective intervention or not for treating patients with TMD. The current study does not address this question, as this trial did not include patients who did not receive any splints. In Norway and, more widely, Scandinavia, the current understanding of splint therapy is that it is helpful for the patient [16,17]. Therefore, conducting a trial with a sample arm receiving only verbal counseling would be considered unethical according to the understanding of the Helsinki declaration that lay people cannot be offered ineffective therapy for the sake of research purposes. The seeming efficacy of both splint types can be explained by factors such as regression towards the mean, a Hawthorne effect, natural fluctuation of the TMD signs and symptoms, and other explanations [23]. The present trial thus does not answer whether both the NTI-tss and the stabilization splint bring about the observed general positive therapy outcomes or if none of them do.

The patients in this sample demonstrated a remarkably high intake of medicine and high prevalence of general musculoskeletal pain and self-reported headache (Table I). This has also been a characteristic of other TMD patient samples in Scandinavia [15–18,21,22,24–27]. The gender proportions and TMD diagnoses of the current patient sample demonstrated a fairly similar distribution to previously reported study samples from the Dental Faculty of Oslo [21,22,27]. Thus, the patients referred to, or seeking treatment here, are mainly women distressed by myofascial pain. Interestingly, neither of the patient groups showed any improvements of the neck and shoulder pain, which is consistent with observations in past patient cohorts [27].

Most of the previous literature supports the efficacy of stabilization splint therapy in spite of a wide spectrum of splint designs [1,5]. However, the exact therapeutic mechanism of the occlusal splint remains unclear, and although many theories have been proposed, there is little experimental evidence to support one theory over another because several factors may operate simultaneously [28]. When considering the positive results obtained with the variety of splint designs used, it is unlikely that a specific occlusal design of the splint is of much importance. Variations of specific details that have been addressed are for example flat plane occlusal splints with [8,9,29–33] or without cuspid ramps [7,34–40]. Another example of variation in detail is simultaneous contact of all opposing teeth [31–33,41], or opposing of only the posterior teeth [38].

It has been hypothesized in the literature that the presence of a foreign object in the palate may reduce nocturnal jaw muscle activity, possibly due to changes in the oral tactile stimuli, a decrease of oral volume, and space for the tongue [11,12]. It has also been hypothesized that an intraoral splint may make the patient aware of the position and potentially harmful use of the jaw [7,9,42,43]; this has been labeled a "cognitive awareness" concept. It may be debated whether this explanatory model can only be applied to day-time splint use, but such a theory is not inconsistent with the claims of positive treatment outcomes for "placebo splints" [7–10,16,17], bite splints with only a frontal plateau [44], and even soft splints [45,46]. In this context, it is perhaps not surprising that there were no differences in treatment outcomes between the two splint designs in this trial.

One negative aspect of the NTI splint is that its design is such that irreversible occlusal changes can develop after prolonged use if the clinician does not monitor the use. Patients who receive a conventional fully occlusal stabilization splint can be advised to keep the splint for future use whenever the need arises. This advice cannot be given to patients receiving NTI splints, and dentists should actually warn against prolonged use of this splint type because of the increased risk of irreversible occlusal changes. Another argument against prolonged use of the NTI splint is its small dimensions, which can lead to swallowing or aspiration. Medical emergencies due to aspirated NTI splints have been reported in the case of three persons in the USA [47], and another occurrence has just been reported in Norway [48].

The current trial was relatively small. It included a heterogeneous patient sample and examined diagnoses, medication, comorbidity, subjective pain and distress experience, and was of limited duration. These factors may also explain the slight discrepancy between the present study results and the recent Swedish RCT [15]. This study could not confirm any positive treatment effect of the NTI splint. However, it is difficult to compare the results directly, since the latter study did not present any statistical analyses.

Several questions remain that can only be addressed in a trial of longer duration and perhaps also with a focus on more specific RCD/TMD diagnostic subclasses. These are primarily questions related to long-term patient compliance with use of the NTI splint and the reality of the potential for movements of teeth due to posterior tooth supra-eruption with or without anterior tooth intrusion. However, undertaking clinical trials must be weighted against the real or appeared health risk hazards relative to the sporadic reports of splint aspirations.

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