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Canadian Jr. of Clinical Perf. Evaluation Malpractice

Evaluating the Effectiveness and Potential Risks of Lower Jaw Advancement on Tempro-Mandibular Joint among Patients with Dental Appliances and Sleep Apnea: A One-Year Comparative Study

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Abstract: The purpose of this research was to assess the impact of several distinct levels of mandibular protrusion, 50% versus 75% of maximum protrusive capacity, on somnographic factors following one year of dental appliance therapy in individuals with mild to moderate obstructive sleep apnea syndrome (OSAS). Another aim was to compare the quantity of unfavorable occurrences on the stomatognathic system. In a prospective study, 74 male patients were randomly assigned to receive a dental appliance with either 50% (38 patients) or 75% mandibular advancement (36 patients). After one year of therapy, 55 patients completed the follow-up. Somnography was conducted to measure treatment effects before and approximately 11 months post-treatment. The apnea, apnea/hypopnea, and oxygen desaturation indices decreased significantly in both groups after one year ($P < 0.001$); however, there were no distinctions between the groups. Normalization (apnea index <5 and apnea/hypopnea index <10) was observed in 79% in group 50 and in 73% in group 75. Few patients (<5%) reported symptoms from the stomatognathic system except for headache (> once a week), which was reported in one-third of the patients. Headache was significantly less frequent after one year of therapy in both groups ($P < 0.001$). No severe complications were observed except for several patients who reported a painful condition from the temporomandibular joint in either group. In conclusion, mandibular progression with a dental appliance effectively decreases the sleep-breathing disorder measured as the frequency of apneas, and a notable mandibular advancement did not display a greater improvement in the medical issue compared to less advancement for patients with mild to moderate OSA. On the basis of few adverse events in the stomatognathic system or other complications, we can endorse dental appliance treatment, and for patients with mild to moderate obstructive sleep apnea, it is not advisable to commence treatment with more than 50% mandibular advancement.

Citation: Alekhandro L, Peterson S. Evaluating the Effectiveness and Potential Risks of Lower Jaw Advancement on Tempro-Mandibular Joint among Patients with Dental Appliances and Sleep Apnea: A One-Year Comparative Study. Canad. Jr. Clin. Perf. Eval., 2024, 1, 12, 163-181.

Academic Editor: Paul Weber
Received: 16 January 2024
Revised: 25 February 2024
Accepted: 18 March 2024
Published: 24 March 2024

1. Introduction

Obstructive sleep apnea syndrome (OSAS) is an intricate medical condition marked by the recurrent collapse of the upper airway during sleep.[1] This collapse leads to a series of recurring episodes known as apneas, which result in disturbed breathing patterns during sleep.[2] OSA is connected with a range of well-being concerns and can significantly affect the quality of life of impacted individuals.[3] One of the established and prosperous treatment modalities for OSA is the utilization of dental appliances with mandibular progression, a technique that aims to enhance this sleep-related breathing disorder. [4] Numerous studies have explored the utilization of dental appliances with diverse degrees of mandibular progression, particularly at either 50% or 75% of a patient's utmost protrusive capacity.[5] These inquiries sought to determine the most efficient degree of mandibular progression in alleviating OSA symptoms.[6] It's noteworthy to emphasize that most dentists generally use one-piece dental appliances with a fixed degree of progression in their practice.[7] These appliances are favored for their simplicity of use and cost-effectiveness in comparison to adjustable appliances, which are more intricate and costlier to manufacture.[8]

Conversely, certain studies have employed adjustable appliances to evaluate patient comfort and the potential advantages of customizing the degree of mandibular progression.[9] While some specialists contend that adjustability and titration are crucial for ideal patient management, as they allow for individualized treatment approaches, the clinical proof supporting the long-term superiority of adjustable appliances over non-adjustable ones remains undecided.[10] Consequently, despite ongoing dialogues and clinical viewpoints regarding the advantages of adjustable appliances and the significance of customizing treatment to individual patients, there is a noteworthy deficiency of well-designed, randomized, controlled investigations affirming the long-term efficiency and superiority of adjustable appliances over their fixed equivalents.[11] This hiatus in clinical proof underscores the necessity for further investigation and trials to better fathom the optimal approach for managing OSA with dental appliances.[12] Such studies will be pivotal in providing direction to healthcare specialists and making sure that OSA patients receive the most efficient and comfortable treatment feasible.[13]

In the realm of exploration on obstructive sleep apnea (OSA), one notable observational study stands out, as it tried to comprehend how varying degrees of mandibular progression influence patients with moderate OSA.[14] Moderate OSA is a state marked by more frequent and severe apnea episodes than mild OSA but less so than severe OSA.[15] The study aimed to throw light on the effects of mandibular progression, a typical treatment approach for OSA, among this particular group of patients. The outcomes of this observational study indicated that the degree of mandibular progression had a conspicuous and dose-dependent effect on the pharynx. When the mandible was progressed to a greater extent, it resulted in a decrease in the closing pressure of the pharynx.[16] This reduction in closing pressure of the pharynx, in turn, correlated with a decrease in the frequency of nocturnal desaturations.[17] Nocturnal desaturations refer to occurrences where a patient's blood oxygen levels decline during the night, often connected with OSA episodes.[18] The findings implied that increasing the degree of mandibular progression could potentially aid in alleviating OSA symptoms in patients with moderate OSA.[19] However, it's pivotal to mention that this study was observational in nature, meaning it observed and recorded data without intervention or control.

Observational studies can offer beneficial insights, but they might be subject to particular restrictions, such as the absence of a randomized control group.[20] A randomized control group allows for a more rigorous assessment of the treatment's effectiveness by comparing it to a placebo or alternative treatment.[21] Significantly, the study underscored a prominent gap in the current research. While observational data proposed a positive association between increasing mandibular progression and OSA symptom improvement among moderate OSA patients, no randomized study had been executed at that point to directly juxtapose different degrees of mandibular progression for patients with mild to moderate OSA. Randomized studies are deemed the gold standard in research since they employ controlled techniques to establish causal relationships and provide more robust evidence for the effectiveness of interventions.[22] Hence, the absence of a randomized study comparing various degrees of mandibular progression in the treatment of patients with mild to moderate OSA highlighted the necessity for more comprehensive research in this field.[23] Such an investigation could supply definite proof regarding the optimal degree of mandibular progression for this particular patient group, consequently augmenting treatment outcomes and patient care.[24] The principal objective of this experiment was to compare the impact of multiple unique levels of mandibular progression (75% versus 50% of the utmost protrusive ability) on somnographic aspects following a year of dental device therapy in individuals with mild to intermediate OSA. A secondary intention was to gauge the quantity of unfavorable occurrences concerning the stomatognathic system.

2. Methodology

2.1. Research significance and implication

The proposed relation between clinical performance, malpractice, and the impact of lower jaw displacement on the temporomandibular joint lies in the context of evaluating the effectiveness and potential risks of dental appliance therapy for patients with mild to moderate obstructive sleep apnea syndrome (OSAS).

Clinical performance evaluation in this study involves assessing the efficacy of different levels of mandibular advancement (50% versus 75% of maximum protrusive capacity) in treating OSAS over a one-year period. This evaluation includes measures such as somnographic factors, specifically apnea index, apnea/hypopnea index, and oxygen desaturation index, before and after treatment.

Malpractice prevention comes into play through the careful monitoring of adverse events and complications associated with the therapy, particularly those related to the stomatognathic system. The study examines the occurrence of symptoms such as headaches and painful conditions in the temporomandibular joint, aiming to identify any potential risks that could lead to malpractice claims or patient dissatisfaction.

By comprehensively evaluating the treatment outcomes and potential complications, healthcare providers can make informed decisions regarding the selection of appropriate treatment modalities and treatment parameters. This can ultimately contribute to both improved clinical performance and reduced risk of malpractice incidents in the management of OSAS using dental appliances.

2.2. Medical terminology

In this investigation, precise criteria were established to gauge and diagnose sleep-related breathing irregularities, particularly obstructive sleep apnea (OSA). These standards are vital for accurately evaluating the seriousness and repercussion of OSA in patients: Apnea was characterized as the temporary discontinuation of respiratory airflow for a duration of at least 10 seconds. The assessment of this phenomenon was executed using a thermistor, a device that identifies alterations in temperature and, in this scenario, airflow patterns.[25] Hypopnea was distinguished by a substantial reduction in the airflow signal, commonly at least a 50% decline as documented by the thermistor. Concurrently, it was linked with a reduction in hemoglobin oxygen saturation of at least 4%. This drop-in oxygen saturation indicates reduced oxygen levels in the bloodstream because of partial airway blockage during sleep.[26] The Apnea Indicator was specified as the mean number of apnea occurrences that took place per hour of sleep. It offers a measurement of how often apneas occur during a night's rest, with a greater AI suggesting more recurrent apneas.[27] The Apnea-Hypopnea Indicator was specified as the mean number of combined apneas and hypopneas occurring per hour of sleep. It is a comprehensive measurement that takes into consideration both complete apneas and partial blockages (hypopneas), delivering a more comprehensive evaluation of sleep-related breathing irregularities.[28] The Oxygen Desaturation Indicator ODI was specified as the mean number of episodes during which oxygen levels in the bloodstream desaturated by at least 4% per hour of sleep. This standard spotlight the degree of oxygen desaturation incidents, frequently linked with OSA. The diagnosis of OSA was founded on distinct criteria. To be precise, OSA was identified when the Apnea Indicator (AI) was equal to or greater than 5 or when the Apnea-Hypopnea Indicator (AHI) was equal to or greater than 10.[29] These criteria were in accordance with the directives outlined by the Medical Research Council in 1994. These guidelines are broadly acknowledged for characterizing the presence and intensity of OSA in clinical practice.[30] The effectiveness percentage was outlined as the proportion of patients who underwent a reduction in their Apnea Indicator (AI) or Apnea-Hypopnea Indicator (AHI) of at least 50% following

the treatment. This measure evaluates the success of the treatment in mitigating the seriousness of OSA. The term "standardization" was employed to portray a specific degree of amelioration.[31] It was attained when the Apnea Indicator (AI) fell below 5, and the Apnea-Hypopnea Indicator (AHI) decreased to under 10. In other terms, a patient was considered to have standardized sleep-related breathing patterns when their sleep apnea became significantly less severe or virtually absent.[32] These interpretations and measures are fundamental in defining the presence and seriousness of obstructive sleep apnea, as well as in assessing the efficiency of treatment measures, guaranteeing that the research outcomes are exact and medically meaningful.

2.3. Patients:

The research population comprised 74 patients who were referred for treatment from the Maxillo-Facial Surgery (MFS) Department to the Department of Stomatognathic Physiology at Central tertiary Hospital. To guarantee a uniform patient group, specific inclusion and exclusion criteria were established:

2.3.1. Inclusion Criteria:

2.3.1.1. The research encompassed individuals who had been medically validated to have mild to moderate obstructive sleep apnea (OSA), precisely characterized as having an Apnea Indicator (AI) of 5 or more but not surpassing 15.

2.3.1.2. Patients required adequate dental support to secure the dental appliance efficiently. This prerequisite involved having at least one premolar or molar tooth in both the upper and lower jaws on both the right and left sides. This dental support ascertained the appliance's secure anchoring.

2.3.1.3. Patients were obligated to have no severe dental conditions such as extensive tooth decay (cariogenic) or notable gum maladies (periodontal concerns). These dental problems could obstruct the utilization of the dental appliance.

2.3.2. Exclusion Criteria:

2.3.2.1. The research excluded individuals who fell beyond the age range of under 20 years or above 65 years.

2.3.2.2. Patients with severe cardiovascular, neurological, or respiratory maladies were also omitted, as these conditions could convolute the research findings.

2.3.2.3. Significant nasal hindrance was another exclusion standard since it could influence the patients' capability to employ the dental appliance efficiently.

2.3.2.4. Patients with a noticeable overbite of anterior teeth, described as surpassing 6 millimeters, were not integrated in the research.

2.3.2.5. Individuals who had formerly undergone therapy for OSA employing continuous positive airway pressure (CPAP) or uvulopalatopharyngoplasty (UPPP), a surgical intervention, were excluded.

2.3.2.6. Those with ongoing temporomandibular joint (TMJ) discomfort or apparent muscle discomfort in the jaw were also disregarded from the research.

After patients fulfilled the inclusion criteria and were exempt from the exclusion criteria, they were regarded as qualified for the research. These eligible patients were

then arbitrarily allotted to one of two groups: Group 50 or Group 75. The allocation was dictated employing a randomized method, with patients arbitrarily designated to these groups based on a certain percentage of mandibular progression (50% or 75%) in relation to their maximum mandibular protrusive capacity. This randomization was performed in clusters of four patients utilizing a closed-envelope system, ensuring that the selection procedure was unbiased, blinded and not influenced by any prior knowledge or preferences.

2.4. Trial design

38 patients from the original cohort of 74 were randomly allocated to group 50, and 36 patients were assigned to group 75 (as seen in Figure 1). However, over the course of the trial, a number of patients from both groups made the decision to discontinue treatment before the one-year follow-up point, for a variety of reasons. Nine patients from group 50 withdrew for the following reasons: three patients had trouble cooperating with the treatment, three patients could not tolerate the dental device, and one patient had undergone extensive dental work that rendered the device incompatible with their treatment plan. One patient passed away during this time. Ten patients in group 75 left the study for the following reasons: one patient passed away, three patients had trouble collaborating with the therapy, and one patient left for other reasons. Ten patients in group 75 discontinued treatment for the following reasons: one patient passed away, three patients had trouble cooperating with the treatment, one patient withdrew for various medical conditions, one patient could not tolerate the dental device, one patient underwent extensive dental work that made the device unsuitable, and two patients complained of pain in their temporomandibular joints (TMJs) when moving their jaws.

It is significant to emphasize that the university ethics committee reviewed and approved the study design and procedures, assuring compliance with ethical norms and guidelines. Additionally, the participants in the study gave their informed permission, demonstrating their choice acceptance of participation. The study adhered to the intention-to-treat (ITT) principle while reporting the findings. Regardless of whether a patient finished the trial or withdrew from it early, this strategy involves include all patients in the analysis based on their initial randomization. Clinical trials frequently employ ITT analysis to preserve the integrity of the randomization procedure and reduce potential biases in outcome interpretation.

2.5. Methods

The treatment duration lasted for a year. Sleep studies were carried out in the patients' own homes using a portable device. Throughout these studies, five important variables were simultaneously recorded:

2.5.1. Hemoglobin oxygen saturation was monitored using pulse oximetry with a finger probe.

2.5.2. Airflow through the nose and mouth was measured using a thermistor.

2.5.3. Respiratory movements were assessed through impedance measurements by placing electrodes on each side of the chest.

2.5.4. The patients' body position was tracked using a sensor attached to the chest.

2.5.5. Snoring sounds were captured using a sound level meter.

All of this data was stored in a digital recording unit and then transferred to a personal computer for comprehensive data analysis. It's worth noting that the technicians responsible for analyzing the data were unaware of the specific treatment groups to which the patients belonged. This blinding of the analysts ensured an objective

assessment of the results without any potential bias. It's important to mention that sleep studies lasting less than 4 hours were not considered valid. In such cases, a second recording session was scheduled to ensure accurate and sufficient data collection. Each patient underwent three separate somnographic assessments: the first at the beginning of the study as the baseline measurement, the second at the 6-month follow-up, and the third after one year of continuous treatment. These multiple assessments allowed the researchers to thoroughly evaluate the impact of the dental appliance treatment over time and make meaningful comparisons.

2.6. Dental appliance treatment

A thorough examination of the stomatognathic system was carried out at two key time points in this study: at the start of the research (baseline) and at the one-year follow-up. This examination involved a comprehensive assessment, which included the following components:

2.6.1. Precise measurement of the range of motion of the lower jaw using a steel ruler, providing measurements accurate to the nearest millimeter.

2.6.2. Evaluation of the position of the upper and lower teeth by assessing overbite and overjet.

2.6.3. Palpation of the temporomandibular joint (TMJ) and the muscles involved in chewing to identify any areas of tenderness or discomfort.

2.6.4. Identification and registration of any pain experienced during jaw movement, as well as monitoring for any sounds from the TMJ that could indicate joint issues.

2.6.5. Assessment of the contact between the upper and lower teeth while in occlusion. This was done using occlusal foil (GHM, occlusal foil) and the Eichner index of occlusal support zones, which measured the number of zones (ranging from 0 to 4) where the teeth made contact. These zones represented the areas where the premolar and molar teeth on both sides of the mouth made contact during biting. Most patients had contact in all four possible zones, while a few had contact in fewer zones due to specific dental characteristics.

2.6.6. Monitoring and recording of any technical issues with the dental appliances used during the follow-up period.

In addition to the clinical examination, patients were given a questionnaire at both the baseline and the one-year follow-up. The purpose of this questionnaire was to gather important information on various aspects, including:

2.6.7. The frequency of headaches, ranging from once a month to daily.

2.6.8. The presence of tiredness or stiffness in the muscles involved in chewing.

2.6.9. Occurrence of sounds from the TMJ.

2.6.10. Pain in the TMJ.

2.6.11. Incidents of the TMJ becoming locked.

2.6.12. Pain experienced during movements of the lower jaw.

2.6.13. Compliance with the use of the dental appliance.

2.6.14. Effects on daytime sleepiness.

2.6.15. Changes in snoring patterns.

2.6.16. Personal experiences of episodes of apnea during sleep.

It is worth mentioning that all the patients in this study received treatment from a team of experienced dentists who specialize in dental appliance treatment. A skilled dental technician was responsible for crafting all the appliances used in the research. These appliances were made from a single piece of heat-cured acrylic polymer and were designed to advance the lower jaw from its resting position. The distance between the upper and lower teeth was consistently set at mm. The appliances included bars that connected the acrylic components in the premolar-molar regions on both the front and back sides of the lower front teeth. In addition, Adam's clasps were used as supplementary attachments and for individual adjustments as needed, mainly on the first molars in each jaw. This meticulous approach ensured that the appliances were custom-made to meet the specific needs of each patient.

2.7. Subjective evaluation of the treatment effect

To evaluate the impact of the treatment on daytime sleepiness and the inconvenience associated with apnea and snoring, patients were requested to answer a series of questions. These questions were specifically designed to capture any changes in their experiences. Each question was assessed using a 7-point scale, enabling patients to rate their responses on a continuum. This scale included clear anchor definitions at each end of the spectrum. The structure of the scale was as follows:

2.7.1. A rating of "1" indicated a significant decrease in the severity of symptoms. Essentially, a score of 1 meant that patients perceived a notable improvement in their condition due to a reduction in symptom severity.

2.7.2. Conversely, a rating of "7" represented the opposite end of the scale, signifying a substantial increase in symptom severity. Therefore, a score of 7 indicated a marked worsening of symptoms, leading to a decline in the patient's condition.

2.7.3. Using this 7-point scale, patients were able to subjectively evaluate changes in daytime sleepiness and the level of inconvenience caused by apnea and snoring following the treatment. This approach allowed for a detailed and personalized assessment of treatment outcomes based on each patient's individual perspective and experiences.

2.8. Statistical analysis

In this study, the numerical results were presented in terms of means along with their corresponding 95% confidence intervals (CI). These means offered a central measure for various parameters, while the confidence intervals provided a range within which the true population value for those parameters was likely to fall. To evaluate differences in somnographic variables, body mass index (BMI), mandibular mobility, and age between the two treatment groups (referred to as "k groups") at different time points (baseline and over time), statistical tests were employed. The significance level chosen for determining statistical significance in this study was set at $P < 0.05$. In other words, if the probability of the observed differences occurring by chance (p-value) was less than 0.05, it was considered statistically significant. This threshold is a common practice in research to ensure that observed effects or differences are likely to be real and not merely the result of random variation. When P-values were below 0.05, it indicated that the results were statistically significant, suggesting that the treatment or other factors under investigation had a genuine impact on the parameters being studied.

3. Results

Patients categorized into two groups, group 50 and group 75. The mean age for patients in group 50 was 51.8 years, with a 95% confidence interval (CI) ranging from 49.0 to 54.6. In group 75, the mean age was 54.4 years, with a 95% CI spanning from 52.4 to

56.4. This information illustrates the age distribution of the patients in each group, providing a range of ages that includes the central estimate (mean) and a level of confidence in the accuracy of these estimates (CI). Before receiving the treatment, the mean BMI in group 50 was 27.4, with a 95% CI from 26.4 to 28.4. In group 75, the mean BMI was 27.9, with a 95% CI ranging from 26.6 to 29.3. It's worth noting that a BMI of 30 or higher is typically classified as obesity. In this study, 30% of the patients had a BMI in the obesity range. The extent of mandibular advancement in group 50 had a mean value of 4.5 mm, with a standard deviation (s) of 0.93. In group 75, the mean mandibular advancement was 6.4 mm, with a standard deviation of 1.16. This information quantifies the degree of mandibular advancement in each group, which is a crucial factor in the study's treatment approach. Patients in both groups used their dental appliances consistently, averaging 6.7 nights per week, with a median usage of 7.0 nights and a range between 5 and 7 nights. All patients, except one, used their dental appliances regularly, meaning they used them at least 5 nights per week. Additionally, most patients in both groups rated the use of their appliances as very good, with 66% in group 50 and 75% in group 75 expressing this positive evaluation of their experience. Compliance with the treatment at the one-year follow-up was relatively high. In group 50, it was 76%, while in group 75, it was even higher at 74%. This indicates that the majority of patients in both groups continued to use their dental appliances consistently over the course of the study. Table 1

Table 1. Comparison of values at baseline and after 1 year for somnographic variables and mouth opening, protrusion capacity, and overbite between individuals in the 2 treatment groups who completed the follow-up

	Group 50 ($n = 29$)		Baseline—1 year *P*-value	Group 75 ($n = 26$)		Baseline—1 year *P*-value	Difference between the 2 groups at 1 year *P*-value
	Baseline	After 1 year		Baseline	After 1 year		
AI	8.9 (±1.8)	2.0 (±1.4)	<0.001	10.5 (±1.8)	2.7 (±1.2)	<0.001	ns
AHI	16.2 (±2.9)	6.0 (±3.7)	<0.001	18.9 (±4.7)	6.3 (±2.0)	<0.001	ns
ODI	17.0 (±4.2)	7.3 (±4.0)	<0.001	20.5 (±6.2)	8.0 (±2.9)	<0.001	ns
Mouth opening capacity (mm)	48.1 (±2.7)	49.4 (±2.8)	<0.05	46.6 (±2.5)	48.4 (±2.4)	<0.05	ns
Protrusion capacity (mm)	9.2 (±0.6)	9.6 (±0.6)	ns	8.3 (±0.5)	8.8 (±0.6)	<0.01	<0.05
Overbite (mm)	2.5 (±0.5)	2.4 (±0.6)	ns	2.9 (±0.7)	3.0 (±0.8)	ns	ns

Data are presented as mean value and confidence interval (±95%).
AI = apnea index; AHI = apnea/hypopnea index; ODI = oxygen saturation index.

3.1. Treatment effect on somnographic variables

Study demonstrated that both 50% and 75% mandibular advancement led to significant improvements in somnographic variables, with no significant differences between the two treatment groups. These findings highlight the effectiveness of the dental appliance therapy in alleviating sleep-related breathing issues, regardless of the degree of mandibular advancement used.

3.1.1. Reduction in AI, AHI, and ODI:

Both treatment groups, group 50 and group 75, experienced a significant reduction in the mean Apnea Index (AI), Apnea-Hypopnea Index (AHI), and Oxygen Desaturation Index (ODI) after one year of treatment compared to their respective values before treatment ($P < 0.001$). This reduction indicates an improvement in sleep-related breathing abnormalities, reflecting the effectiveness of the treatment in mitigating apnea and associated issues.

3.1.2. No Significant Group Differences:

There was no significant difference observed between the two treatment groups (group 50 and group 75) regarding any of the somnographic variables. This suggests that the extent of mandibular advancement (50% or 75%) did not lead to significant variations

in treatment outcomes concerning these variables. Both groups benefited similarly in terms of improving their sleep-related breathing issues.

3.1.3. Individual Variation in AI:

The individual values of Apnea Index (AI) were tracked at various points in the study, including before intervention, at the 6-month follow-up, and at the one-year follow-up. The figures (presumably Figures 2 and 3) likely illustrate how AI values varied for each patient over the course of the study. This individualized assessment allows for a more detailed understanding of how treatment affected each patient's AI.

3.1.4. Success and Normalization Rates:

The study assessed the efficacy of treatment based on the success rate and normalization rate. The success rate was defined as a 50% reduction in the initial Apnea-Hypopnea Index (AHI). Normalization was defined as both the Apnea Index (AI) dropping below 5 and the AHI decreasing to less than 10. The data revealed that there were no significant differences between the two treatment groups (group 50 and group 75) in terms of these efficacy measures. This suggests that both groups had similar rates of success and normalization, indicating that the extent of mandibular advancement did not notably influence these treatment outcomes. Table 2

Table 2. Success and normalization rates at the 1-year follow-up in the 2 treatment groups

	Group 50 $n = 29$	Group 75 $n = 26$	Difference between groups, P-value
Success rate (≥50% reduction)			
AI	86%	77%	ns
AHI	79%	62%	ns
Normalization (AI <5 and AHI <10)	79%	73%	ns

AI = apnea index; AHI = apnea/hypopnea index.

3.2. Subjective evaluation of the treatment effect

The study found that the treatment using dental appliances with either 50% or 75% mandibular advancement was effective in reducing daytime sleepiness and problems related to apneas and snoring. The majority of patients experienced a decrease in these symptoms, and none reported worsening of symptoms following treatment. These findings emphasize the positive impact of the dental appliance therapy in improving sleep-related issues in patients with obstructive sleep apnea.

3.3. Daytime Sleepiness:

In group 50, 82% of the patients reported a decrease in daytime sleepiness after one year of treatment. Similarly, in group 75, 84% of the patients experienced a reduction in daytime sleepiness. This indicates that the treatment was effective in alleviating daytime sleepiness for a majority of patients in both groups.

3.3.1. No Difference in Daytime Sleepiness:

In group 50, only 11% of the patients reported no change in their daytime sleepiness after one year of treatment. In group 75, this percentage was slightly higher, with 17% of patients reporting no difference in daytime sleepiness. These results suggest that the treatment had a positive impact on the majority of patients in terms of reducing daytime sleepiness, but a small percentage did not experience a significant change.

3.3.2. Improvement in Apneas and Snoring:

Both groups, 50 and 75, showed significant improvements in problems related to apneas and snoring. In group 50, problems with apneas and snoring decreased by 87%, while in group 75, these problems decreased by 79%. This indicates that the treatment was highly effective in reducing the occurrence of apneas and snoring in both groups.

3.3.3. No Worsening of Symptoms:

Importantly, none of the patients in either group reported increased problems with daytime sleepiness, apneas, or snoring at the follow-up assessment. This demonstrates that the treatment did not lead to a deterioration of symptoms or the development of new issues.

3.4. Adverse events on the stomatognathic system

The study found that the treatment led to significant changes in mandibular movements, particularly in mouth opening capacity and protrusion capacity for group 75. However, these changes did not affect tooth contacts at intercuspidation. Additionally, few patients reported symptoms related to the stomatognathic system, suggesting that the treatment had minimal adverse effects in this regard. Furthermore, the most commonly reported symptom, headache, significantly decreased in frequency after one year of treatment in both groups, indicating an improvement in patient comfort and well-being.

3.4.1. Mandibular Movements:

Both groups experienced significant changes in mandibular movements. The capacity for mouth opening showed a noticeable difference for both group 50 and group 75. Additionally, the protrusion capacity changed significantly for group 75. These changes suggest that the treatment may have had an impact on the range of motion and positioning of the jaw, especially for those in group 75. However, it's important to note that these changes did not affect tooth contacts at intercuspidation, indicating that the treatment did not result in significant alterations to the bite or tooth alignment.

3.4.2. Stomatognathic System Symptoms:

Very few patients in either group reported symptoms related to the stomatognathic system, such as issues with the jaw, muscles, or teeth. This suggests that the treatment had minimal adverse effects on the stomatognathic system, and most patients did not experience problems in this regard.

3.4.3. Headache:

Headache occurring at least once a week was the most commonly reported symptom before the intervention. However, after one year of treatment, this symptom was significantly reduced in both group 50 and group 75. This reduction in headache frequency indicates an improvement in this aspect of patient well-being following treatment. Table 3

Table 3. Number of patients with reported symptoms from the stomatognathic system at baseline and 1-year follow-up in the 2 treatment groups

	Group 50		Group 75	
	Baseline $n = 29$	After 1 year $n = 29$	Baseline $n = 24$	After 1 year $n = 24$
Tiredness/stiffness on jaw function	3	4	3	1
TMJ pain	2	2	0	1
TMJ sound	2	2	4	2
TMJ locking	1	1	0	1
Headache, Once a week or more often	6	1	12	3

3.5. Technical failures of the dental appliance

The assessment of the dental appliances at the one-year follow-up revealed that the primary components, including the acrylic structure and metal bars, remained intact and without damage. However, the study noted that the Adam's clasps, which are a relatively weaker component, broke in a small number of dental appliances. This information is valuable for understanding the durability and potential areas for improvement in the construction of these dental appliances.

3.5.1. Acrylic Parts and Metal Bars:

The acrylic parts of the construction, as well as the linking metal bars, showed no signs of damage or wear during the one-year follow-up. This suggests that the main components of the dental appliances, such as the acrylic structure and the metal bars that held them together, remained structurally intact and functional. This is a positive result as it indicates the durability and reliability of these components in providing the intended treatment.

3.5.2. Adam's Clasps:

The study identified that the weakest part of the construction, which in this case was the Adam's clasps, experienced breakage in a total of six dental appliances. Specifically, four dental appliances in group 50 and two in group 75 had broken Adam's clasps. Adam's clasps are used as additional attachments and for individual adjustment, but their susceptibility to breakage suggests that they may not be as durable as other components of the dental appliances. Figure 4 and 5

Figure 1. Trial profile.

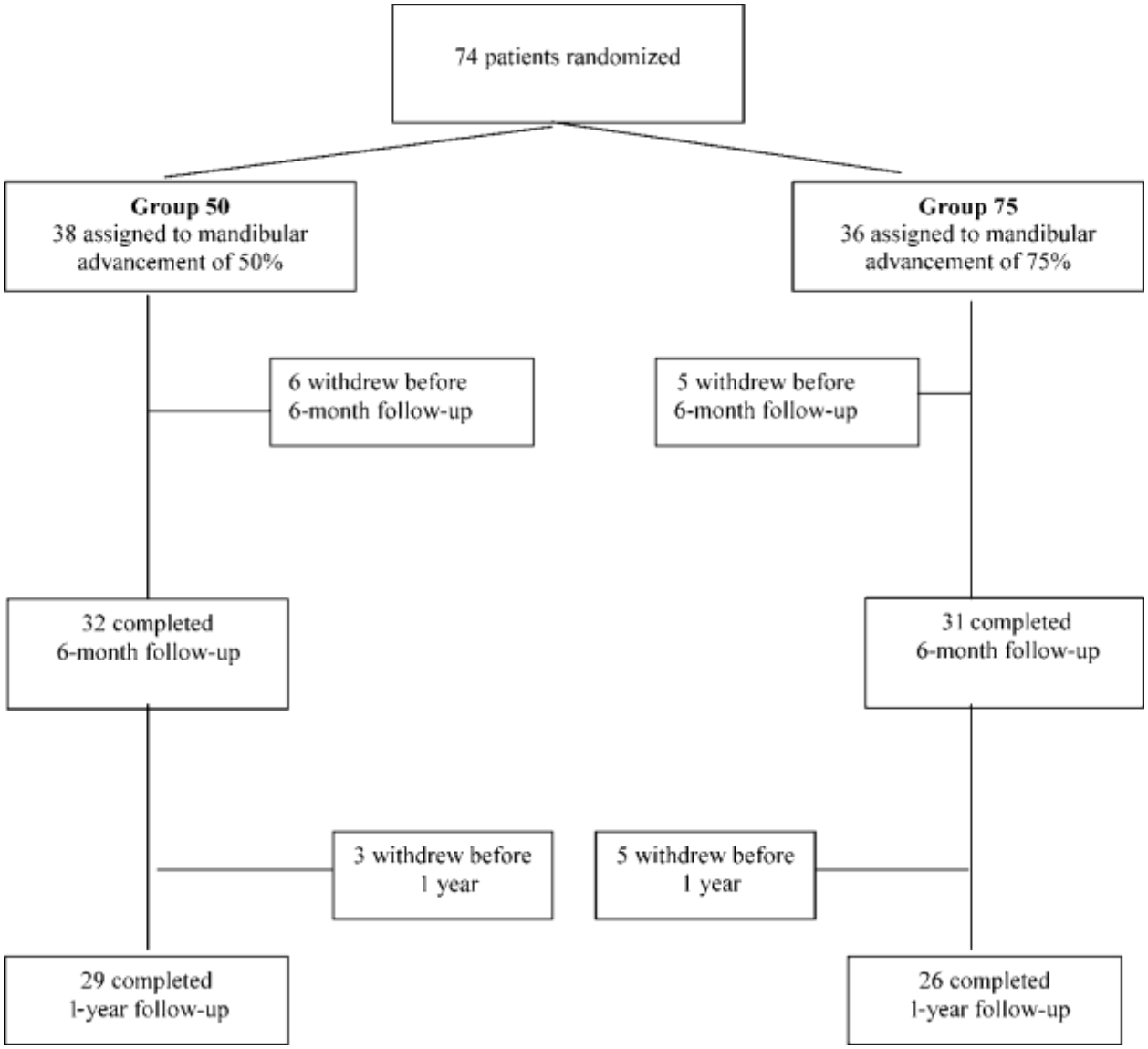

Figure 2: Individual AI values (n = 38) in group 50 before intervention (median 8.0), at the 6-month follow-up (median l.0), and at the l- year follow-up (median l.0).

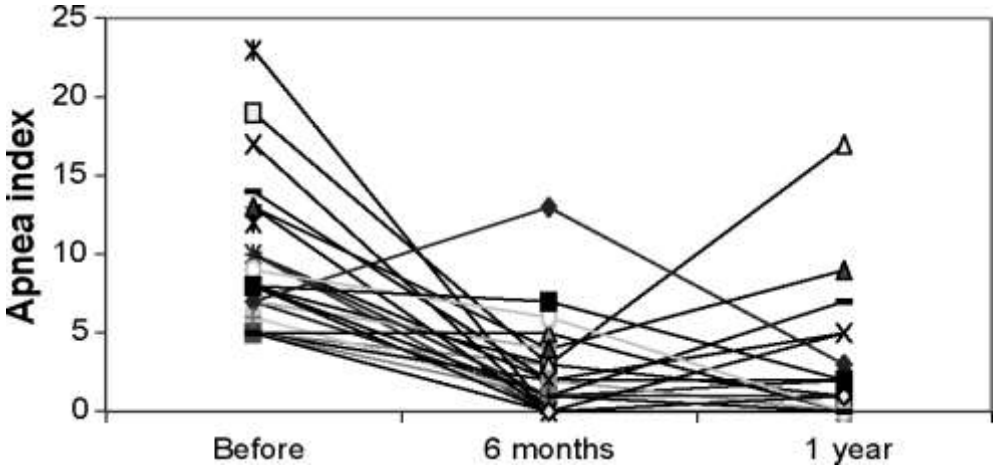

Figure 3. Individual AI values (n = 36) in group 75 before intervention (median 9.5), at the 6-month follow-up (median 2.0) and l-year follow-up (median 2.0).

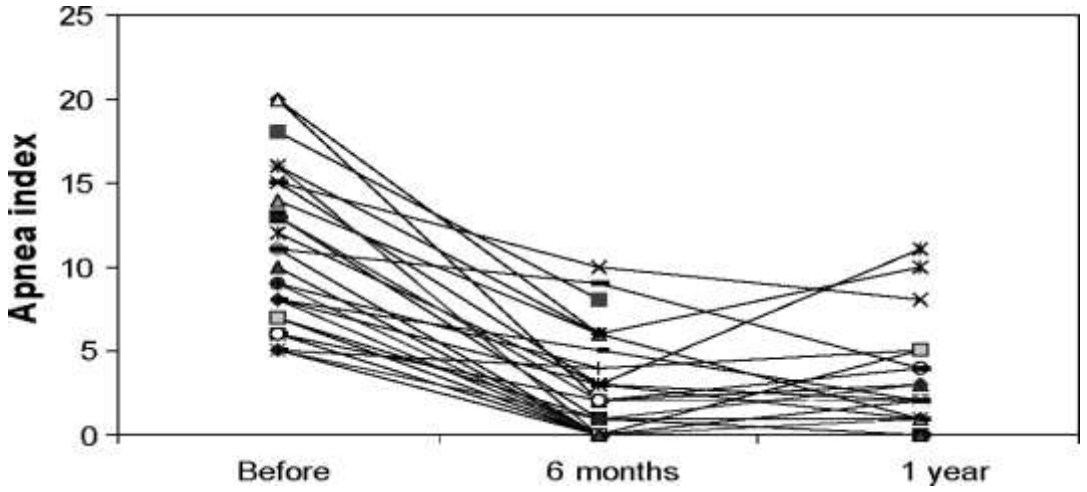

Figure 4: The dental appliances used in this study were manufactured in one-piece heat-cured acrylic polymer

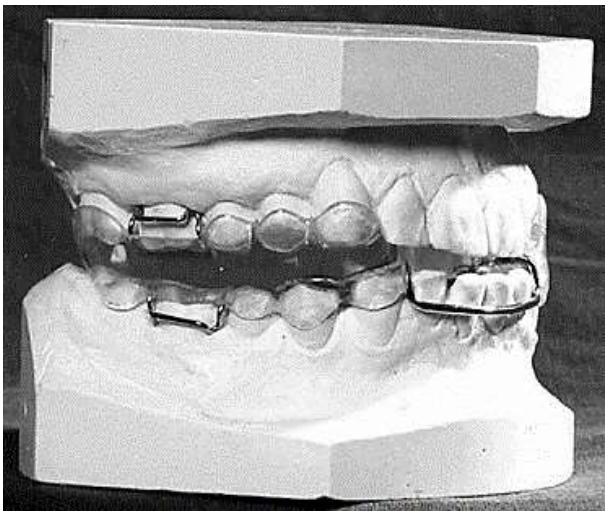

Figure 5: The dental appliances used in this study were manufactured in one-piece heat-cured acrylic polymer

4. Discussion

The study contributes to our comprehension of how dental appliances with mandibular advancement can effectively address sleep-related breathing disorders, particularly apneas. It emphasizes the significance of personalized treatment and further research to determine the most suitable degree of advancement for optimal treatment outcomes. The study showcased that the utilization of a dental appliance with mandibular advancement effectively decreases the frequency of apneas, which are a characteristic feature of sleep-breathing disorders like obstructive sleep apnea.[33] This decrease in apnea frequency is a positive outcome, suggesting the potential advantages of this treatment approach. Interestingly, the research uncovered that the treatment effect with a dental appliance featuring less mandibular advancement was comparable to the effect achieved with a more pronounced advancement. This implies that achieving a higher degree of mandibular advancement did not significantly outperform a less pronounced advancement in terms of normalizing sleep-related breathing patterns in patients with mild and moderate obstructive sleep apnea.[34]

One important takeaway from this study is that the degree of mandibular advancement in relation to an individual's capacity may not always be reflected in the assessment of treatment effectiveness with dental appliances. This indicates that personalized treatment, which takes into account an individual's unique characteristics, may be a key factor in achieving successful outcomes.[35] The findings of this study align with previous research, such as the work of Venza et al., who observed that different degrees of mandibular advancement within the same patient led to improvements in reducing nocturnal desaturations. In their study, an advancement of approximately 10 mm was associated with a therapeutic effect, highlighting the potential benefits of a more pronounced advancement.[36] Similarly, Burlon et al. reported a higher success rate with advancements greater than 5 mm. Despite these findings, the study raises an important question about the optimal degree of mandibular advancement that would provide effective treatment outcomes for the majority of patients with sleep-breathing disorders.[37] This topic is still under investigation, and understanding the threshold at which most patients respond positively to treatment is crucial for tailoring therapies to individual needs.

The fact that the study had a significant dropout rate of 26% (equivalent to 6% of the initial participants) is a critical finding. It strongly indicates that not all individuals with obstructive sleep apnea (OSA) find intra-oral appliances comfortable or suitable for their needs. This highlights that while this type of treatment may be effective for some, it is not a one-size-fits-all solution for all OSA patients. It is important to evaluate each patient's comfort and suitability for the treatment on an individual basis. Interestingly, the study also found that there were no notable differences in the number of dropouts between the two groups, despite differences in the degree of mandibular advancement. This suggests that the degree of advancement was not the primary reason for patients dropping out of the study. It reinforces the idea that factors such as patient comfort and acceptance of the appliance play crucial roles in treatment adherence.[38]

The study revealed a compliance rate of 74% for using dental appliances, which is consistent with similar studies of similar duration. Compliance, in this context, refers to how consistently patients used the dental appliance.[39] The finding that the majority of patients used the appliance regularly is encouraging and indicates a high level of acceptance among the study participants. The wide variation in compliance rates observed in different studies can be attributed to various factors, including differences in study design, characteristics of the study population, evaluation methods, and follow-up duration.[40] These factors can significantly impact patients' willingness and ability to adhere to the treatment. The importance of patient compliance with the treatment cannot be emphasized enough. In this study, the results showed that successful treatment outcomes were strongly linked to regular use of the appliance. This aligns with previous research, as demonstrated in a study

by Jin et al., where it was found that using the appliance for one-night improved somnographic values, but these benefits were reversed when the appliance was not used the following night.[41] This underscores the necessity of consistent and ongoing use of the appliance to achieve positive treatment effects.

Patients who adhered to the treatment until the one-year follow-up period frequently mentioned using the dental appliance regularly. The reason behind this compliance can be attributed to a feeling of subjective well-being that they experienced, which included a decrease in daytime sleepiness. Patients likely continued to use the appliance because they felt better and more refreshed during the day. The study acknowledges that the reasons for discontinuing treatment among certain patients were not completely clear. Although the study did not provide specific explanations, it is possible that patients who stopped the treatment may have encountered side effects or discomfort that outweighed the benefits. These reasons could include difficulties in adjusting to the appliance or other individual concerns.[42]

Most of the reported side effects were minor and did not show significant differences between the two groups. These findings are consistent with other research, highlighting that minor side effects are common and do not have a major impact on patient compliance.[43] One positive aspect of treatment with dental appliances was a noticeable decrease in the frequency of headaches. This reduction is significant because headaches are a result of untreated sleep-disordered breathing. It is suggested that the decrease in headache frequency was likely due to improved oxygen saturation when normalizing breathing patterns.[44] The reduction in headaches can greatly contribute to an overall positive patient experience with the dental appliance treatment. In the group with a more prominent advancement of the lower jaw, symptoms related to the stomatognathic system were not reported as more frequent. This finding suggests that the muscles involved in chewing and the temporomandibular joint (TMJ) function could be normalized after overnight use of a dental appliance. It is proposed that the overall improvement in sleep quality might overshadow any potential side effects related to the stomatognathic system.[45]

The purpose of this study was to examine the dental appliances that were used to position the lower jaw forward. By doing so, the mandible is able to activate the tongue and the associated muscles. The goal of advancing the mandible is to move the tongue away from the back wall of the throat and the soft palate, which can potentially reduce airway obstruction. However, the treatment of obstructive sleep apnea (OSA) is more complex than simply increasing the size of the airway by moving the mandible and tongue forward. Other factors, such as the vertical opening between the front teeth, also play a role in the effectiveness of dental appliance treatment. Increasing this opening can actually decrease the size of the airway in the throat. To prevent the mandible from rotating backwards, the vertical opening between the front teeth was minimized in this study. These considerations emphasize the importance of fully understanding the mechanics of the treatment.[46,47]

The study found that in the short term, the dental appliance had similar efficacy to other studies. However, over time, the effectiveness of the treatment decreased according to long-term compliance data. Without adjustments to the degree of mandibular advancement, the treatment may become less effective over time. This underscores the need for regular check-ups to ensure that the treatment continues to work, especially since OSA treatment is often a lifelong process. The study also noted that complaints related to the chewing muscles and the temporomandibular joints (TMJs) may occur, even with moderate mandibular advancement. However, these effects were more common when the mandible was significantly advanced, such as with the use of a Herbst appliance. Nonetheless, these side effects were infrequent in both groups studied.[37,46]

The dental appliance utilized in the research featured a straightforward design with only a few components, and it was securely fastened to the teeth. The incidence of technical malfunctions was minimal, less than 5%, which is comparable to the outcomes of similar studies employing monobloc techniques. This demonstrates the dependability of this particular type of dental appliance in practical use. OSA, a potentially life-threatening condition, can worsen in severity as time goes on. Hence, the research underscores the significance of collaborating with a sleep apnea specialist medical doctor when utilizing dental appliances for treatment. It is advised to conduct regular short and long-term follow-up assessments, employing somnography (sleep studies), to evaluate the treatment's effectiveness over time.[48]

5. Conclusion

The findings of the study support the efficacy of using a dental appliance to advance the lower jaw in reducing sleep-breathing disorders, specifically by decreasing the frequency of temporary cessations of breathing (apneas) in patients with mild to moderate obstructive sleep apnea (OSA). Importantly, the results indicate that a more pronounced advancement of the lower jaw did not result in significantly greater improvements in the medical issue compared to a less pronounced advancement for this specific group of patients. Based on these findings and the low occurrence of negative events in the mouth, jaw, and related structures (stomatognathic system), as well as other complications, the study concludes that dental appliance treatment is a viable choice for individuals with mild to moderate OSA. Furthermore, the study suggests that there is no need to start treatment with a lower jaw advancement that exceeds 50% of a patient's maximum protrusive capacity for this particular group of patients.

In practical terms, this means that a moderate level of lower jaw advancement, approximately 50% of a patient's maximum capacity, seems to be effective and adequate for treating mild to moderate OSA, while also minimizing the likelihood of negative events or complications in the stomatognathic system. This conclusion has important implications for healthcare professionals involved in the treatment of OSA patients, as it provides guidance on the optimal degree of lower jaw advancement when using dental appliances to manage this condition.

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