



RESEARCH ARTICLE

“EFFICACY OF CUSTOM-MADE ORAL APPLIANCE FOR TREATMENT OF OBSTRUCTIVE SLEEP APNEA”

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Abstract

Introduction: Obstructive sleep Apnea (OSA) is a condition characterized by complete obstruction or reduction in the upper airway during sleep with repeated episodes, often associated with symptoms and co-morbidities which includes snoring, obesity, hypertension, type 2 diabetes mellitus, reduced quality of life, increased risk of industrial and road traffic accidents. The purpose of the study was to evaluate the efficacy of an intraoral appliance in patients with mild to moderate Obstructive Sleep Apnea.

Materials and Methods: The study was conducted on 7 males and 3 females with mild and moderate obstructive sleep apnea. Polysomnography was done for each patient before (T0) and after the appliance (T1) therapy.

Results: The results of the study showed a statistically significant improvement in the upper and Lower, Apnea-Hypopnea index, The mean oxygen desaturation index. The ESS values showed statistically significant reduction in the score and also Statistically significant reduction in the mean heart rate.

Conclusion: The results of this study support the use of this Oral Appliance and which shows that most of the parameter evaluated showed significant improvement. Therefore, this custom-made Oral Appliance can be effectively used in the treatment of mild to moderate Obstructive Sleep Apnea.

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Introduction:-

Obstructive sleep Apnea (OSA) is a condition characterized by the excessive day time sleepiness, with complete (Apnea) obstruction or reduction (hypopnea) of the upper airway during sleep with repeated episodes, often resulting in an arterial oxygen desaturation. When the air flow is completely interrupted for a period of 10 seconds or more it is termed as an Apnea and when there is a reduction of breathing capacity by at least 50% termed as hypopnea.

W. H. Broadbent, a physician from St. Mary's hospital in London, was one of the first to describe in an article published in The Lancet in 1877, what we term today “obstructive sleep apnea”.¹

An article “Extreme Obesity associated with Alveolar Hypoventilation- A Pickwickian Syndrome,” published by Bickelmann et al. in 1956. The article describes an obese man whose daytime sleepiness became so severe that he

fell asleep playing poker.² And in this memorable story, accurately depicted the effect of sleep apnea on daytime sleepiness.

Obstructive sleep apnea is associated with symptoms and co-morbidities which includes snoring, obesity, hypertension, type 2 diabetes mellitus, exacerbation of chronic obstructive pulmonary disease, reduced quality of life and increased risk of industrial and road traffic accidents. It is also a risk factor for ischemic stroke and cardiovascular disease. The neurocognitive problems associated with Obstructive sleep Apnea includes reduced performance in neuropsychologic test, slower reaction times, reduced creativity and executive function³.

Due to this event of apnea which results in the lack of oxygen, the brain responds by alerting the body by awakening from sleep. This pattern occurs several times during the sleep causing the sleep fragmentation that often produce an excessive daytime sleepiness.

The severity of Obstructive Sleep Apnea (OSA) is commonly assessed by the Apnea-Hypopnea index (AHI) which represents the number of Apnea or hypopnea events per hour of sleep. The prevalence of OSA is estimated to be 24% in males and 9% in females aged 30-60 years⁴. OSA affects people of all ages, most prevalent among middle aged and elderly individual.

Obstructive Sleep Apnoea Syndrome in Children is associated with an upper airway anatomic abnormality. Most commonly due to hypertrophic tonsils and adenoids which reduced the airway space and increase the nasal resistance.

The diagnosis for the obstructive sleep Apnea is done using a laboratory recording procedure called Polysomnography. Polysomnography is also known as sleep study that measures many variables to diagnose OSA. The measurements include Electrocardiography, Eye and jaw muscle movement, Oxygen saturation, Brain electrical activity, limb movement and body position. The measurements reveal the severity of the disorder with Apnea-Hypopnea index or Respiration Disturbance index (RDI) that is the number of Apnea and Hypopneas per hour of sleep⁵.

Continuous Positive Airway pressure (CPAP) therapy is the standard non-invasive procedure for the Obstructive Sleep Apnea⁶. Due to the poor compliance of the patients for CPAP therapy, oral appliance becoming popular for the treatment of mild to moderate OSA. Other treatment modalities for OSA includes uvulopalatopharyngoplasty⁷, Adenotonsillectomy, Surgical mandibular advancement thereby increasing the airway space.

The action of mandibular advancement results in an increase in pharyngeal airway space and reduces airway collapsibility⁸. The Oral appliance used to treat OSA can be divided into Mandibular Advancing appliance and Tongue Retaining appliance.⁹ The former consists of the upper and lower part and induce the mandibular advancement and most commonly used, the later consists of a bulb in the anterior region of the appliance that creates a negative pressure that holds the tongue in the anterior position during sleep.

The intra oral appliance in this study is a modification of the mandibular advancing device. It was made up the thermoforming materials, the upper and the lower part was held together with self-cure acrylic, a space of 1-2mm was provided in the anterior region to assist breathing. The full coverage of the appliance was intended to eliminate any occlusal alteration.

Methodology:-

Clearance was obtained from Ethical committee of Yenepoya deemed to be university for this study (Protocol No:2017/305). Ten patients including both males (7) and females (3) with mild and moderate obstructive sleep apnea was assigned after undergoing routine sleep study known as Polysomnography and diagnosed with mild to moderate Obstructive Sleep Apnea. The patients were explained with the advantages and disadvantages of the mandibular advancement appliance therapy and the procedures involved during the therapy. An informed consent was taken from all the patients before start of the treatment.

The patients with mild to moderate OSA, Adult patients, Patients with OSA who are noncompliant to CPAP and who refused surgical intervention are included in the study.

patients with temporomandibular joint disorder, edentulous patients, nasal obstruction and lower respiratory airway diseases are excluded.

Initial thorough dental evaluation was done, oral prophylaxis and oral hygiene maintenance was carried out. Intraoral and extra oral photographs of the patients were taken.

An impression was made with an alginate impression material using a standard impression trays selected according to the maxillary and mandibular arch (fig 5). Two sets of impressions were made and poured with a dental stone. The first set was used for the appliance fabrication and the second for the articulation with the wax bite. The bite registration determines the amount of mandibular advancement. Modelling wax was rolled to form a U-shaped arch and was softened in the water bath. The patient was trained to bite in a forward. wax bite relationship was taken with 60% of the maximum protrusion of mandible¹⁰. The first set of dental casts were used to fabricate the appliance. The undercuts and the embrasures in the dental casts were filled with the dental plaster to prevent the tight fitting of the appliance (fig 7), to prevent undesirable tooth movement and to maximize the patient comfort for the appliance wear. After blocking the undercuts with the dental plaster, the upper and lower components of the appliance was fabricated using the thermoforming sheets of 1mm thickness with the biostar thermoforming machine (fig 8). Trimming and finishing of the edges of the thermoform trays are done for better comfort of the patient. The second set of casts were mounted in an articulator along with the wax bite on it (fig 9). After the articulation, the wax bite was removed and the trimmed thermoform trays were placed on the cast. Self-cure acrylic resin was mixed in a dough stage and placed on the occlusal surface of the upper and the lower posterior region of the tray to make it as a single appliance. A 2 mm of space was given between the upper and lower anterior region to facilitate breathing in case of severe obstruction. Lateral cephalogram of the patients were taken before the starting of the oral appliance therapy and after the therapy.

The first cephalogram were taken with patient biting in a centric occlusion¹¹ and the second radiograph with the oral appliance in place. Both the lateral cephalogram were traced manually with 0.5 mm microtip pencil. The McNamara airway analysis consisting of the upper pharyngeal width and lower pharyngeal width were done for every cephalogram. The upper pharyngeal width: it is measured from the outline of the soft palate (posterior) to the posterior pharyngeal wall (closest point). The lower pharyngeal width: it is measured from the posterior pharyngeal wall to the intersection of the inferior border of the mandible and the posterior border of the tongue. Epworth sleep scale (ESS), It is a questionnaire consists of 8 questions and the patients were asked to rate based on their usual chances of falling asleep, on a 4 point scale (0-3), if the score of the patient was towards the higher score it denotes higher daytime sleepiness, the ESS score can range from (0-24). ESS scoring was done before the oral appliance therapy and after the therapy. Polysomnography also called as sleep study was done for each patient before initiation of the appliance therapy and after the therapy with patient wearing the oral appliance.

Statistical Analysis

Statistical analysis was carried out by using paired t test. Continuous variables were presented as mean $\pm$ standard deviation parametric paired t-test was used for comparing the averages of sleep parameters of PSG at different time periods (T0, T1). $P < 0.05$ was considered significant at the power of 80% and confidence of 95%. Comparing the groups with SPSS software (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results:-

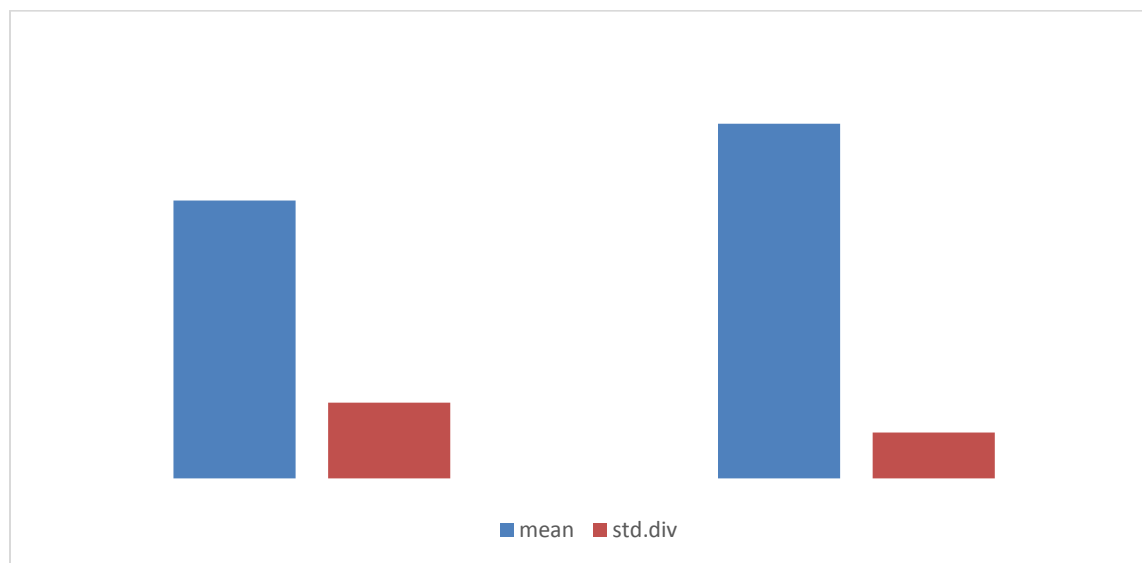
The result of the study shows that a statistically significant improvement in the upper pharyngeal width a p value of 0.004 and mean value of 7.60 ± 2.066 at T0 and 9.70 ± 1.252 at T1 This shows an improvement in the upper airway dimensions (Table 1) (Graph 1)

Table 1:- Results Paired Samples Test.

PARAMETERS	T0		T1		P -Value
	MEAN	Std.Div	MEAN	Std.Div	
UPPER PHARYNGEAL WIDTH	7.60	2.066	9.70	1.252	.004
LOWER PHARYNGEAL WIDTH	10.60	2.066	12.70	1.160	.002
AHI INDEX	26.16	2.79	10.32	1.344	.000

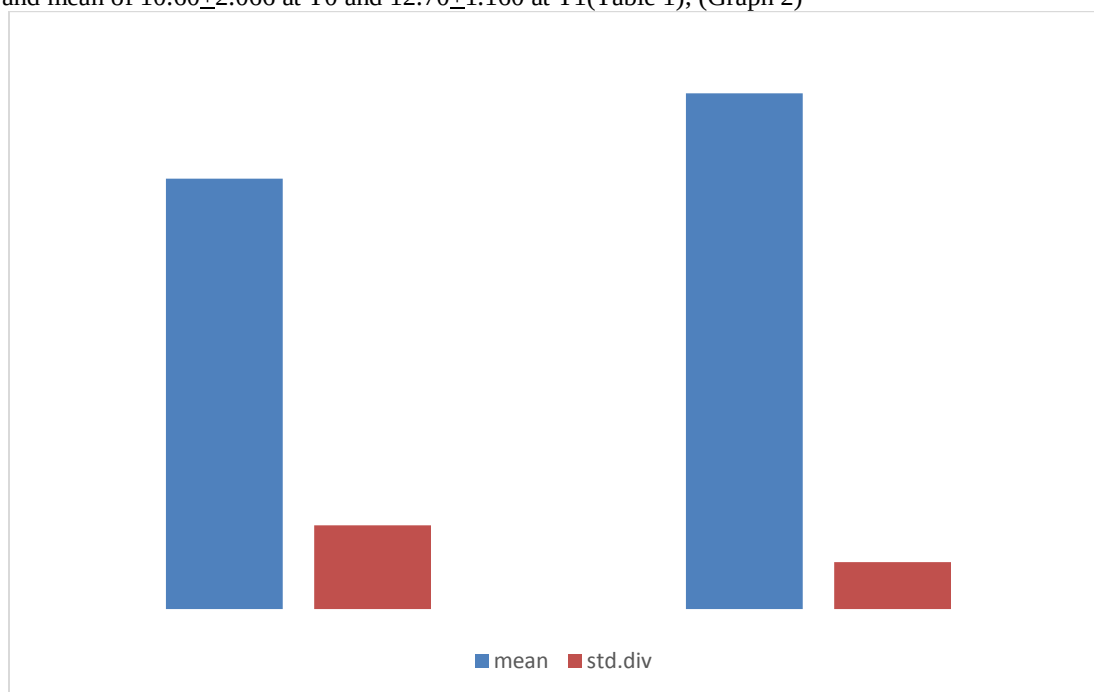
MEAN DESATURATION INDEX	25.39	3.684	4.950	1.175	.000
EPWORTH SLEEP SCALE	11.60	1.897	7.70	1.418	.003
MEAN HEART RATE INDEX	78.70	3.278	58.74	1.365	.000

*Paired t Test p value <0.005 significant. *T0- before treatment with intra-oral appliance, T1- after treatment with intra-oral appliance.



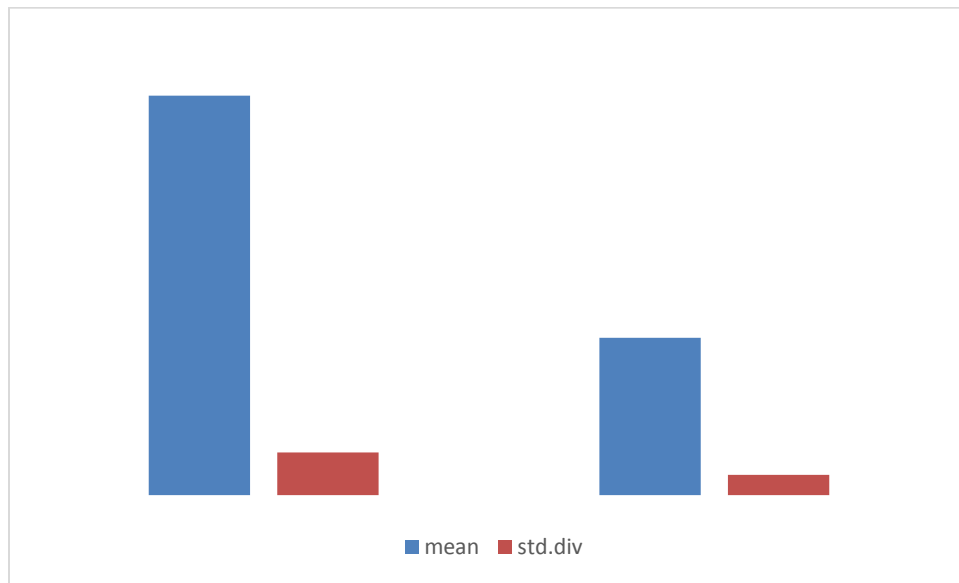
Graph 1:- Mean and Std. Division of Upper Airway Width.

Lower pharyngeal width shows a statistically significant improvement in the pharyngeal width with a p value of 0.002 and mean of 10.60 ± 2.066 at T0 and 12.70 ± 1.160 at T1 (Table 1), (Graph 2)



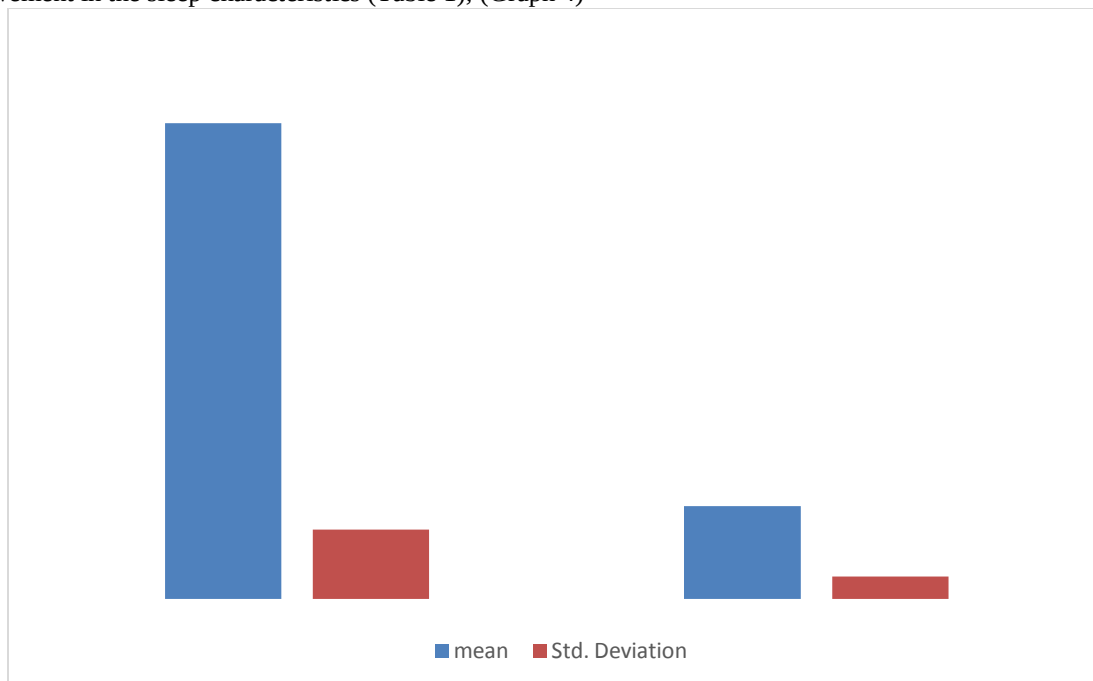
Graph 2:- Mean and Std. Deviation of Lower Pharyngeal Width.

AHI index shows a statistically significant improvement with a p value of 0.000 and mean value of 26.16 ± 2.79 at T0 and mean of 10.32 ± 1.34 at T1 which is a positive correlation showing changes following the improvement in the sleep characteristics (Table 1), (Graph 3)



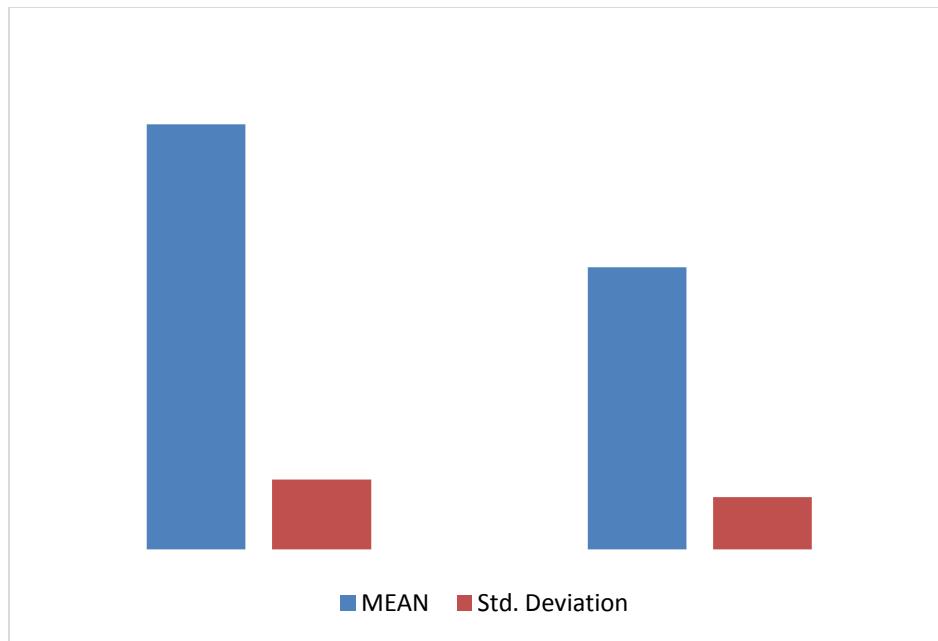
Graph 3:- Mean and Std. Deviation of AHI index.

And the mean desaturation index shows statistically significance with p value of 0.00 and mean value of 25.399 ± 3.68 at T0 and mean value of 4.95 ± 1.175 which is a positive correlation showing changes following the improvement in the sleep characteristics (Table 1), (Graph 4)



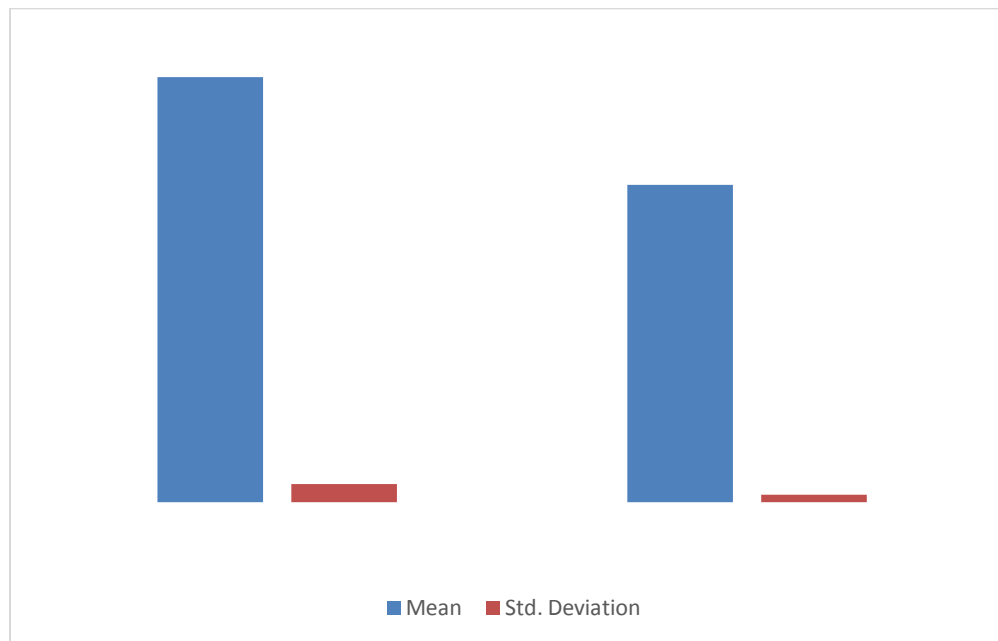
Graph 4:- Mean and Std. Deviation of Mean desaturation index.

The ESS values showed statistically significant reduction with p value of 0.003 and an overall reduction in the score from a mean value of 11.60 ± 1.897 at T0 and mean value of 7.70 ± 1.418 (Table 1), (Graph 5)



Graph 5:- Mean and Std. Deviation of ESS.

Statistically significant reduction in the mean heart rate showed a p value of 0.000 with mean values of 78.70 ± 3.27 at T0 and mean value of 58.7430 ± 1.36 (Table 1), (Graph 6).



Graph 6:- Mean and Std. Deviation of Mean Heart Rate.

Discussion:-

Intra-oral appliances therapy in patients with obstructive sleep apnea have become a popular mode of treatment due to its simple design, reduced bulk, patient comfort and social acceptance. These oral appliances have fewer side effects so that they have increased acceptance by the patients. Oral appliances in the treatment of glossoptosis in infants with micrognathia was been used in 1905. The American Academy of Sleep Dentistry was formed in 1991 and in the year 2000, a section of Oral Appliances was created in the academy of sleep medicine.

This study was done to evaluate the efficacy of custom-made intra-oral appliance for the correction of Obstructive Sleep Apnea. The study was conducted on ten patients including mild to moderate obstructive sleep apnea. After patient selection following records were acquired which includes case history, study model, working model, bite registration, photographs, lateral cephalogram. Two sets of impressions were made and poured with a dental stone. The first set was used for the appliance fabrication and the second for the articulation with the wax bite. After blocking the undercuts with the dental plaster, the upper and lower components of the appliance was fabricated using the thermoforming sheets of 1mm thickness with the biostar thermoforming machine. Bite registration was performed and appliance was fabricated the materials selected for the study was biocompatible. According to the Marklund et al.¹², occlusal changes were one of the long-term effects of oral appliance. The thermoplastic material, which is used in essix retainer was used as a base material in this study. This is expected to minimize the occlusal alteration. Lateral cephalogram of the patients were taken before the starting of the oral appliance therapy and after the therapy and was evaluated for the airway obstruction. Polysomnography was performed before and after the oral appliance therapy. Epworth sleep scale (ESS) was taken, it is a questionnaire which consists of 8 questions and the patients were asked to rate based on their usual chances of falling asleep. It was done before and after the intra oral appliance therapy.

The results of the study show a statistically significant improvement in the upper pharyngeal width with a p value of 0.004 and mean value of 7.60 ± 2.066 at T0 and 9.70 ± 1.252 at T1. This indicates an improvement in the upper airway dimensions. Lower pharyngeal width shows a statistically significant improvement in the lower pharyngeal width with a p value of 0.002 and mean of 10.60 ± 2.066 at T0 and 12.70 ± 1.160 at T1. AHI index shows a statistically significant improvement with a p value of 0.000 and mean value of 26.16 ± 2.79 at T0 and mean of 10.32 ± 1.34 at T1 which is a positive correlation indicating changes following the improvement in the sleep characteristics. The mean desaturation index also shows statistical significance with p value of 0.00 and mean value of 25.399 ± 3.68 at T0 and mean value of 4.95 ± 1.175 which is a positive correlation indicating changes following the improvement in the sleep characteristics. The ESS values showed statistically significant reduction with p value of 0.003 and an overall reduction in the score from a mean value of 11.60 ± 1.897 at T0 and mean value of 7.70 ± 1.418 . Statistically significant reduction in the mean heart rate showed a p value of 0.000 with mean values of 78.70 ± 3.27 at T0 and mean value of 58.7430 ± 1.36 (Table 1).

Similar improvement in airway was reported by Bonham et al.¹³ his results shows that improvement in the airway by increase in the velopharyngeal space using Oral Appliances. Schmidt-Nowara et al.¹⁴ found that an improvement in the efficacy of the Oral Appliances by guiding the forward positioning of the mandible. Studies done by Lowe et al.¹⁵ show similar opinion regarding the overall improvement in the airway space using Oral Appliances. Studies done by Kushida et al.¹⁶ with the use of Oral Appliances pointed out that Oral Appliances indicated as a primary treatment of choice for patients with mild-to-moderate OSA and as a treatment alternative in patients suffering with severe OSA, who failed to comply with the CPAP treatment. Oral Appliances has better patient compliance than other conventional treatment modalities.

Lettieri et al.¹⁷ the role of Oral Appliance as a cost-effective treatment for OSA is in demand, as there is a rapid increase in the prevalence rate of sleep disordered breathing. Other factors such as easy portability and no power source for the operation increases its acceptance. Rose et al.¹⁸ had found out a positive co-relation between the greater amounts of mandibular protrusion and its ability to reduce the AHI which support this study.

This modified intra-oral appliance is effective in the treating patients with mild to moderate obstructive sleep Apnea with the referral of physician and the medical examination. The appliance was readily accepted and worn by the patients due to its simple design and patient comfort. With the full coverage of the dental structure with the appliance eliminate any occlusal alteration, but long-term evaluations are needed.

Conclusion:-

Obstructive Sleep Apnea is a common respiratory disorder characterized by recurrent upper airway Obstruction during Sleep. In normal respiration the air from the external environment enters the lungs, where gaseous exchange with the blood stream takes place by contacting with the alveolar membrane. The unimpeded movement of humidified air to the tracheobronchial tree is the simple function of upper airway.

Apnea results from complete or partial interference in the airway. Upper airway obstruction is the most common disorder. Upper airway is very susceptible to Obstruction elicited by hypotonicity associated with sleep, and the most obvious manifestation of such upper airway obstruction is snoring. Although snoring has been the subject of countless humorous literary references, medically it is now well recognized as an important sign of the potentially lethal condition that we call Obstructive Sleep Apnea. Snoring can range from entirely benign condition to serious Cardiopulmonary and behavioural sequelae. The most common initial complaints in sleep apnoea are excessive daytime sleepiness, depression and snoring, irritability.

Treatment of sleep apnea can reduce snoring dramatically. However even a dramatic reduction of snoring may not necessarily result in improvement in sleep apnea, so careful monitoring is essential.

Oral appliances are a treatment option in the management of sleep apnoea syndromes. While many patients experience a complete or partial resolution of their symptoms, some do not improve or may even become worse. It is therefore imperative that physicians conduct progress evaluations while the respective dental care provider continues to adjust optimize the effectiveness of the chosen appliance.

A variety of removable devices have been designed to provide improved patient comfort and compliance. While the materials now are being used to construct mandibular protrusion devices include heat-softening acrylics and plastics with soft liners.

The serious consequences of the Obstructive sleep apnea may lead to heart disease and a chance of sudden death, which can be reduced to larger extent by use of this, modified custom-made Oral Appliance which is cost effective and simple to manufacture and require less patient compliance and can improve the quality of life. The results of this study support the use of this Oral Appliance and which shows that most of the sleep parameter evaluated showed significant improvement.

The intra oral appliance used in this study is a modification of the mandibular advancing device. It was made up the thermoforming materials, the upper and the lower part was held together with self-cure acrylic, a space of 1-2mm was provided in the anterior region to assist breathing. The full coverage of the appliance was intended to eliminate any occlusal alteration.

Therefore, this custom-made Oral Appliance can be effectively used in the treatment of Obstructive Sleep Apnea.

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