Effect of material type and thickness of occlusal splints on maximum bite force and sleep quality in patients with sleep bruxism: A randomized controlled clinical trial

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Research Article

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Abstract

Objective: To evaluate the short-term effects of hard and soft splints of different thicknesses on maximum bite force (MBF) and sleep quality (SQ) in participants with sleep bruxism (SB).

Methods: One-hundred-fifteen patients were randomly allocated to five groups: Groups H2(Hard splint-2 mm), H3(Hard splint-3 mm), S2(Soft splint-2 mm), S3(Soft splint-3 mm), and C (control). Outcomes were MBF (assessed with a digital gnathodynamometer) and SQ (assessed with the Pittsburgh Sleep Quality Index). Measurements were performed at T0 (before the splints), T1 (1-month follow-up), and T2 (2-months follow-up). Data were analyzed using one-way ANOVA, Tukey's HSD, and chi-square tests.

Results: At T1, the highest MBF values were in group H3 (658.01 ± 22.6 N), while the lowest was in group S2 (585.45 ± 8.68 N). For T2, the highest values belonged to the H3 group (676.85 ± 21.9 N), and the lowest values were observed at group S2 (565.65 ± 10.9 N) ($p< 0.05$).For SQ, groups S2 and S3 revealed the lowest PSQI values at T1 (9.1; 9.6) and T2 (9; 9.5) ($p<0.001$).

Conclusions: The use of both 2 and 3-mm thick soft splints resulted in a decrease in MBF. The improvement in SQ formed by the soft splint groups occurred in the 1st month and was maintained in the 2nd month.

Clinical Relevance: This study provides clinical tips in terms of material type and thickness of the occlusal splint, which should be applied according to the needs of SB patients (such as improving SQ and regulating MBF).

Introduction

Bruxism is described by the 3rd edition of the International Classification of Sleep Disorders as 'repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible' [1]. Bruxism most commonly occurs during sleep (named sleep bruxism(SB)) and the prevalence of SB, which is more common in young adults, ranging from 8–10% [2, 3]. This sleep-related movement disorder is recognized as one of the main risk factors for temporomandibular disorders (TMD), headaches, tooth wear, and even failure or damage of implant or dental restorations [4, 5]. The pathophysiology and etiology of SB are not well understood, but sleep-related central factors were shown to play a major role in the emergence of SB [5].

Since it is a critical problem in dental clinics, various treatment methods, including occlusal, psychological, pharmacological, and physiotherapy, have been suggested for SB [3, 6]. Among these methods, occlusal splint therapy is accepted as the 'gold standard' [7]. Occlusal splint used during sleep helps to inhibit the outcomes of tooth grinding and SB (tooth wear, pain, and grinding sounds), distributes occlusal force, and reduces stress in the structures of the masticatory system and temporomandibular joint [7, 8]. It has also been reported in the literature that occlusal splints significantly reduce SB-related events and the sleep motor activity index of SB patients [3, 5]. These splints, which have different

thicknesses, are generally produced in two forms as hard and soft [9, 10]. Although there is no clear information in the literature until now, it is generally thought that the therapeutic effect of hard occlusal splints is equal to or superior to soft splints [11–13].

One of the most common parasomnias in adults is SB [8]. Sleep quality is an effective factor in the emergence of bruxism and it has been shown that SB is associated with poor sleep quality in these patients [8, 14, 15]. Micro-awakenings, repeated arousals during sleep, increased stress, and anxiety are shown as the main reasons for this negative relationship between SB and sleep quality [16, 17]. In order to improve sleep quality, occlusal splints of various designs were used in patients with SB and positive clinical results were obtained [3, 18–20]. However, these studies have not comprehensively considered which splint type (soft or hard) and thickness are ideal for improved sleep quality. This question constitutes one of the starting points of the current study.

Although little is known about the mechanism of occlusal splints' action, this treatment has a reducing effect on nocturnal masticatory muscle activities and protects the teeth from damage caused by jaw muscle contractions related to SB [21, 22]. The occlusal splint also plays a role in the maintenance of a stable and physiologically optimal occlusal force, as it has a reducing effect on asymmetry and hyperactivity of the jaw elevator muscles [23]. Thus, occlusal splints can change occlusal forces due to their force-distributing and bruxism-reducing effects [21]. When the few studies in the literature evaluating the occlusal splint-occlusal force relationship are examined, it is seen that there are variable results [12, 21, 23–25]. While some of these studies applying different splint usage times claimed that soft splints were more advantageous in terms of regulation of occlusal force, other groups of researchers reported results in favor of hard splints [12, 21, 23–25]. Despite these studies, there is no study evaluating how hard and soft occlusal splint types in different thickness options affect occlusal force, and this lack of data is another question that reveals this study.

In light of the above-mentioned information, the aim of the present study was to evaluate the effects of hard and soft splints of different thicknesses on occlusal force and sleep quality in patients with SB. The null hypotheses of the study are as follows: 1) Hard/soft occlusal splints of different thicknesses are equivalent in improving the sleep quality of SB patients. 2) Different occlusal splint thicknesses do not affect the occlusal force.

Materials And Methods

Study design

This five-arm parallel design, randomized clinical trial was performed on subjects from the Istanbul University, Faculty of Dentistry, Istanbul-Turkey. Intervention and follow-up sessions were performed between August 2021 and December 2021. The study was approved by the Ethics Committee of the Istanbul University, Faculty of Medicine (protocol number 2019/19; ClinicalTrials Identifier: NCT04934449), and the ethical guidelines of the Declaration of Helsinki were followed. Patients gave written informed consent to participate in the study after a full explanation of the procedures. This study

fulfilled the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) to enhance the quality of the results.[26]

Study population

Subjects were recruited from the student list of Istanbul University, Faculty of Dentistry. Students who had SB signs and symptoms were enrolled in the study if they met the following inclusion criterion:

1. Being healthy with complete permanent dentition.

The exclusion criteria were as follows:

1. Presence of a systemic disorder that could compromise the masticatory system (e.g., epilepsy, neurological disorders, cerebral palsy, among others),

2. Presence of signs and/or symptoms of TMD based on Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) [27],

3. Current use of drugs or systemic disorders that could interfere with muscle activity and sleep (directly or indirectly),

4. Inappropriate behavior and/or refusal to cooperate with data collection and dental procedures,

5. Tooth loss (except for third molars),

6. Toothache report,

7. Active periodontitis (presence of periodontal pockets involvement of the supporting tissues),

8. Caries lesions,

9. Use of orthodontic appliances,

10. Use of dental prosthesis (removable or fixed partial),

11. Subjects with moderate to severe malocclusions, diagnosed by using the Orthodontic Treatment Need Index (IOTN) (scores 5 or 6-severe and extreme need for orthodontic treatment),

12. Alcohol or drug abuse.

Sample size assumption, allocation, and study groups

The sample size determination was performed based on previous studies, evaluating interocclusal appliance therapy on bite force and/or sleep quality [19,21]. Power analysis (PS software; Dupont and Plummer, 1997) was conducted by considering power = 0.80, and alpha = 0.05 with a d = 0.76 effect size.

The minimum number of samples required for each group was 18, but 115 patients were invited to this study due to potential losses.

Groups were allocated based on a randomized controlled trial, and the random sampling method was performed using a web-based number generator [28]. All files were enumerated and divided into one to five groups consecutively. Patients were randomly assigned to one of the following groups, depending on the type of occlusal splint applied:

Group H2: Test group; hard occlusal splint with 2-mm thickness; *n*=23

Group H3: Test group; hard occlusal splint with 3-mm thickness; *n*=23

Group S2: Test group; soft occlusal splint with 2-mm thickness; *n*=23

Group S3: Test group; soft occlusal splint with 3-mm thickness; *n*=23

Group C: Control group; without occlusal splint therapy; *n* = 23

Clinical examination

Due to the presence of signs and/or symptoms of TMD being an exclusion criterion for the groups, diagnostic Criteria for Temporomandibular Disorder (DC/TMD) were used to define TMD patients [27]. Axis I of the DC/TMD was administered by one trained examiner and axis II was carried out by the patients individually without time restriction. Patients exhibiting symptoms and signs of TMD were excluded from the study.

The SB diagnosis of the participants was determined by the following criteria:

1. Reporting nocturnal tooth grinding and sounds mostly by the room partner at least three days a week, awakening with cervical and/or facial muscle fatigue and/or pain with dental and/or joint discomfort, and having fractures in dental restorations or teeth.
2. Presence of shiny and polished wear facets between opposing teeth detected during mandibular excursions and clinical examination.
3. Having moderate frequency SB according to the results of the polysomnography exam.[29] Patients who met the first two criteria mentioned above were considered eligible for polysomnography to provide a definitive diagnosis of SB.[30] Polysomnographic exams were performed by using the laboratory-based system in a temperature-controlled and quiet room from 9 PM until the patient woke [19]. One trained technician evaluated the electromyography results based on the American Association of Sleep Medicine criteria [19].

Occlusal splint therapy and group applications

Mandibular and maxillary casts were obtained from the groups for hard (H2 and H3 groups) and soft occlusal splint (S2 and S3 groups) construction and these casts were mounted on semi-adjustable articulators (Hanau™ Wide-Vue Articulator; Whip Mix Corporation, KY, USA) at maximum intercuspation. Wax-up was performed on the maxillary casts and hard stabilization splints were fabricated from heat polymerized acrylic resin (Trevalon; Dentsply Sirona, NC, USA) according to the instructions of the manufacturer. Complete coverage maxillary splints were 2 mm and 3 mm thick between the mandibular and maxillary first molars, and the splint thickness in the anterior region varied between 3-5 mm according to the occlusal relationship of the patient. Symmetric and simultaneous occlusal contacts with canine guidance were established and all devices were finished and polished [31].

For soft occlusal splint groups (S2 and S3), ethylene vinyl acetate-based material with two different thickness values of 2 mm and 3 mm (KEYSTONE - Soft Eva; Keystone Dental Inc., Cherry Hill, NJ, USA) was used for the fabrication of the splints. Soft sheets were formed by using a dental vacuum forming machine (Ultraformer; Ultradent Products Inc., South Jordan, UT, USA) according to the manufacturer's instructions. All devices were fabricated and adjusted by one researcher. All test groups used occlusal splints for at least 8 hours during sleep for 2 months.

For the control group, the patients did not receive any treatment and were informed that they would be eligible for SB treatment after one year of symptom follow-up. Group C was not reported to be a control group throughout this study, but they were asked to come to the clinic several times in order to increase group homogeneity, and these patients were evaluated using the same parameters. All groups were requested to avoid taking any medications like antidepressants, tranquilizers, sleeping pills, or muscle relaxants during the research. In addition, no further advice was given to patients, such as sleep hygiene, to avoid confounding factors.

Data collection

Data collection was carried out by a single-blinded researcher by interviewing all patients face to face. Parameters of maximum bite force and sleep quality were evaluated three times: T0, before occlusal splint therapy, T1, one month, and T2, two months after occlusal splint therapy began [19].

Maximum bite force

Maximum unilateral bite force was measured using a digital gnathodynamometer (Model DDK/M; Kratos, Sao Paolo, Brazil) with fork connection [32]. Maximum force values were provided in Newtons(N) by bite fork with the following dimensions: 10 mm thickness, 15 mm width, and 12 mm high. The appliance was calibrated by loading known force values on the gnathodynamometer.

The examination was performed in a quiet room by having participants seated with their heads in a natural posture, providing the Frankfurt plane parallel to the ground. The fork was placed between the mandibular and maxillary arches and on the first permanent molars, which are the higher force-generating teeth [19].

Before recordings, the participants were trained and instructed to bite the fork with maximum force. After that, they were asked to apply their maximum bite force on both sides (left and right) of the dental arches for three times. The highest value of each bite force was recorded and the mean value of these measurements was considered as the final value with approximately 0.1 N.

Sleep quality

Evaluation of sleep quality was performed with the Pittsburgh Sleep Quality Index (PSQI) consisting of 19 self-report questions and 5 questions to be answered by a spouse or roommate [33]. The 19 scored questions of the index consist of 7 components and each component is evaluated over 0-3 points. These components are subjective sleep quality, sleep latency, sleep duration, the efficiency of habitual sleep, sleep disturbances, use of sleep medication, and diurnal dysfunction, respectively. The total score of these 7 components gives the final score, and the final score ranges from 0 to 21. Accordingly, a total score greater than 5 indicates "poor sleep quality".

Statistical analysis

Statistical analysis was carried out using standard statistical software (SPSS V23; IBM Armonk, NY, USA), considering a significance level of $p < 0.05$. Conformity to normal distribution was evaluated by the Shapiro-Wilk test. Intra-group time comparisons of normally distributed data were analyzed by repeated-measures analysis of variance (ANOVA). The difference between groups over time was analyzed by one-way ANOVA. Multiple comparisons were performed with Tukey's HSD. ANOVA was applied to compare quantitative descriptive statistics by groups, and the chi-square test was performed for the comparison of categorical data.

Results

During the study, the participants did not report any adverse effects or compliance issues related to the use of the occlusal splints.

Demographic data

As shown in the flowchart of the study **(Figure-1)**, 115 SB patients out of 132 were selected to be eligible and randomly assigned. Eleven patients (2 from Group H2, 4 from Group S2, 3 from Group S3, and 2 from the control group) dropped out of the study as they did not respond and were not able to come to the clinic. Statistical analyzes showed that those who dropped out after randomization were not significantly different from those who completed the study in terms of pretreatment demographics or dependent variables.

The demographic data of the participants are displayed in **Table 1**. The duration of the SB ranged from 3.5 to 5.1 years, and the ages were between 18 and 33 years. The majority of the participants were female ($p = 0.63$), and height and weight parameters were significantly different between the groups ($p < 0.05$).

Table-1: Demographic data of the study groups.

Demographic data (Mean±SD)	Groups					
	H2(N=19)	**H3**(N=21)	**S2**(N=19)	**S3**(N=20)	**C**(N=21)	***p****
Age (years)	21.8±5.9	23.2±5.4	22.5±5.6	21.5±5.1	23.5±6.6	0.76
Height (cm)	171.5±11.5	166.7±9.1	172.2±11	167.6±9	161.2±11.3	**0.01**
Weight (kg)	71.5±11.4	66.7±8.8	73.8±13.5	67.6±9.1	63.2±8.5	**0.02**
Duration of disease (years)	4.7±2.5	5.1±1.6	4.1±2.5	3.9±2.3	3.5±2	0.14
	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	***p*****
Gender						
Male	7 (36.8%)	12(57.2%)	7 (36.8%)	9 (45%)	8 (38.1%)	0.63
Female	12 (63.2%)	9 (42.8%)	12 (63.2%)	11(55%)	13 (61.9%)	
Marital status						
Married	2 (10.5%)	3 (16.6%)	1 (5.2%)	3 (15%)	4 (19%)	0.75
Single	17 (89.5)	18(83.4%)	18 (94.8%)	17 (85%)	17 (81%)	
Residence						
Rural	1 (5.2%)	1(4.7%)	1(5.2%)	1(5%)	1(4.7%)	0.99
Urban	18(94.8%)	20(95.3%)	18(94.8%)	19(95%)	20(95.3%)	

Maximum bite force (MBF)

The mean and standard deviation of MBF values of the groups at T0, T1, and T2 are shown in **Figure-2**. At T0, total MBF values were equivalent for all groups (Group C = 626.65 ± 6.5 N; Group S2=625.9 ±8.24 N; Group S3=634.45 ±29.9 N; Group H2=624.6 ±10.35 N; Group H3=632.95 ±15.84 N) ($p > 0.05$). However, there were intragroup and intergroup differences in the right and left values ($p < 0.05$). While there was a significant decrease in total MBF values of S2 (585.45 ±8.68 N) and S3 groups (601.20 ±25.63 N) at T1 time, an increase was detected in H2 (654.5 ±13.21 N) and H3 groups (658.01 ±22.6 N) ($p < 0.05$). The increase and decrease trends observed in the groups (except group C) at time T1 continued in the same way at time T2 and the values were as follows: C=626.8 ±5.8 N, S2=565.65 ±10.9 N, S3=579.85 ±24.94 N, H2=672.25 ±11.62 N, H3=676.85 ±21.9 N) ($p < 0.05$).

Sleep quality (PSQI)

Participants included soft splint had statistically significant improvement in PSQI value after treatment **(Figure-3)** (p <0.001). When the sleep quality values were compared in the groups before and 2 months after the placement of the splints, an insignificant difference was found in the C, H2, and H3 groups (p >0.05). Although similar values were observed at T1 and T2 hours, the sleep quality improvement achieved at both times in the S2 and S3 groups was more significant than in the others.

Discussion

The null hypotheses of this study were rejected as MBF decreased in the soft splint groups (S2 and S3) but increased in the hard splint groups (H2 and H3). Apart from this, soft splint groups demonstrated superior PSQI values over the others.

Occlusal splints are elements that balance the force distribution in the entire masticatory system[34]. Despite this importance, only one study in the literature investigated the occlusal splint types of two different thicknesses (3 mm and 6 mm) in individuals with bruxism, and one study evaluated the effectiveness of hard and soft occlusal splints[21, 35]. Therefore, the current study is the first in the literature to evaluate both different occlusal splint types (soft and hard) and different thickness values (2 mm and 3 mm) together. While Abekura emphasized that 3 mm-thick occlusal splints were more comfortable in their study, Karakis et al. found that both soft and hard splints helped to improve clinical symptoms of bruxism [21, 35]. In this study, soft occlusal splints of both thicknesses were found to be clinically more effective in terms of PSQI, whereas the results obtained in both splint types in terms of MBF were variable, warranting further studies.

It is known that occlusal splints in different thicknesses can cause a change in occlusal force, and occlusal force has an effect on the functional state of the masticatory system and muscle efficiency [21, 36]. Regarding the increased MBF values of 2 and 3 mm thick hard occlusal splints, the results of this study were in line with those of previous studies evaluating 0.6, 1, 2, and 3 mm thick splints [19, 21, 36]. The present study also found a significant increase in MBF on both sides (right/left) during hard occlusal splint therapy, and this increase may be associated with the positive effect of hard occlusal splints on neurobiological regulation of jaw-muscle activity (Figure-2) [37]. While there is only one study in the literature showing that the use of hard splints (1 mm) reduces MBF in patients with bruxism, there are also studies showing that the use of hard splints does not affect MBF (1.5 mm, 2 mm, 3 mm and 6 mm thick splints) [12, 21, 24, 38]. These variable findings may be from splint usage time, diversity of participants, frequency of therapy, type of splint material, the production method of occlusal splints, and evaluation methods.

In the current study, it was observed that the use of soft occlusal splints in both thicknesses reduced MBF (Figure-2). The reduction of MBF in soft splints was consistent with the findings of other previous studies evaluating 2 and 3 mm thick occlusal splints and reporting similar MBF values [12, 20, 21, 36]. This decrease in MBF may be attributed to muscle relaxation or increased awareness of the patient as a result

of the use of soft splints [20, 21]. As there is only one study investigating both soft and hard occlusal splints in sleep bruxism, a direct comparison of this study with the current study showed partial consistency with the findings of Karakis et al., who reported no significant change in MBF for hard occlusal splints and a decrease for soft occlusal splints (2 mm thickness) [21].

At the beginning of the study (T0), there was a significant difference between the right and left MBF values of all groups (Figure-2). This situation did not change at T1 and T2 times, regardless of the occlusal splint type and thickness used, and continued to be different within the groups ($p < 0.001$). These data of the current study are corroborated by the study of Canay et al, who reported no significant change in the asymmetry index after four weeks of splint therapy [39]. Additionally, MBF levels are accepted to be related to bruxism and the findings of the current study may change based on occlusal contact area, interocclusal separations, malocclusion, the location of the measuring device on the jaw, body size, age, weight, height, gender, and posture of the patient [36, 40–43]. Thus, above mentioned parameters may be evaluated in future studies in patients with bruxism.

The choice of biomaterial for occlusal splints has a significant effect on the neurobiological regulation of jaw muscle activity during sleep, and splint thickness has been reported to play a role in the incidence of SB [14, 37]. In this study, the soft splint groups (S2 and S3) showed the lowest PSQI scores among all groups, indicating an improvement in sleep quality with soft splint use (Figure-3). These findings may be attributed to the theory that soft splints increase awareness of tiredness of the muscles by reducing occlusal force, as stated in the study by Narita et al [12]. The current study showed inconsistency with the findings of the only study in the literature that evaluated soft and hard splints (2 mm thickness) together and found that the use of both soft and hard splints improved sleep quality in individuals with SB [21]. Another point worth noting is that patients included in this study reported a better sleep quality after one month of soft splint use, with a non-statistically significant decrease in PSQI scores in the second month. Taken together, one month of splint use may be accepted as sufficient to increase sleep quality based on the findings of this study, while the placebo effect should be evaluated in future studies [44, 45].

Since there are not enough studies in the literature in which soft splints are used in patients with SB, the comparison was made over studies evaluating hard splints. The current study did not corroborate with the results of a study from Harada et al., who reported that the use of hard splints (1–2 mm thickness) was effective only immediately after the insertion and that the use of splints for 6 weeks did not produce a clinical effect [7]. Because the use of hard splints in the current study did not cause a significant decrease in PSQI scores from the beginning of the study to the completion of the 2-month follow-up period. The reason for this variation may be the difference in splint thicknesses, the production method of splints, the characteristics of the included population, and the difference in the evaluation methods. Last but not least, some studies evaluating hard splints (1 mm, 2 mm, 3 mm thickness) reported improvement in sleep quality, whereas others showed no change (1 mm, and 2 mm thickness) [3, 5, 7, 9, 11, 14, 18, 19, 46–49]. Thus, the efficacy of hard and soft splints in sleep quality remains controversial.

The limitations of this study are not determining the degree of SB, not considering SB duration, not blinding, the inclusion of only SB, a short span for follow-up, and one-way therapy evaluation (using PSQI). Future research should use polysomnography to further evaluate specific areas of sleep improvement after an occlusal splint is used. Therefore, further studies using a larger participant population are needed to yield more consistent data regarding the effect of hard and soft occlusal splints.

Conclusions

The use of soft occlusal splints (2 mm and 3 mm thick) indicated a significant decrease in MBF, while the use of hard occlusal splints (2 and 3 mm thick) was accompanied by an increase in MBF in patients with SB. The findings suggested that 1 month of therapy with a soft occlusal splint had a positive effect on sleep quality and continued this improvement at 2 months of follow-up.

Declarations

Ethical approval

The study was approved by the Ethics Committee of the Istanbul University, Faculty of Medicine (protocol number 2019/19), and the ethical guidelines of the Declaration of Helsinki were followed.

Competing interests

The authors declared that they have no conflict of interest.

Authors' contributions

MB and MO designed and planned the study, MB performed the experiments, MO made statistical analysis, MB and MO wrote the manuscript. Authors have read and agreed with the final version of the manuscript.

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Availability of data and materials

The data that support the findings of this study are available in Clinical Trials [repository name] at

ClinicalTrials.govhttps://clinicaltrials.gov, reference number [ClinicalTrials Identifier: NCT04934449].

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Figures

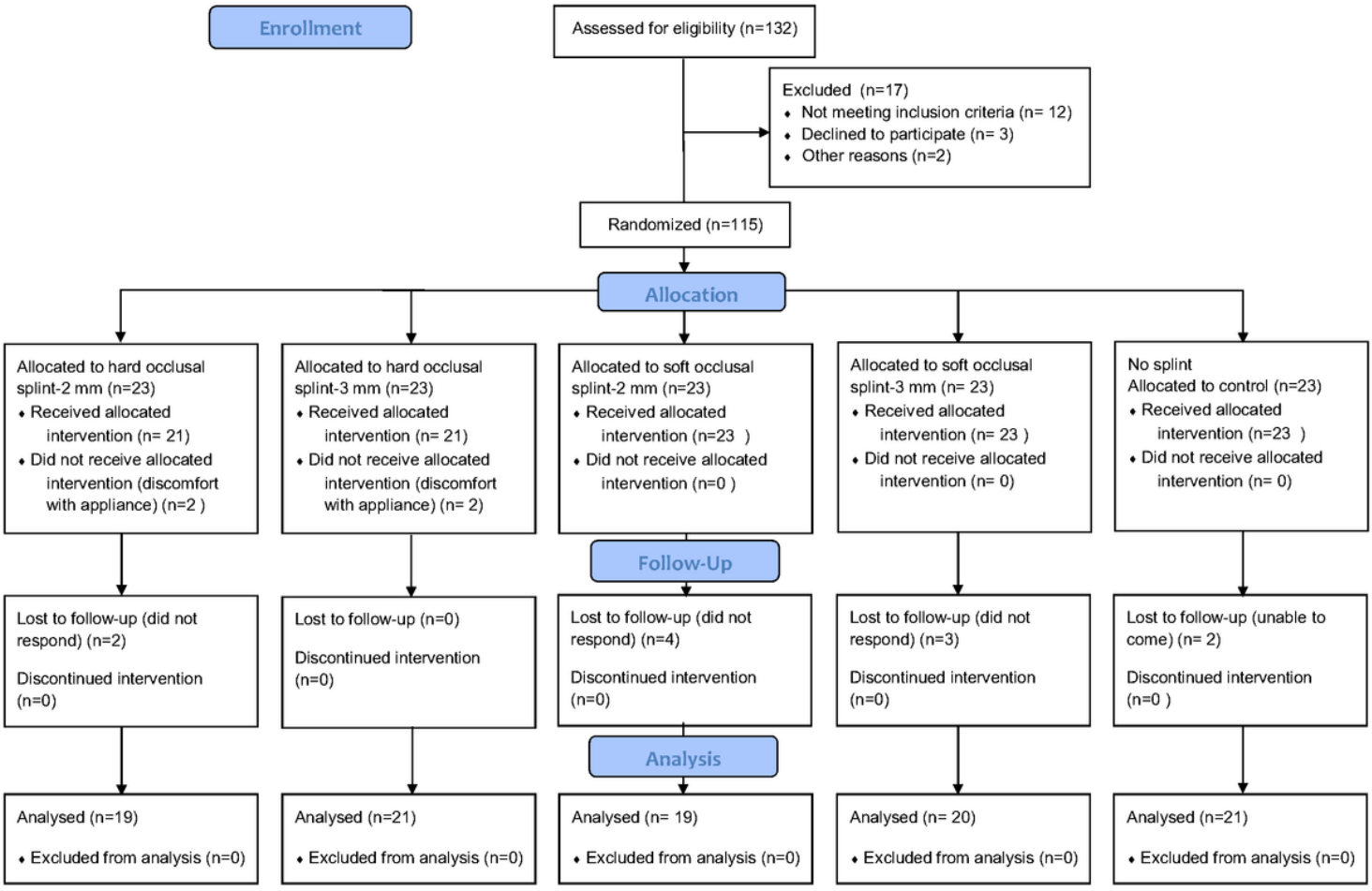

Figure 1

Flowchart of the study.

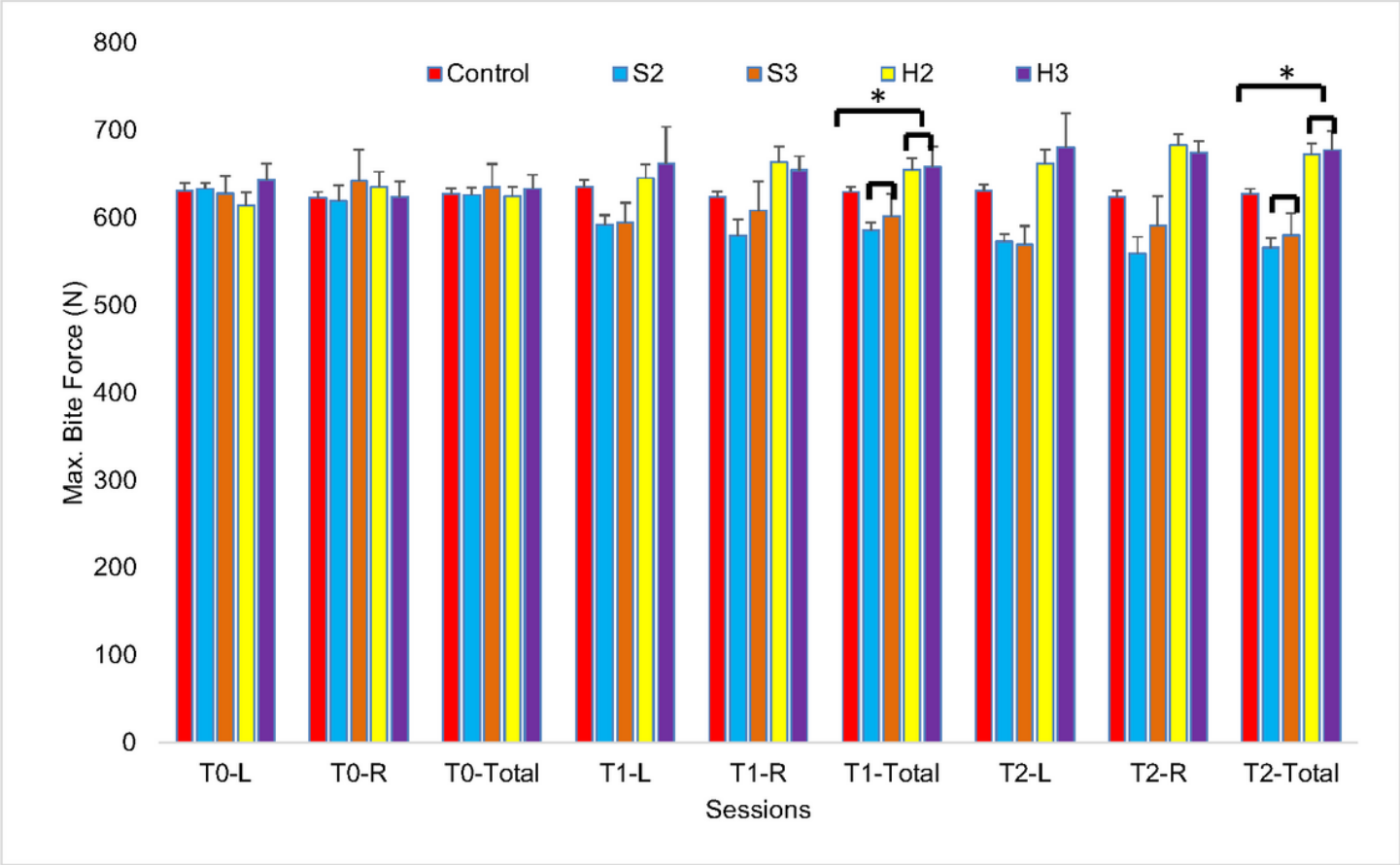

Figure 2

Maximum bite force values of the groups from baseline to 1 and 2 months (Newton). (R=Right, L=Left)*

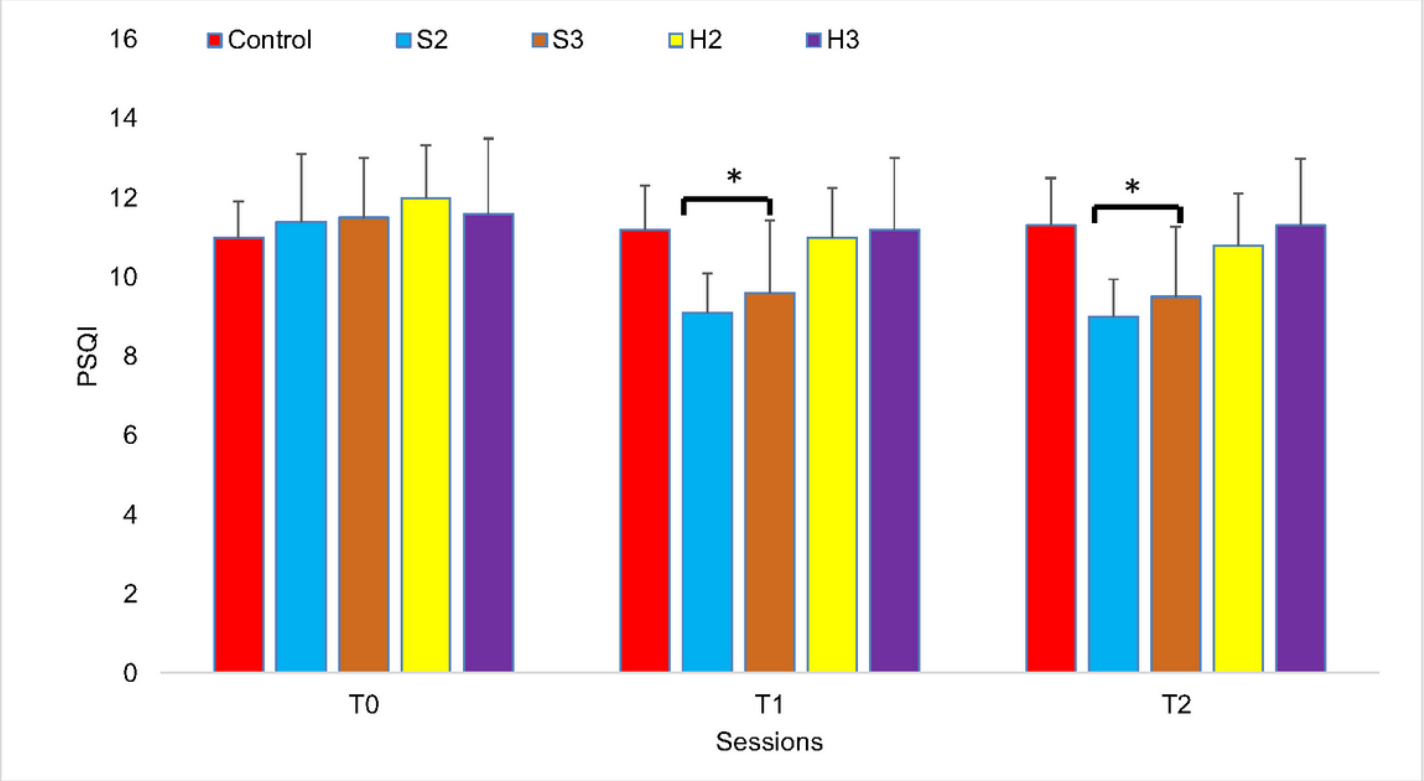

Figure 3

Comparison of PSQI global score from baseline to 1 and 2 months. (PSQI= Pittsburgh Sleep Quality Index)