THE CONTROL OF SNORING AND OBSTRUCTIVE SLEEP APNOEA USING A MANDIBULAR ADVANCEMENT DEVICE

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INTRODUCTION

Intra-oral devices in the treatment of snoring and related problems such as obstructive sleep apnoea have only been used for the last 10-15 years. Among the first appliances used in the treatment of snoring and obstructive sleep apnoea (OSA) were modified functional orthodontic appliances which is not surprising given that such appliances are used to induce changes in skeletal relationships.

There have been a variety of designs, the most common being those which reposition the mandible in an open, protrusive position. However, appliances have become more sophisticated and complex in design and therefore more expensive. The development of an appliance that could be constructed simply and economically and yet still be effective in managing snoring was necessary.

Most studies of intra-oral devices had used strict entry requirements in terms of oral health and number of teeth. This present study aimed to treat a wide representation of patients referred from a sleep clinic. Patients were only excluded if they had no natural teeth remaining. This study aimed to use a simple method and inexpensive materials. Previous studies had shown that airway patency was improved with an oral device by using a variety of evaluation methods, including cephalometric analysis, magnetic resonance imaging, fluoroscopy, computerised tomography and polysomnography.

This study chose to use simple success criteria, questionnaires to patients and their partners as the method of evaluation. In effect this was a treatment of both the patient and partner as snoring more often disturbs the partner more than those who snore. However, patients were also evaluated by a home sleep study before and after treatment with the appliance to objectively measure the effect of the appliance on sleep variables.

AIMS AND OBJECTIVES

The aim of the project was to investigate the acceptability and effectiveness of a dental device of simple design and construction in the treatment of snoring and obstructive sleep apnoea in patients with varying backgrounds and dental states.

Specific aims were:

- to assess the effect of a simple mandibular advancement appliance on snoring
- to assess the effect on sleep quality of patients and partners
- to assess the effect on daytime sleepiness
- to assess the longevity of the appliance
- to assess the effect of the mandibular advancement device on sleep study parameters

DECLARATION

This thesis is an original work of the author.

PUBLICATIONS

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To
Margaret and Stephanie

CHAPTER 1

REVIEW OF THE LITERATURE

1.1 Introduction

The Oxford English Dictionary (1998) defines snoring as " To make harsh or noisy sounds in sleep through the open mouth and nose". Snoring is often regarded as merely a social problem that disturbs others rather than the snorer. However, snoring affects breathing during sleep and is also a principle symptom of the potentially serious condition of obstructive sleep apnoea (OSA). Obstructive sleep apnoea syndrome is one of a number of a problems referred to as Sleep Breathing Disorders.

1.2 Apnoea

1.2.1 Definition

Sleep Apnoea may be defined as "transient attacks of failure of automatic control of respiration resulting in alveolar hypoventilation which becomes more pronounced during sleep" (Dorland Medical Dictionary, 1994) and comes from the Greek for "want of breath". The sleep apnoea syndrome was first described by Gastaut et al (1966) as a disorder associated with repetitive cessation of breathing during sleep although Kryger (1983) and Lavie (1984) reported that references were made to sleep apnoea symptoms in medical and literary papers long before this time but misdiagnosis of patients with sleep apnoea and scepticism regarding sleepiness as a clinical sign appear to be the main reasons for the syndrome being overlooked.

This may be why Whyte et al in 1989 reported that the sleep apnoea/hypopnoea syndrome was rare up to this time in Britain. Sleep apnoea may be divided into obstructive sleep apnoea or central sleep apnoea.

1.2.2 Obstructive Sleep Apnoea (OSA)

OSA may be defined as "sleep apnoea resulting from collapse or obstruction of the airway with the inhibition of muscle tone that occurs during REM sleep" (Dorland Medical Dictionary, 1994). People with OSA may have several hundred apnoeic episodes per night, each lasting 10 to 200 seconds (Knudson and Meyer, 1993). Obstructive sleep apnoea is the temporary cessation of breath through closure of the pharynx, although the diaphragm continues to function and there is a suggestion that there may be failure of the reflex protective mechanisms in the pharynx. There are receptors in the pharynx that detect falls in pressure that distort the airway and these receptors provoke protective increases in pharyngeal dilator tone. Snoring itself may also be one of the stimuli that activates the dilator reflex. Interruption of this reflex may occur through years of pharyngeal trauma from snoring, mucosal oedema or toxic agents such as cigarette smoke and alcohol.

1.2.3 Central Sleep Apnoea (CSA)

CSA occurs when the drive to breathe is abnormally reduced during sleep, leading to arousal, asphyxia and associated oxygen desaturation.

CSA is characterised by simultaneous cessation of both airflow and respiratory effort. Most patients suffering from central apnoeas also have intermittent obstructive episodes but when more than 55% of events are central in nature, the apnoea is defined as central (Meyer and Knudson, 1989).

1.2.4 Mixed Sleep Apnoea

This term is used when a combination of central and obstructive sleep apnoea occurs, where apnoeic episodes are accompanied by no respiratory effort initially but are followed by respiratory muscle movement and finally airflow.

1.2.5 Hypopnoea

Hypopnoea is defined as a decrease in inspiratory flow and chest movement, coupled with oxygen desaturation. An apnoea-hypopnoea index (AHI) is the number of episodes per night of 10 seconds or more. This is also called the Respiratory Disturbance Index (RDI). The sleep apnoea/hypopnoea syndrome is defined as the occurrence of at least 30 apnoeas plus hypopnoeas over a seven hour period of sleep together with specific symptoms (Cartwright and Samelson, 1982). However, Stradling (1994) defined sleep apnoea as "A sleep disruption syndrome, sufficient to cause symptoms, that is due to a respiratory problem engendered by sleep itself, but may be also due to problems of respiratory drive."

Apnoeic episodes cause the oxygen level in the blood to drop and carbon dioxide levels to rise. Blood pressure may rise and the heart slows. The elevated blood pressure may eventually remain elevated during the day as well.

1.2.6 Symptoms of Sleep Apnoea

Some complaints that might suggest sleep apnoea include the following:

Loud snoring, often interrupted by loud gasps and long pauses in breathing
Excessive daytime sleepiness
Need for frequent naps
Decrease in concentration
Loss of memory
Decreased ability to function at work
Irregular heartbeat during sleep
Frequent accidents
Irritability/short temper
Morning headaches
Changes in mood or behaviour
Anxiety or depression
Decreased libido
Impotence
Frequent wakening/need to urinate during sleep
Hypnogogic hallucinations occurring while awake, but very groggy
Sudden wakening with a sense of disorientation.

Obstructive sleep apnoea is generally categorised as mild, moderate or severe depending on the number of apnoeas with oxygen desaturation below a certain level (i.e., <90%, <80%, <70%): the amount of time below a specific level of oxygen saturation and sleep fragmentation that is affected by the number of arousals during sleep. In general, mild OSA is 5-20 events per hour, moderate OSA is 20-50 events per hour and severe is over 50 events per hour.

The prevalence of sleep apnoea syndrome has been estimated at 4 percent of men and 2 percent of women in the middle-aged work force (Young et al, 1993).

The upper airway resistance syndrome (UARS) is partial collapse of the upper airway with increased resistance and arousal which leads to symptoms of OSA (Clark et al, 1996,b).

1.3 SLEEP

As snoring and obstructive sleep apnoea occurs during sleep, it is appropriate to discuss sleep itself. Sleep is a normal, regular state of rest of an organism. In contrast to the waking state, sleep is characterised by relative inactivity of physiological functions (breathing, heartbeat, and blood pressure) and a relatively low response to external stimuli. Brainwave patterns, recorded by electroencephalography (EEG), are used to define sleep because of their unvarying association with sleep behaviour.

1.3.1 Stages of Sleep

Dement and Kleitman (1957) described the different stages of sleep and produced criteria for scoring sleep stages based on eye movements, body motility and dreaming recorded during sleep. This followed the observation first noted by Loomis et al (1937) that sleep is not a steady state and that sleep stages follow an ordered pattern. Rechtschaffen and Kales (1968) produced a manual of standardised terminology, techniques and a scoring system for sleep stages in human subjects.

These stages are classified as stages 1 to 4.

In the waking state the EEG of the brain waves is characterised by alpha waves of 8 to 12 Hz and low voltage activity of mixed frequency. With the onset of sleep the alpha activity disappears. Stage 1 is considered the lightest stage of sleep and is characterised by low voltage desynchronised activity and sometimes by regular low voltage activity of between 4 to 6 Hz. Stage 2 follows after a short period of time (minutes), with the EEG showing what are called sleep spindles (after their pattern shape) at 13 to 15 Hz. Stage 3 shows the appearance of delta waves (high voltage activity with low waves, 0.2 to 2.5 Hz). In stage 4, these delta waves occupy the major part of the record (Rechstchaffen and Kales,1968).

During the course of a night's sleep (7-8 hours), these stages form a continuous cycle of 4 or 5 periods of change from stages 2, 3, and 4 to a stage similar to stage 1. Persons awakened at this similar stage report in 60 to 90 per cent of cases that they have been dreaming. These periods at the end of stage 4 are characterised by stage 1 EEG patterns and by rapid eye movements (REM). These periods of sleep are also referred to as D- (desynchronised or dreaming) sleep with the remaining stages known as S- (synchronised) sleep. The D and S states are also known, respectively, as REM (rapid-eye-movement) and NREM (non-rapid-eye-movement; as paradoxical sleep and orthodox sleep; or active sleep and quiet sleep).

The stages in normal adult sleep patterns are;

Stage 1- 2 - 3 - 4 - 3 - 2 - REM (70 - 90 minutes after sleep onset) -2 - 3- 4 - 3 -2 - REM.

It has been noted that not only does sleep lead to profound changes in breathing and its control, but problems with breathing lead to gross fragmentation of sleep (Stradling, 1994). Polysomnography is the term used to monitor a patient in a sleep laboratory and includes electroencephalogram (EEG), chin encephalogram (EMG), and eye movement. The determination of respiratory effort is achieved by recording chest wall movements, oral air flow by means of a thermistor probe clipped to the lip, nasal air flow with a thermistor clip attached to one of the nostrils and blood oxygen saturation by means of a ear oximeter (Guilleminault et al, 1978).

1.4 Snoring

Snoring is an inspiratory noise caused by vibration of the soft palate, uvula or posterior pillars of the fauces, associated with a narrowing of the airway (Seifert, 1980; Berry and Block, 1984; Wagner and Price, 1987; Hoffstein et al, 1988; Paskow, 1988; Schmidt-Nowara et al, 1991; George, 1993; Lugaresi and Partenen, 1994). Wild animals do not snore because they sleep on their stomachs or sides. Man alone has developed the alternative of sleeping on his back, aided by the development of a curved bed in ancient Egypt, headrests, pillows, and hammocks (Dille, 1987).

There is no generally accepted terminology to distinguish between different kinds of snores. However there are differences, both qualitative and quantitative, that may be associated with either nasal based or tongue based vibration. Nasal based snoring can occur with partial blocking of the nose which reduces the pressure in the throat whilst taking a breath, which in turn can result in the walls of the throat being sucked together. Tongue based snores occur when the tongue falls back in the throat, narrowing the airway. Snores that can be regarded as "conventional" are rhythmic noisy breaths that occur when a person is asleep. However, there are those very loud snores that follow the silence of a sleep apnoea. Snorers have been shown to snore more during slow wave sleep and REM sleep, whereas light snorers snored uniformly during all sleep stages (Hoffstein et al, 1991).

Snoring is also associated with sleep apnoea, where obstruction of the airway causes a temporary cessation of breathing.

1.4.1 Snoring as a Social Problem

Snoring is associated with a number of social and physical problems such as restless sleep and daytime sleepiness, cognitive dysfunction and abnormal cardiovascular excitation (Guilleminault et al, 1991). Snoring and sleepiness have long been considered with derision and humour. The term "Pickwickian" was used to describe patients who were obese and suffered with difficulty in breathing and snoring, after a character, Joe, the sleepy red-faced fat servant boy

in Charles Dickens' novel *The Posthumous Papers of the Pickwick Club* (1836). The loudest reported snoring in the *Guinness Book of Records* (1998) is 93 decibels, which is the equivalent to working in a noisy environment. The Health and Safety Executive of the Department of Employment recommends protection is used at a minimum noise level of 85dB in the workplace. Loud snoring disturbs the sleep of the spouse or partner and it is common for heavy snorers and their partners to sleep in separate bedrooms. Cartwright and Knight (1987) reported that marriages did not necessarily represent social support but rather appeared to be an added burden for sleep apneoic patients. In a study by Chourd et al (1986) 24 out of 43 men had to sleep in a separate bedroom because of the disturbance caused by their snoring. However, after uvulopalatopharyngoplasty, a surgical procedure that removes part of the soft palate and uvula, 17 of the 24 men returned to sharing a bedroom with their wives.

1.4.2 Anatomical Factors Involved in Snoring

Snoring can be observed from any age but normally begins before the age of 30. Physical conditions that can effect snoring are narrowing of the upper airway because of relaxation of the muscles of the tongue, pharynx, soft palate, and jaw; masses in the airway including tonsils, adenoids, cysts, larger amounts of fat in the obese; excessive length of the soft palate or of the uvula; or restricted nasal airflow as with septal deviations, colds, allergies, and sinus infections. Snoring is related to the morphology of the nasal and pharyngeal airway (Hoffstein et al, 1988).

In addition, a study of the effects of mouth opening on upper airway collapsibility in normal sleeping subjects showed that this may contribute to the occurrence of sleep-related breathing abnormalities (Meurice et al, 1996). Mouth opening is associated with an inferior movement of the mandible that decreases the pharyngeal diameter.

1.4.3 Prevalence of Snoring

In a large scale study carried out in Bologna, Italy, by Lugaresi et al (1980), 24% of men (n = 2858) and 13% of women (n = 2855) were found to snore. A study in the U.K. by Norton and Dunn (1985) reported that 42 per cent of 2629 people claimed to snore. Another large study was carried out in Finland by Koskenvuo et al (1987a) who reported that 9% of men (n = 3847) and 3.6% of women (n = 3664) in an age range of 40-69 years snored always or almost always.

Schimdt-Nowara et al (1990) in a survey of respiratory disease among 1222 Hispanic-American adults, found a prevalence of regular loud snoring of 27% in men and 15% in women. Snoring has been shown to increase with age up to 60-65 years, but decrease thereafter (Cirignotta et al, 1989). However, this may be as a result of mortality in the population sample, as the prevalence of snoring in the elderly is more than in any other group.

It has been estimated that there are 40 million snorers in the USA in the 41 to 64 years age group and that apnoea may affect 10 million (George, 1993). The British Snoring and Sleep Apnoea Association, formed in 1991, reported that 3.5m Britons, including up to a quarter of all middle-aged males, snore regularly (Pigott,1996).

It is generally accepted that men snore more than women, probably as a result of fat distribution in the body (male - upper body, female - lower body), and that after the menopause the number of women snorers is similar to men (possibly because progesterone stimulates respiration).

In a U.K. telephone interview of 2894 women and 2078 men aged 15-100, 40 % reported snoring regularly and 3.8% reported breathing pauses during sleep (Ohayon et al, 1997).

1.4.4 Classification of Snoring

There is no generally accepted index for snoring, although Lugaresi et al (1983) have proposed the following for classifying the different stages of the heavy snorers disease (HSD). Heavy snorers were divided into four groups:

1. subjects with heavy snoring presenting apnoeas sporadically or in short clusters;
2. subjects with heavy snoring alternated with prolonged sequences of obstructive apnoeas;

3. subjects with obstructive apnoeas lasting for almost the whole length of sleep;

4. subjects with typical obstructive breathing pattern and alveolar hypoventilation persisting during wakefulness.

The suggested four stages of HSD classification were:

Stage 0 (or preclinical) : heavy and habitual snoring with sporadic apnoeas confined to REM and stages 1-2 sleep;

Stage I (or initial): almost continuous apnoeas during light and REM sleep;

Stage I I (or overt): apnoeas persisting for almost the whole length of sleep;

Stage I I I (or complicated): alveolar hypoventilation persisting during wakefulness.

A classification of daytime drowsiness was also proposed by means of the multiple sleep latency test as a standard measure of sleepiness (Carskadon et al, 1986). Sleep latency (SL) is the interval between the time when the individual tries to sleep and the time when electroencephalographic patterns of sleep first develop.

Group O: with a mean SL greater than or equal to 10 min, considered normal daytime alertness;

Group A: with a mean SL between 10 and 7 min, considered borderline sleepiness;

Group B: with a mean SL of between 7 and 4 min, considered excessive or pathological sleepiness;

Group C: with a mean SL less than 4 min, considered severe sleepiness.

1.5 Questionnaires Used in Obstructive Sleep Apnoea

Questionnaires have been used previously in studies of obstructive sleep apnoea by Partinen et al (1988), Stradling and Crosby (1991) and George (1993), (see Appendix B). Questionnaires used to assess sleepiness include the Stanford Sleepiness Scale (a self-rating scale to quantify subjective changes in sleepiness for any time period of the day or night; Hoddes et al, 1973); the Multiple Sleep Latency Test (a standard measurement of sleepiness; Richardson et al, 1978), and the Epworth Sleepiness Scale, (eight questions related to how sleepy someone may become in normal situations, Johns 1991), (see Appendix B).

The Epworth Sleepiness Scale is widely used by physicians in sleep breathing disorders clinics where obstructive sleep apnoeas are suspected (Johns, 1994; Hardinge et al, 1995; Engleman et al, 1996).

1.6 Visual Analogue Scale

One of the most widely used non-verbal measurement techniques is the visual analogue scale (VAS). This consists of a line, (usually 10-cm) which can be horizontal or vertical and at each end is an anchor or maximum response.

Subjects place a mark on the line at an appropriate point between the two extremes. This technique has been widely used in medicine and has been shown to be a valid, reliable tool, particularly for measuring both clinical and experimental pain (Sriwatanakul et al, 1983; Duncan et al, 1989). The primary disadvantage of a verbal descriptor is that the given word does not necessarily have the same meaning for each person. However, visual analogue scales indicate the extremes only as end points on the 10-cm line and subjects can easily rate the general magnitude of the stimulus in relationship to the line length without necessarily considering the meaning of the anchors, (Duncan et al, 1989). Sriwatanakul et al (1983) reported that horizontal lines were preferable to vertical lines in terms of accuracy, as the usage of vertical lines tends to produce greater variation.

1.7 Risk Factors for Snoring

1.7.1 Obesity

An important risk factor for heavy snoring is obesity. An indication of obesity is the body mass index (BMI) which is weight in kilograms divided by the square of the height in meters (kg/m^2) (Khosla and Lowe, 1967). A body mass index of 20-25 kg/m^2 is considered normal. Adults with a BMI over 27 kg/m^2 may be considered obese.

Koskenvuo et al (1987b) found that habitual snoring occurred in 7% of men and 2.8% of women with a BMI below 27 kg/m2 and in 13.9% and 6.1% respectively of all those with a BMI above this level.

It has been proposed that upper body obesity may be related to heavy snoring, and this would explain why men are affected more than women.

In a study by Katz et al (1990) neck size was reported to be a useful indicator of upper body obesity because of the distribution of fat deposits. In a study by Cartwright (1984) of 30 male patients who were evaluated by all night polysomnography, 24 of the subjects had an apnoea index which was twice as high during the time spent sleeping on their back as it was when they slept on their side, but this difference was inversely related to obesity. Although the number of respiratory events per hour was highly correlated with obesity, the increase in severity when sleeping on their back was most striking in those close to normal weight.

The relationship between obesity and craniofacial structure in obstructive sleep apnoea was studied by Ferguson et al (1995). In three groups of patients it was found that those with a normal neck size were less obese and had more craniofacial abnormalities (such as a smaller mandible and maxilla and a more retrognathic mandible). Patients with intermediate neck size had both upper airway soft-tissue and craniofacial abnormalities. Patients with a large neck size were more obese with larger tongues and soft palates and an inferiorly placed hyoid; this group had fewer craniofacial abnormalities. However, there was no difference between airway size in the three groups.

1.7.2 Smoking

Cigarette smoking has been shown to increase the risk of snoring (Bloom et al, 1988; Kauffman et al, 1989) and this is thought to be because of irritation and inflammation of the upper airway by cigarette smoke. The study by Bloom suggested that a higher prevalence of snoring occurs among those who smoked more cigarettes and that snoring prevalence remained high in smokers who had recently stopped, although this declined in ex-smokers within four years of quitting.

1.7.3 Alcohol

Issa and Sullivan (1982) reported that alcohol exacerbated sleep induced breathing abnormalities, caused lowering of arterial blood oxygenation during sleep and caused OSA in some asymptomatic snorers. A study by Mitler et al (1988) found that respiratory events were significantly augmented by alcohol consumed by moderate social drinkers. Both of these studies found that alcohol increased snoring and produced apnoeas, particularly in the first two hours after ingestion, although the number of subjects in each study was small (7 and 6 respectively). However, the studies by Bloom et al, (1988) and Kauffman et al, (1989) which used much larger samples (2187 and 457 subjects), suggested that the time that alcohol was consumed before sleep was more important than the quantity consumed.

1.7.4 Hostility

Koskenvuo et al (1987b) reported an association between hostility and habitual snoring exists, as daytime sleepiness leads to hostility.

1.8 Evaluation of airway size

A review (Shepherd et al, 1991) suggested that information on upper airway size could be obtained by a variety of methods which included direct or fibreoptic visualisation, cephalometric radiographs, fluoroscopy, acoustic reflection, computerised tomography, and magnetic resonance imaging. Narrowing of the upper airway was usually located in the velopharyngeal or retropalatal segment of the upper airway. Obesity with enlargement of soft tissue structures was considered the predominant mechanism leading to upper airway narrowing although abnormal craniofacial development, either genetic or developmental, also played a contributory role. Lowe (1993) used cephalometrics and computerised tomography and suggested that a high apnoea index (AI) was associated with a large tongue and soft palate volume, a retrognathic mandible, an open bite tendency and obesity. Cephalometry can be useful for estimating the volume of the tongue, nasopharynx and soft palate but not the oropharynx or hypopharynx. Tongue posture appears to have a substantial effect on upper airway structures. On the basis of cephalometric studies, it has been shown that tongue cross-sectional area increases and oropharyngeal cross-section decreases when the OAS patients change their body position from upright to supine (Lowe, 1993).

A further study by Lowe et al (1995), using 80 subjects with OSA and 25 controls, found that a higher apnoea index was seen in subjects in association with large tongue and soft palate volumes, a retrognathic mandible, an anteroposterior discrepancy between the maxilla and the mandible, an open bite tendency and obesity.

1.9 Prevalence of Obstructive Sleep Apnoea

In a study of the clinical features of obstructive sleep apnoea, Whyte et al (1989) reported that up to the time of his study OSA was considered rare in the U.K. However, an increase in referral rate from 19 patients in year 1 of the study to 61 patients in year 4 suggested that the prevalence of this disease had been underestimated. Costello (1996) reported that the question of excessive daytime sleepiness and driving was examined in a report published in 1996 by the Transport Research Laboratory, (Department of Transport). Conclusions were based on interviews with 1000 Heavy Goods Vehicle drivers and 4600 car drivers and found that drivers who snored were twice as likely to have an accident as non-snorers.

The predictors and prevalence of obstructive sleep apnoea and snoring were investigated in 900 men over a four-year period by Stradling and Crosby (1991). Questionnaires were used as well as overnight oxymetry. The results showed a prevalence of symptomatic sleep apnoea of 0.3% for men aged 35-65 years of age, which means that each chest physician covering 150,000 people (the recommended ratio in Britain) should have about 100

such male patients. These figures suggest a total of approximately 36,000 patients in the U.K. The prevalence in women compared to men was 1:15.

A report from the Royal College of Physicians (1993) on sleep apnoea and related conditions stated "estimates of the prevalence of OSA depend on age and sex of the population surveyed, the method of sampling and the criteria used for diagnosis" and suggested a prevalence of approximately 4% in middle aged men and 2 % in women, (Young et al, 1993).

Douglas (1994) described sleep apnoea as one of the commonest medical conditions in the United Kingdom that would be missed until all physicians remembered to ask about daytime sleepiness and loud snoring whenever they were taking a history.

1.10. Snoring and Sleep Apnoea in Special Groups

1.10.1 Children

Upper airway obstruction with snoring is commonly seen in children of all ages and is similar to that seen in adults (Guilleminault et al, 1978). Enlarged tonsils and adenoids is the most common cause of airway obstruction in infants and children.

1.10.2 The Elderly

There is a high prevalence of sleep apnoea in the elderly, and it has been suggested that this may be one mechanism contributing to sleep-related mortality. Block (1981) suggested that predisposition to snoring and the consequent sleep disordered breathing and oxygen desaturation had been neglected in considering the important risk factors for mortality. The prevalence of every-night snoring appears to decrease after the age of 65 (Cirignotta et al, 1989) but it is possible that the number of snorers are smaller due to an increase in mortality.

1.11 Associations between Snoring, Sleep Apnoea, and Specific Disorders

Associations have been found between snoring, sleep apnoea and other specific disorders; these include arterial hypertension (Lugaresi et al, 1980), heart disease (Koskenvuo et al, 1987a; Shepherd et al, 1991; Partinen and Guilleminault, 1990), brain infarction (Koskenvuo et al, 1987b; D'Alessandro et al, 1990), sudden death, (Shepherd et al, 1992).

1.11.1 Arterial Hypertension

An association between snoring and hypertension has been found (Lugaresi et al, 1980; Norton and Dunn, 1985; Koskenvuo et al, 1987a). In heavy snorers, pulmonary arterial pressure may increase to pathological levels during sleep. Systemic arterial pressure also increased slightly and reached the highest values during REM sleep (Lugaresi et al, 1994).

1.11.2 Mortality

He et al (1988) calculated the cumulative survival in a study of 385 male patients with obstructive sleep apnoea and found that those with an apnoea index (AI) greater than 20 had a greater mortality than those with AI equal to or less than 20.

1.12. The Treatment of Snoring and Obstructive Sleep Apnoea.

Various remedies have been proposed to prevent snoring and there have been more than 300 patented devices in the USA alone. These remedies include taping a marble to the patients back, pyjama tops with a pocket sewn into them for a tennis ball, night-shirts with inserts to train the wearer to sleep on their side, special pillows, collars, chin straps, electric shocks, nasal devices and dental devices. Treatments of OSA using non-surgical methods include weight loss (Meyer and Knudson, 1990a), changes in sleep posture (Cartwright, 1984), drug therapy (Meyer and Knudson, 1990a), supplemental oxygen therapy (Meyer and Knudson, 1990a), nasopharyngeal tubes (Nahmais et al, 1987), continuous positive airway pressure (Sullivan et al, 1981), intra-oral and extra-oral devices. Surgical procedures (Sher et al, 1996) include correction of gross anatomical deformities, nasal septoplasty, uvulopalatopharyngoplasty (UPPP) (Fujita et al, 1981), and tracheotomy. Treatments have aimed to increase upper airway dilator tone, reduce the closing pressure by making the airway less collapsible, increase upper airway pressure above the closing pressure, and improve the

dimensions of the upper airway. Combinations of these treatments have also been tried to produce both normal sleep and breathing.

1.12.1 Conservative Treatment; Weight loss

A loss of weight is considered by many authors as the first form of therapy for mild to moderate symptoms. Lowe (1993) demonstrated that the tongue and soft palate volumes increase as the body mass index increases, which supports weight loss as a treatment for OSA. However, there has been some suggestion that there is no direct relationship between the degree of obesity and OSA (Meyer and Knudson, 1989).

1.12.2 Sleep Posture

Snoring and sleep apnoea are usually worse while sleeping in the supine position and it has been reported that a change in sleep posture from supine to the lateral decubital position can reduce the tendency for airway relapse (Cartwright, 1984; Cartwright et al, 1985). Changing sleep position may have some validity, particularly in patients who have position related obstruction, or who are close to their ideal weight.

1.12.3 Drug Therapy

There are a number of drugs, which have an influence on the upper airway muscle activity. Alcohol and sedatives are associated with decreased upper airway muscle tone and can induce sleep-disordered breathing.

A number of pharmacological treatments have been proposed which include strychnine and nicotine. Progesterone is a recognised respiratory stimulant and has been found to be beneficial in treating OSAS. However, there are major side effects in male patients such as feminization, decreased libido, impotence and alopecia. The high dosage (60-120mg/day) also makes the treatment expensive. Other drugs that have been used are acetazolamide, protriptyline and theophyiline, which are all respiratory stimulants. Protriptyline appears to be effective in reducing the amount of REM sleep, the stage in which apnoeas tend to last longest. Complications, including urinary retention and anticholinergic effects, have been reported in 60%-100% of patients by Meyer and Knudson (1990). The use of supplemental oxygen may have the effect of prolonging apnoeas by removing the major stimulus (hypoxemia) for their termination.

1.12.4 Continuous Positive Airway Pressure (CPAP)

The use of continuous positive airway pressure (CPAP), first described by Sullivan et al (1981), is the most common and most effective treatment for obstructive sleep apnoea (Clark et al, 1996a). Wali and Kryger (1995) considered the use of CPAP as the treatment of choice for obstructive sleep apnoea, a view widely shared by sleep physicians. Berry and Block (1984) proposed the use of CPAP as a treatment for snoring in patients who had no symptoms of OSAS. Nasal CPAP is thought to act as a pneumatic splint for the nasopharyngeal airway. Low levels of pressure are applied via a nasal mask to prevent upper airway closure.

Nasal CPAP is a relatively safe mode of therapy and is generally well tolerated although Clark et al (1996a) reported that between 10 to 50 % of patients treated with CPAP find it uncomfortable and discontinue use after a short period of time. Others have suggested that about 25% of patients may not tolerate CPAP (Riley et al, 1990; Lyon et al, 1992; Wali and Kryger, 1995). Common minor complications include dryness of the upper airway, sneezing, nasal drip, nasal congestion, local skin irritation, eye irritation, sinusitus, and nosebleeding. The patient is required to wear the mask throughout the night and it can be uncomfortable and inconvenient to use and is not aesthetically acceptable.

Alternatives to nasal masks are nasal pillows that insert tightly into the nares or a mask that goes over the mouth and nose. Another model is called BIPAP (Bi-level Positive Airway Pressure) which delivers a higher pressure during inspiration and a lower during expiration. However, Riley et al. (1990) suggests that 35 % of patients discontinued this form of therapy after only five months.

A randomised crossover trial of 32 patients compared CPAP directly with a placebo. This study found improvement in multiple sleep latency time and vigilance but no significant difference in patient preference after one month follow up (Engleman et al, 1997). CPAP is said to be used for 3 to 7 hours per night, Engleman et al. (1996). Cobb and Rommerdale (1996) reported that in approximately 20 % of patients who use CPAP, air is forced through

the nostrils but escapes through the mouth rather than being forced past the obstruction. Their solution to this problem was to use a custom oral device to prevent air escape from the mouth, which was worn in conjunction with CPAP.

1.13 Surgical Treatments

The efficacy of surgical therapy in adults with obstructive sleep apnoea was reviewed by Sher et al (1996) for the American Sleep Disorders Association. Operations to treat snoring and obstructive sleep apnoea syndrome include surgery to the nose, uvula and soft palate, tongue and changing the skeletal relationship and include nasal septal reconstruction; uvulopalatopharyngoplasty; uvulopalatopharyngoglossoplasty; laser midline glossectomy; lingualplasty; inferior sagital mandibular osteotomy and genioglossal advancement, with hyoid myotomy and suspension (GAHM); maxillomandibular osteotomy and advancement, and tracheotomy. More recently, laser-assisted uvulopalatoplasty has been advocated (Ryan, 1997).

1.13.1 Mandibular Advancement

A low hyoid bone or a posterior position of the mandible result in posterior positioning of the tongue, thus reducing the posterior airway size. Riley et al (1990) reviewed 40 patients treated with maxillary, mandibular and hyoid advancement and reported that snoring was eliminated in all but three patients. They claimed a success rate of 97% in correcting OSA.

However, results from a study by Miles and Nimkarn (1995) indicated that OSA did not appear to be associated with abnormal presurgical mandibular morphology.

1.13.2 Uvulopalatopharygoplasty

Uvulopalatopharygoplasty involves removal of the uvula and part of the soft palate to tighten the soft tissues in an attempt to reduce the amount of vibration of these tissues. The success rate for this treatment has been defined as a 50% reduction in apnoea index and was of the order of 50-60 % (Fujita et al, 1981). Saunders et al (1989) reported on eighteen patients who had UPPP surgery as a treatment for snoring. These patients were followed up for three to eight months and snoring was eliminated in one case and there was a reduction in noise in fourteen. However, recurrence of apnoea frequently occurs after 1-2 years which suggests that the procedure does not treat the underlying cause of snoring or apnoea. There is significant postoperative pain as well as possible postoperative stenosis and infection. An excessive resection during UPPP could result in palatopharyngeal insufficiency with resulting hypernasal speech and nasal regurgitation. Uvulopalatopharyngoglossoplasty (UPPGP) is an operation that incorporates a modified UPPP together with limited resection of the tongue base.

Laser Assisted Uvulopaloplasty (LUAP) consists of shrinking the soft tissues by scarring and tightening and so no tissue is usually removed.

Current data do not support the efficacy of LAUP in sleep related breathing disorders, although it may be of more relevance in the treatment of snoring (Ryan, 1997).

1.13.3 Tracheotomy

Tracheotomy refers to the creation of a percutaneous opening into the trachea. Tracheotomy was the treatment of choice for obstructive sleep apnoea but with the introduction of other forms of treatment, particularly CPAP it is rarely used these days.

1.14 Treatment of Snoring and OSAS with Non-Dental Devices

There are many non-dental devices to stop snoring; the majority concentrate on improving breathing through the nose. These include nasal dilator devices, such as the Nosovent described by Petruson (1988; 1990), and are made in flexible plastic (Nosovent) or stainless steel wire (Snore-no-More). They are inserted in the anterior part of the nose to dilate the nostrils. An external nasal dilator is also available (Breath Right nasal strip). These nasal strips have proved popular as a nasal dilator with sportsmen such as American Football players, rugby players, and footballers to improve their breathing while playing. However, the effect of these strips to prevent snoring is not supported by clinical trials.

Nasopharyngeal tubes placed beyond the clinical obstruction can have a positive effect in OSA patients. A 2.5-3.3 mm paediatric endotracheal tube is inserted to a level of 5 mm above the epiglottis with the aid of fibreoptic visualisation. This treatment can be used temporarily while the patient achieves the necessary weight loss. Nahmais et al (1987) reported on seven patients who were treated with this method, although two were unsuccessful because of mucous plugging of the tube. However, Meyer and Knudson (1990a) reported that most patients refused long-term nasopharyngeal tubes because of chronic irritation, pain, and possible hypertrophy of tissue that may occlude the tube.

Cartwright et al (1985) suggested sleep position training as a treatment for sleep apnoea syndrome. Ten male patients were trained to avoid the back sleeping position by wearing a gravity-activated position monitor/alarm on the chest. This device emitted an auditory signal if the patient remained on his back for more than ten seconds. The number of apnoeic events was significantly reduced, as were the number of periods of significant oxygen desaturation.

1.15 Treatment of Snoring and OSAS with Dental Devices

Various dental devices have been reported to have an effect on reducing snoring and OSA (Clark, 1988; Clark and Nakano, 1989; Paskow and Paskow, 1991; Lowe, 1994; Schmidt-Nowara et al, 1995, Clark et al, 1996b, Loube and Strauss, 1997).

The most common appliances are those which prevent the tongue from adopting a retruded position and appliances which reposition the mandible. All appliances that reposition the mandible also have an effect on retaining the tongue in a forward position. There are also two devices of similar design, which are specifically for treatment of snoring and apply to the soft palate tissues (Paskow and Paskow, 1991; and Wagner and Price, 1987). The tongue retaining appliances include the tongue retaining device (Cartwright and Samelson, 1982), the tongue locking devise (Princell et al, 1992), and the tongue positioner and exerciser (Lowe, 1993).

The mandibular positioning appliance has been described in various forms by Meier-Ewert and Brosnig (1986), Soll and George (1985), George et al (1992), Schimdt-Nowara et al (1991), Nakazawa et al (1992), Clark et al (1993), Eveloff et al (1994), Reimao et al (1994), Yoshida (1994), Osseiran (1995), O'Sullivan et al (1995) and Menn et al (1992). Many of these appliances have been patented and are known by trade names such as the Equaliser, (Nahmais et al, 1987), Nocturnal airway patency device or NAPA, (George, 1987), Sleep and nocturnal obstructive apnea reducer or SNOAR, (Viscomi et al, 1988) and Snoarguard (Schmidt-Nowara et al, 1991).

A review of 13 appliances by Lowe (1994) evaluated 246 subjects with snoring and 456 subjects with OSA.

Schmidt-Nowara et al (1995) reviewed 21 publications describing 320 patients treated with oral appliances and concluded that oral appliances presented a useful alternative to CPAP. These appliances were especially for patients with simple snoring and patients with mild to moderate obstructive sleep apnoea who cannot tolerate CPAP therapy. A later survey (Loube and Strauss, 1997) of dentists treating obstructive sleep apnoea patients listed twenty-five different oral appliances used among members of the Sleep Disorders Dental Society of which only 11 of the 25 had been evaluated using pre-treatment and post treatment polysomnography.
The American Sleep Disorders Association in 1995 provided clinical guidelines and recommendations on the use of oral appliances for the treatment of snoring and obstructive sleep apnoea.

1.16 Tongue Retaining Oral Appliances

1.16.1 The tongue retaining device

The tongue retaining device (TRD) (Cartwright and Samelson, 1982), (Figure 1.1) was designed to hold the tongue forward during sleep. It was made of a soft co-polymer, in the form of a bi-maxillary mouthguard, and holds the tongue by suction in a bubble or cup positioned between the anterior teeth. The device holds the mandible in an open position of approximately 15 - 20 mm between the incisor teeth but there is no protrusion.

Cartwright and Samelson (1982) reported the TRD to be effective in a study of 20 patients, 14 of whom had polysomnography on two nights, three patients had not been followed-up and three could not tolerate the appliance. Patients were evaluated with and without the device on each night of monitoring. The number of apnoea episodes was cut by half with the number of oxygen desaturation episodes reduced from 44 to 25. A disadvantage of the TRD was that the retention of the tongue was not always effective, most subjects could wear the device for 3 to 4 hours before suction was lost. Another disadvantage is aesthetic, as the tongue must protrude between the teeth. The TRD forces nasal breathing, which may be difficult for some patients, although the appliance can be modified by the addition of lateral airway tubes. The tongue can also become irritated from the restricted blood supply.

A study by Adachi et al (1993), reported that genioglossus muscle activity and the relation to inspiratory effort is of physiological importance to OSA patients. A TRD helps compensate for the altered genioglossus muscle activity during inspiration by bringing the tongue forward.

A single case study was reported by Alvarez (1992) of a patient who had failed treatments with surgery and CPAP and by Farrow (1991) of two cases of central sleep apnoea that had been treated with a tongue retaining device.

1.16.2 The Tongue Locking Device

The tongue locking device is a pre-formed elastic device available in different sizes (small, medium, large) that provides a cavity for the tongue and holds it forward during sleep (Princell et al, 1992). Lateral breathing holes assist airflow if nasal obstruction occurs. An evaluation of ten subjects found that five had a reduction of Respiratory Distress Index and five individuals became worse with the tongue locking device in place.

1.16.3 The Tongue Positioner and Exerciser

This device contacts the upper and lower teeth with a ramp at occlusal plane height invented by Richard North and is designed to "retain the tongue and musculature to be in the proper rest and saliva swallowing position". The appliance opens the jaw by 1-1.5 mm and the mandible is not advanced (Lowe, 1994). No published outcome data are available.

1.16.4 The Tepper Proprioceptor Stimulator (TOPS)

This appliance was designed by Tepper and is fitted to the maxillary arch with a posterior tongue extension which is held inferiorly with an elastic band (Lowe, 1994). It has a padded bar lingual to the incisors to direct tongue placement. The aim is to strengthen the tongue, particularly the dorsal muscles, and reposition the tongue against the hard and soft palate to create more airway space. There are no outcome data to date

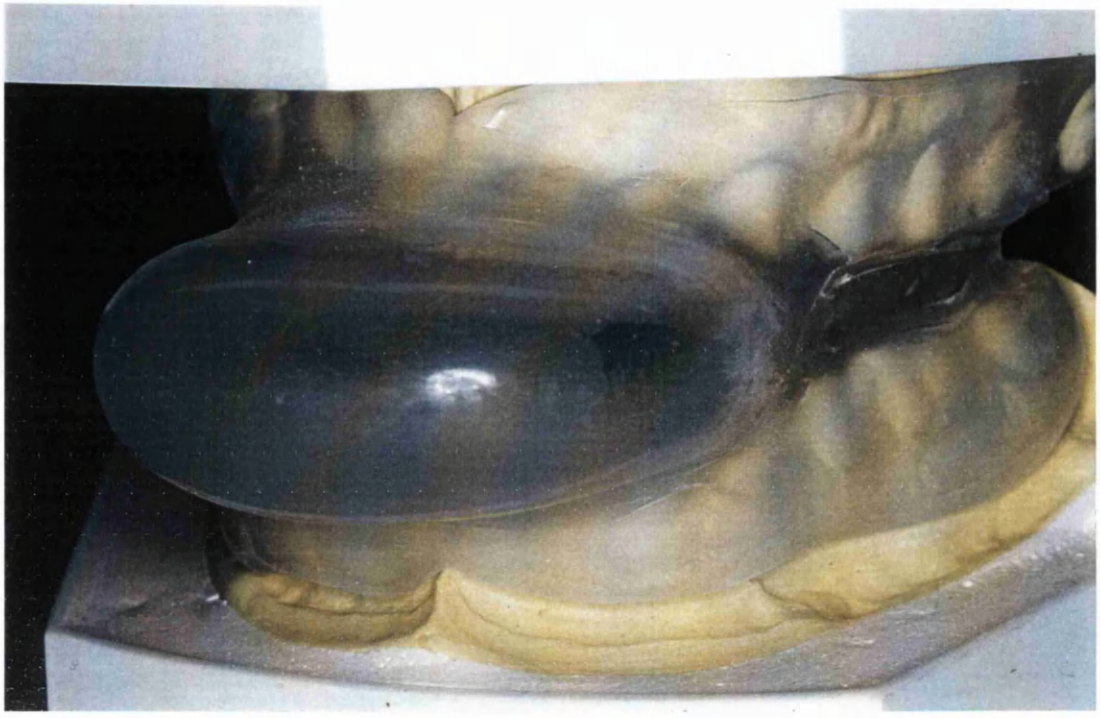

Figure 1.1 The tongue-retaining appliance (Cartwright and Samelson,1982). The tongue is held by negative pressure in the soft acrylic bulb.

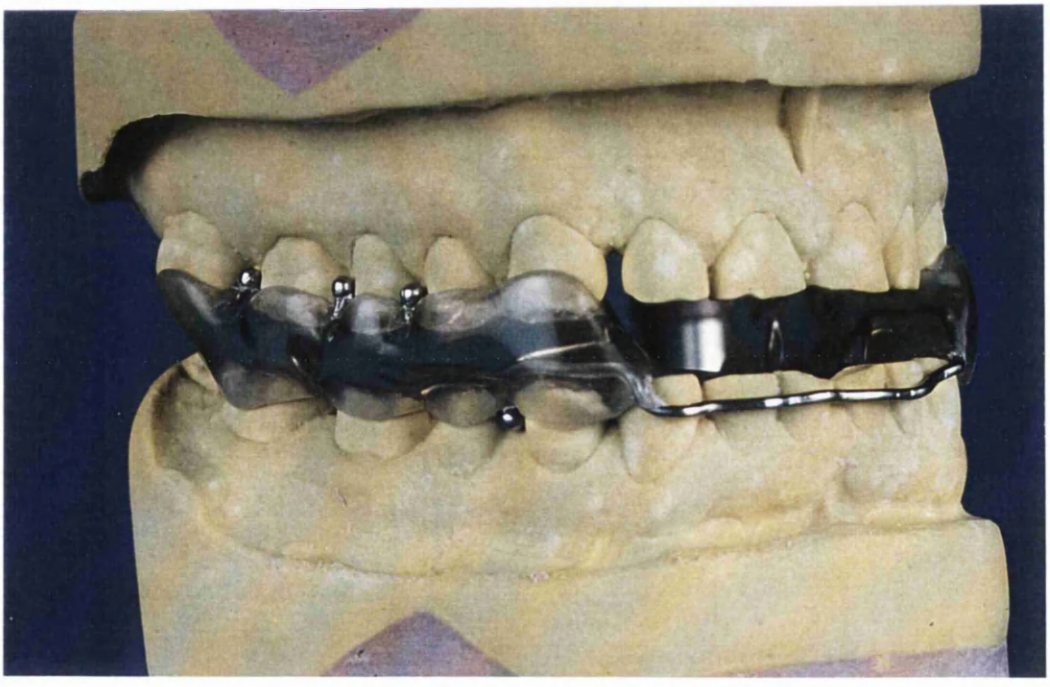

Figure 1.2 The mandibular positioning appliance (Meier-Ewert and Brosnig 1986). This type of appliance was based on functional orthodontic appliances.

1.17 The Mandibular Repositioning Appliances

Johnson et al (1992) has reported airway changes at the level of the oropharynx and hypopharynx when the mandible is postured anteriorly. A mean increase of the posterior airway space of approximately 56% was recorded in their study of ten patients, although there were wide variations. The mandibular positioning appliances reposition the mandible in a forward, open position, which also brings the tongue forward and so enlarges the retroglossal space. Stradling et al (1998) suggested that an alternative explanation for the effect of mandibular repositioning appliances might be that by "pulling the mandible forward the lateral walls of the pharynx could be made taut and would therefore be less likely to vibrate or collapse, without necessarily increasing the retroglossal space or lowering upper airway resistance".

The effectiveness of these appliances was reported by Clark and Nakano (1989) to be greater than 85% in patients with OSA. There are a number of variations of design but a consistent feature is that the mandible is moved forward by several millimetres, being between 50%-75% of the maximum protrusive opening (Clark et al, 1996a). The success of these appliances depends on their ability to maintain the jaw in a forward position even though the patient is asleep. Appliances that position the mandible forward are either one-piece designs that cannot be adjusted or they are two-piece and are adjustable.

1.17.1 The Mandibular Positioning Appliance

The first rigid repositioning appliance that was effective in reducing OSA was first described by Meier-Ewert, Schafer and Klob in 1984 at the 7th European Sleep Congress and subsequently by Meier-Ewert and Brosnig (1986). In a group of seven subjects the mean AHI was reduced from 38 to 12.1 after wearing the appliance.

In a larger study of 44 subjects by Lowe (1993), a reduction of mean AI from 50.4 to 23.1 was recorded. The design of these appliances was based on a monoblock functional appliance, again used in orthodontics to advance the mandible and promote forward growth (Figure 1.2).

Bonham et al (1988) described a modified functional appliance in patients with obstructive sleep apnoea. Of twelve patients fitted with the appliance, ten had a decrease in the total apnoea index from a mean of 53.82 to 35.99 events per hour.

Another device was described by Menn et al (1996). This consisted of full maxillary and threequarter mandibular coverage acrylic splints joined with acrylic resin pillars. These pillars which were not permanently fixed and thereby allowed for serial modification of mandibular protrusion and jaw separation. Of 29 patients fitted with the device, 16 showed a decrease in respiratory disturbance index.

1.17.2 The Nocturnal Airway Patency Appliance (NAPA)

This appliance, which is a fixed one-piece design, is a modified functional appliance and advances the mandible about threequarters of maximum protrusion. The device was first described by Soll and George (1985), and was used for one patient. This appliance is designed to keep the airway open during sleep by positioning the tongue more anteriorly and inhibiting wide jaw opening while still assuring adequate intake of air through the mouth whenever nasal obstruction occurs. This air supply can be via an external breathing "beak". The appliance is constructed in acrylic with as many as eight Adam's cribs for retention. All the teeth must be firmly held in acrylic, with the acrylic overlapping the facial and lingual surfaces of the teeth. The NAPA rigidly stabilises the mandible in both the horizontal and vertical directions. A study of five subjects that was reported by George (1987), while a retrospective study by George et al (1992) showed an average respiratory disturbance index of 42.2 which was reduced by 78 % when wearing the appliance. This study supported the contention that a low hyoid bone relative to the mandibular plane is an etiological factor in snoring and OSA.

1.17.3 The Sleep and Nocturnal Obstructive Apnea Reducer

The SNOAR™ open airway appliance is an acrylic mandibular positioning appliance that advances the mandible 6-9 mm and opens it vertically 17 mm or more.

When the mandible is moved anteriorly and inferiorly, the tongue is correspondingly repositioned anteriorly away from the posterior wall of the pharynx and inferiorly from the soft palate (Lowe, 1994). Viscomi et al (1988) reported the treatment of snoring and sleep apnoea in six patients using a SNOAR™ device. In this limited study using the appliance the RDI was reduced from 45.5 to 9.7 and snoring was absent. All patients were evaluated using polysomnography.

1.17.4 The Snoar Guard

The Snoar Guard (Therasnore appliance) is a prefabricated device which is placed in hot water and moulded to fit the patient. The appliance covers only the anterior teeth and is lined with soft polyvinyl for comfort. The mandible is positioned 3 mm behind maximum protrusion with a opening of approximately 7 mm. Schmidt-Nowara et al (1991) found that snoring was eliminated in 6 out of 14 patients and reduced in 8. After 7 months of use in 68 patients, 75 % used the appliance regularly. Snoring was decreased in 67 subjects and eliminated in 29 of these.

Ferguson et al (1996) used the Thereasnore in a randomised crossover study of an oral appliance versus nasal CPAP in the treatment of mild to moderate OSA patients and concluded that an oral appliance was effective in some patients and was associated with fewer side effects and greater patient satisfaction than nCPAP. This appliance has subsequently been redesigned to allow adjustment in increments of 1.5mm.

1.17.5 The Equaliser

The Equaliser was designed to position the mandible forward, equalise intra-oral and extra-oral air pressure, and elevate the soft palate without impairing nasal breathing (Haze, 1987a). A study of 14 patients treated with the Equalizer reported a mean RDI of 36.5 before reduced to 18.9 (Haze, 1987b).

1.18 Adjustable Appliances

Adjustable appliances allow the mandibular advancement to be adjusted if required. A variety of designs are available which generally use pre-formed attachments. Some of these designs also allow opening of the mandible.

1.18.1 The Herbst Appliance

The Herbst appliance (Figure 1.3) has been used for many years in orthodontics to encourage growth of the mandible. In 1988, Rider described the use of a Herbst appliance for the treatment of sleep apnoea. In a study of 16 patients over a 10 month period, 15 patients showed improvements of 70 to 100 per cent (one could not tolerate the appliance).

Clark et al (1993) described the use of an anterior mandibular positioning device that consisted of upper and lower acrylic bases held in position by two Herbst attachments.

These allowed opening, protrusion, and some lateral movement but no retrusive movement. Bilateral inter-arch elastics were used to keep the jaw closed, with interproximal ball end clasps to retain each individual appliance firmly in position. The appliance advanced the mandible by 5-7 mm, or at least 75% of maximum protrusion. After 36 months, 15 of 24 subjects were still wearing the appliance. The mean respiratory disturbance index before treatment was 48.4 ± 33.4, and was 12.0 ± 21.3 after the treatment. Eveloff et al (1994) also reported on the use of Herbst mandibular appliances in 14 subjects who were not able to tolerate CPAP, but the Herbst appliance was successful after a two-year follow up.

In a study by Sjoholm et al (1994), a Herbst appliance was compared to a muscle relaxation appliance that covered the maxillary teeth but produced no protrusion. The Herbst appliance was adjusted to achieve 50% of maximum protrusion. The Herbst appliance did bring about some alleviation of upper airway obstruction, but did not lead to sufficient control of apnoea. However, the muscle relaxation appliance also reduced partial upper airway obstruction. The explanation offered was that this effect could have been secondary to the discomfort arising from the appliance, this discomfort leading to increased sleep fragmentation and reduced relaxation during sleep.

A Herbst appliance was also used in a cross-over study with the efficacy CPAP (Clark et al, 1996a). The oral device was successful in most cases but was less effective than CPAP, especially for the more severe cases.

In general, the oral device was strongly preferred to CPAP.

A variation of the Herbst appliance, the Jasper Jumper, was also used to position the mandible forward (Lowe, 1994). However, the appliance did not generate enough forward force to overcome the muscle pull on the mandible.

1.18.2 The Silencer

Halstrom (1994) described this appliance as consisting of upper and lower splints articulated by means of a commercially pure titanium hinge (Figure 1.4). This permits the incremental advancement of the mandible through a range of 10 mm by a series of five holes. It also provides a lateral movement of 6 mm and a 1mm vertical movement while the mandible is in the desired protrusive position. There is a recommended registration technique provided with this system in the form of a modified Gothic Arch tracing to position the hinge correctly. This appliance was used in a short-term controlled trial of an adjustable appliance to CPAP for the treatment of mild to moderate sleep apnoea in 24 patients (Ferguson et al, 1997). Of 20 patients who completed the study, 11 were treatment successes (reduction of AHI to <10/hour and relief of symptoms), one was a compliance failure and eight were treatment failures (failure to reduce AHI to < 10/hour or relieve symptoms). Fourteen of the 20 who used CPAP were treatment successes with six compliance failures.

Six patients with OSA were treated with a Silencer and titration of the appliance was completed during one night of polysomnography (Raphaelson et al, 1998). The device was adjusted until snoring, oxygen desaturations and apnoeas were improved. Patients were instructed to sleep in the supine position until they had completed the first period of REM sleep or 2 hours if the patient did not enter REM sleep. It was suggested that there was generally an under-estimate of the amount of anterior mandibular repositioning required.

1.18.3 The Thornton Adjustable Positioner (TAP)

Described by Thornton and Roberts (1996), this device uses a single latch and hook which restricts all retrusive movement but allows the patient forward and lateral movement. The amount of protrusion can be adjusted by turning the hook, which is attached to a screw that extends extra-orally. In a telephone survey of 208 of 300 patients who had worn the appliance for 6 months, 81% were said to use it for 25 days per month. They also reported that only 4 patients out of the 208 felt that the appliance had not improved their snoring.

1.18.4 The Klearway Appliance

The Klearway appliance is a patented device that consists of upper and lower arch splints connected by a Hyrax expansion screw. This allows 11 mm of mandibular advancement in 44 separate 0.25 mm increments.

The appliance also uses a temperature sensitive resin which is softened in hot water before insertion to provide increased retention and to reduce tooth discomfort. The hinge position was then adjusted. Five out of six patients reported improvement with the appliance in positions changed from the baseline position. This device permits lateral and vertical jaw movement, which enables patients to yawn and swallow without dislodging the appliance.

This appliance is currently being used in a long term multicentre clinical trial comparing it with CPAP in a large population of OSA patients (Lowe et al, non published data). A total of 270 patients were to be recruited for the trial with covert compliance monitors used in both the appliance and CPAP (Lowe et al (a), personal communication). A preliminary report on 10 OSA patients who had polysomnography before and after using the Kleerway showed a reduction in RDI of all patients (Lowe et al, (b) personal communication).

1.18.5 The Silensor

This appliance (E.M.Natt Ltd, England) is similar in principle to a Herbst appliance, the difference being that two plastic rods (two different sizes available) are used with upper and lower thermoformed splints (Figure 1.5). A study of 29 patients with mild or moderate apnoea were fitted with this device in a randomised crossover study with CPAP (Tan et al, 1998). It was found that the Silensor was as effective as CPAP.

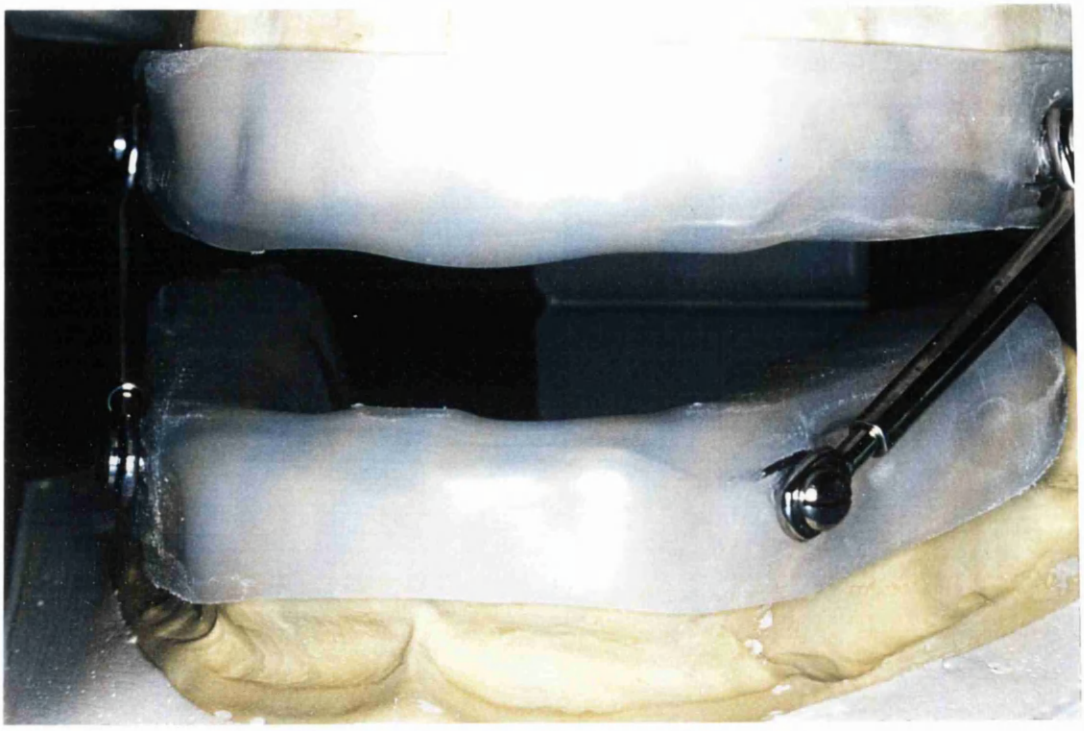

Figure 1.3 Herbst appliance. The rod and tube prevent posterior movement of the mandible and allow opening. The completed appliance would have inter-arch elastics on the anterior to limit excessive mouth opening.

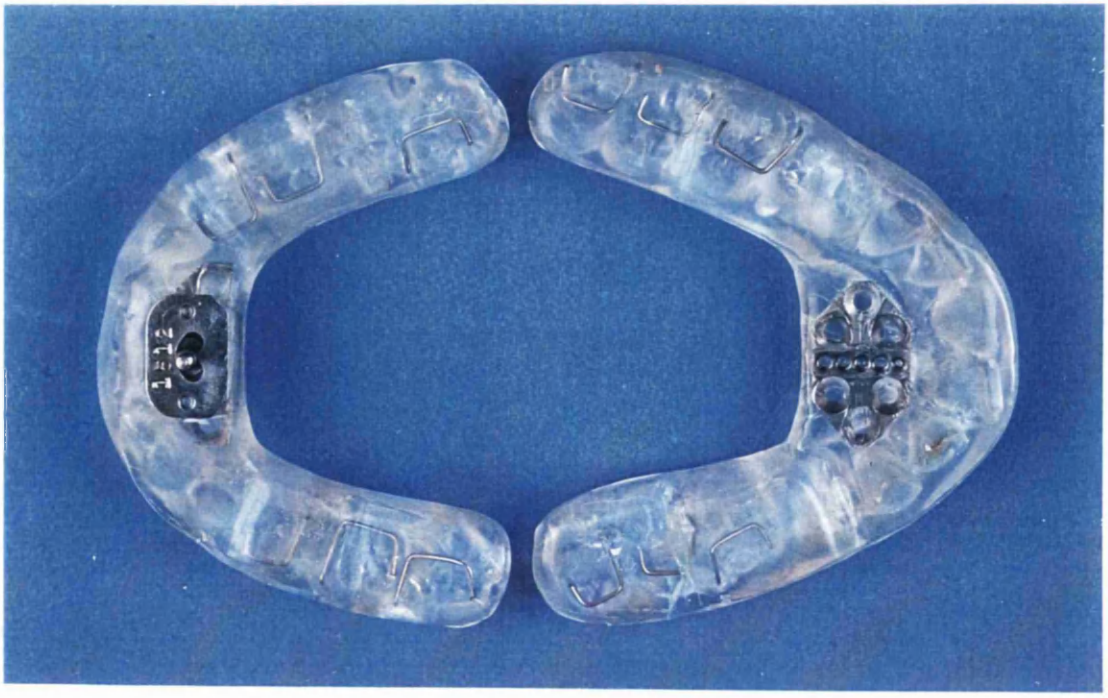

Figure 1.4 Silencer appliance. The appliance can be titrated by means of the hinge (lower) and holes (upper) by 5 increments up to a maximum of 10mm.

1.19 Other Mandibular Repositioning Appliances

A variety of other mandibular positioning appliances have been described which include the use of both hard acrylic and soft polyvinyl materials. A device was described by Ichioka et al (1991) in a preliminary study of 12 male and 2 female patients. The device was an acrylic splint fitted to upper and lower teeth that advanced the mandible 5 to 7 mm. The upper teeth were securely held but the lower teeth were loosely held. When the patient's mouth opened during sleep the lower teeth were easily released from the splint but when the patient's mouth closed the lower teeth slid into the lower part of the sleep splint and the mandible was moved forward. Evaluation was by polysomnography. A 50% reduction in AI was found in 13 of the 14 patients.

A hard acrylic appliance was described by Knudson et al. (1992) which was made to an incisal edge-to-edge position with 12-15 mm opening. Cephalograms were used to evaluate spacial change between the base of the tongue and the pharyngeal wall. In two cases described the RDI was reduced from 42 to 9 in one and from 18 to 3 in the other (Knudson and Meyer, 1993). Wong et al (1992); Nakazawa et al (1992) and Osseiran (1995) have also described this procedure.

Athanasiou et al (1994) described an appliance used for 45 patients consisting of a one-piece acrylic device that fitted over all the lower teeth and the upper posterior teeth, with Adam's cribs and a labial bow for retention.

Lateral cephalograms were taken to evaluate the position of the pharynx, soft palate, adenoid tissue, tongue, and hyoid bone before and after wearing the device. The results indicated that significant changes in pharyngeal space, hyoid bone and tongue position takes when a mandibular positioning device is used. A 40-year-old male was treated with an orthodontic appliance, the Bionator Basic, for obstructive sleep apnoea (Reimao et al, 1994). A significant improvement of excessive daytime sleepiness and decrease in apnoeas was recorded.

O'Sullivan et al (1995) described a mandibular advancement splint (MAS), that maintained an inter-arch separation of approximately 10-mm at 75% of maximal protrusion used to treat 57 patients with habitual snoring, 39 of whom had OSA. The appliance was made in polyvinyl acetate polyethylene. The design of this device differed from most appliances in that it was in contact with all the teeth except the upper anteriors. Snores per sleep minute, corrected for time in apnoea, sound intensity of snores (% snores >50dB) decreased with the MAS from 11 ± 5.8 and $42.0 \pm 25\%$ to 9.0 ± 6.0 ($p < 0.001$) and 26.2 ± 25.2 ($p<0.001$) respectively.

Cohen (1995) described a variation in design of a mandibular positioning appliance. This appliance consisted of thermoformed soft vinyl coverage of the teeth and soft tissues with a polymethyl methacrylate wafer to maintain the registered jaw position. This position was usually with 5-6 mm of protrusion and an opening of 5-8 mm.

A vacuum formed appliance was also used by Stradling et al (1998) for the control of snoring in a retrospective study in a highly selected group of patients (n = 15) who had worn a mandibular advancement device and had reported subjective improvement to their symptoms. Home monitoring over two nights with and without the appliance showed that the appliance did make a difference to the frequency of snoring and the level of noise.

Menn et al (1992) reported on the use of a mandibular advancement device in 19 patients. Evaluation involved cephalometric radiographs, CT scanning of the TMJ and polysomnography. Their results showed a significant improvement in the apnoea index, nocturnal oxygenation, and reduction in daytime sleepiness.

All of the appliances so far discussed have been for dentate patients, but an appliance that can be used in edentulous patients has been described (Meyer and Knudson, 1990b).

Knudson and Meyer (1993) reported on the use of an appliance for one edentulous patient. The result was a reduction of obstructive episodes from 111 to 14 and the respiratory index dropped from 18 to 3. Robertson (1997) also described a single case where a similar device was used.

1.20 The Adjustable Soft Palate Lifter

This device is only for the treatment of snoring and was described by Paskow (1988) and Paskow and Paskow (1993), (Figure 1.6). The device is worn in the upper arch with a soft palate lifting portion that may be adjusted in all three dimensions.

Wagner and Price (1987) described a similar device. However, both these devices were used on single case studies without any objective follow-up measure and problems with gagging are significant.

1.21 Other Dental Devices

Seifert (1980) described a device that prevents air being inhaled through the mouth whenever it opens. This device consists of a soft acrylic sheet of 1-mm thickness that fits between the teeth and lips. The restriction of air through the mouth is intended to cause the sleeping person to change position without losing depth of sleep.

A device described as a labial shield (Campion, 1985) was reported to prevent or restrict oral airflow, thereby forcing nasal breathing to reduce snoring. The labial shield (Snore-no-more, Dentec Australia Pty Ltd) is intended to prevent or restrict oral airflow, thereby forcing nasal breathing. However, a study by Bushell et al (1991) of 14 patients with a history of chronic snoring concluded that snorers using this device were unlikely to experience any benefit.

The device did not change the mean frequency or intensity of snores although the number of disordered breathing events per hour of sleep decreased by approximately one third.

There are also a large number of commercially available oral devices advertised for direct sale to the public but none so far have been subjected to clinical trials.

In evaluating the choice of dental appliance, the American Sleep Disorders Dental Association listed properties of the "ideal" intraoral appliance (Barsh, 1996) which included:

- Produce minimal damage to the teeth and periodontium;
- Produce no changes in perception of occlusion after its removal and not create TMJ dysfunction:
- Be considered a long-term appliance; therefore, there should be no adverse effects on the teeth, periodontium, occlusion, or TMJ over many years.

Fleetham et al (1996) was of the opinion that mandibular advancement appliances require at least 10 teeth in each of the maxillary and mandibular arches and that in addition to advancing the mandible they also produce downward rotation of the mandible.

1.22 Outcome measures for oral appliances

A medical and dental history and examination, polysomnography, radiographs and patient/partner questionnaire are the standard method of evaluation.

Another method of evaluation is the use of image intensification fluoroscopy (IIF) in conjunction with tooth guided mandibular protrusion with the patient in the supine position (L'Estrange et al, 1995). This method enables the study of the adaptive behaviour of patterns of oral and oropharyngeal structures in response to mandibular advancement and thus may determine whether an advancement splint may be effective. It is claimed that IIF is as useful as cephalometric analysis (L'Estrange et al, 1995).

For patients with primary snoring without features of OSA or upper airway resistance syndrome, the subjective assessment (usually by partner) is appropriate.

However, there have been a number of studies where oral appliances have been effective in reducing snoring but OSA have been worse when an objective measure was used.

A study by Clark et al (1993) showed that of fifteen patients who had follow-up polysomnography, fourteen had a reduction of RDI but one had an increase. This was also shown by Schmidt-Nowara et al. (1991), where one patient in twenty did not show a reduction in AHI. Bonham et al (1988), and Eveloff et al (1994) also reported that one patient in fifteen in each study had a worse AHI on follow-up.

The American Sleep Disorders and Sleep Research Report in 1995 recommended that although polysomnography was not indicated for patients with either primary snoring or mild OSA, patients treated with oral appliances should return at regular intervals. It would appear to be important that diagnosis by a sleep physician is carried out before referral to a dentist for an oral device.

1.23 Summary of Review of Literature

Obstructive sleep apnoea with associated snoring is one of a number of sleep breathing disorders and is a potentially serious condition with a high morbidity. Problems associated with these conditions are excessive daytime sleepiness and increased risk of stroke and heart disease. A study by He et al (1988) suggested that subjects with OSA (AHI > 20) have an increased risk of mortality. A study by Young et al (1993) suggested a prevalence of OSA of 2% for women and 4% for men. Sleep disordered breathing may be as prevalent as asthma and diabetes and is a rival to smoking as a major public health problem (Phillipson, 1993), although sleep disordered breathing remains largely misdiagnosed in most patients, (Fleetham, 1997).

Of the treatments currently available there are four routes open.

1. Behavioural
2. Continuous positive airway pressure
3. Surgery
4. Oral Appliances.

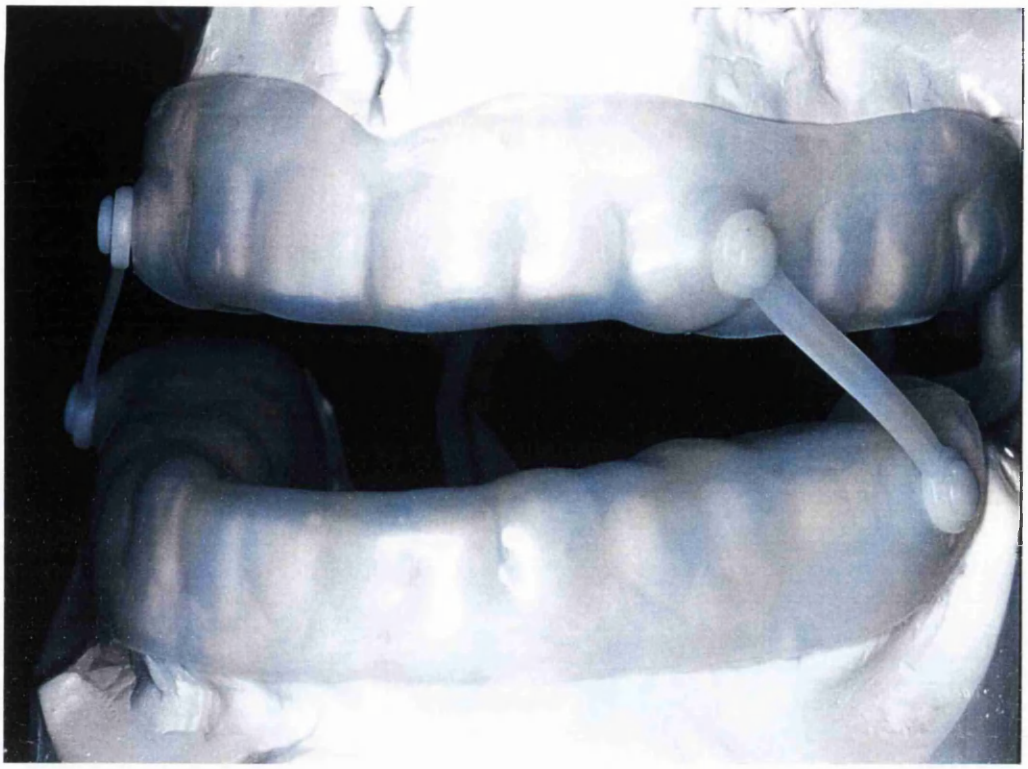

Figure 1.5 The Silensor appliance. The plastic rods allow opening while preventing retrusion of the mandible.

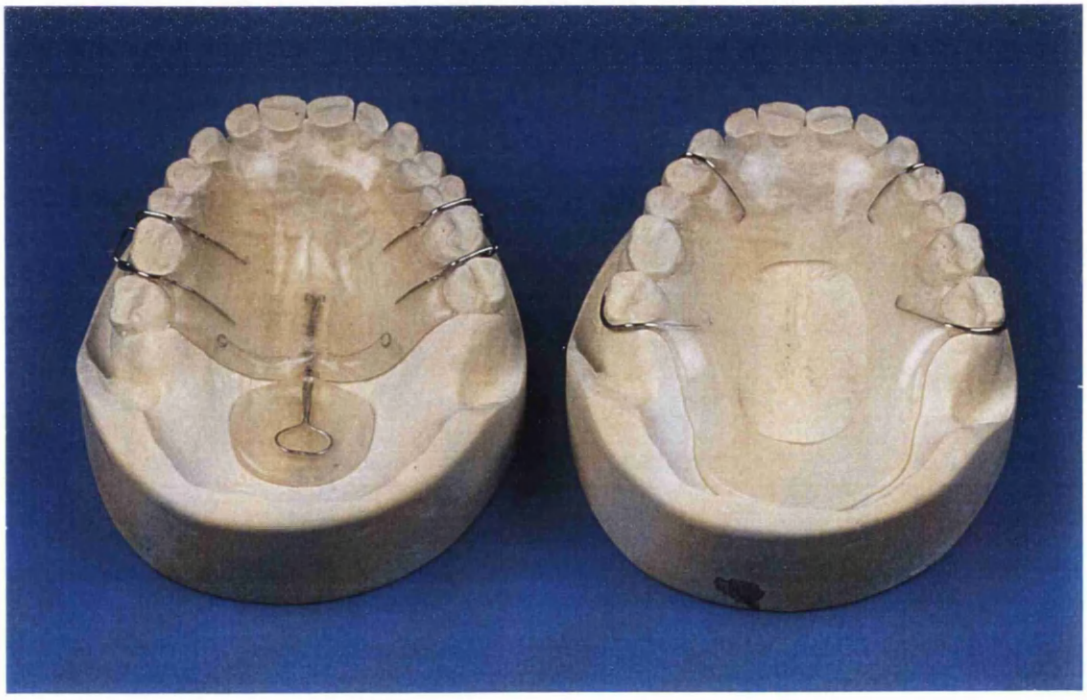

Figure 1.6 Soft palate lifter appliances. The adjustable (left) design by Paskow (1988) and non-adjustable by Wagner and Price(1987).

No one treatment fits all patients (Cartwright, 1997), therefore it is important that accurate diagnosis by a sleep physician is made before the decision on the appropriate treatment is made.

Conservative or behavioural treatments include weight loss, sleep position training and reduced alcohol and tobacco consumption. The "gold standard" therapy among sleep physicians is nasal CPAP. Surgery may range from simple nasal surgery (deviated septum), to major oral surgery (maxillo-mandibular advancement). In a systematic review of published research from 1966-96, Wright et al, (1997) suggested that the relevance of sleep apnoea to public health was exaggerated with the effectiveness of continuous positive airway pressure poorly evaluated. It was suggested that patients with daytime sleepiness might benefit from large randomised placebo controlled trials of CPAP versus an effective weight reduction programme or other interventions.

The use of various intra-oral devices have been reported in the dental and medical literature. Studies by Clark et al (1996b), Ferguson et al (1996,1997), and Tan et al (1998) comparing the efficacy of CPAP with mandibular re-positioning reported that the oral appliances achieved substantial success in reducing the AHI, improving oxygen saturation, and improving sleep quality. Although the oral appliance was not as effective as CPAP, especially for the most severe cases, the oral appliance was strongly preferred by the patients.

Following a review by Schmidt-Nowara et al (1995) of 21 papers, which included 320 patients treated with oral appliances, the American Sleep Disorders Association issued guidelines for the use of oral appliances in the treatment of snoring OSA. Despite considerable variation in the design of oral appliances used, the clinical effects were consistent. Snoring was improved and almost eliminated in patients who use an oral appliance. OSA improved in the majority of patients. There appears to be a case for the use of such devices to treat snoring and mild OSA, and as a treatment therapy where patients reject CPAP.

There are two broad categories of intra-oral device; those which hold the tongue forward and the mandibular advancement device. Following the use of cephalometrics and computerised tomography to assess the success dental appliance therapy, Lowe (1993) concluded that the success of dental appliance therapy could not be predicted with a significant degree of accuracy based on anatomical considerations. There seems to be general acceptance that mandibular advancement devices achieve success by moving the lower jaw, tongue, soft palate and hyoid bone into a better position to help create a more patent airway. These appliances help to prevent airway closure during sleep by stabilising the lower jaw, tongue and hyoid bone. This type of appliance also gives the tongue an increased muscle tone, which makes the tongue less likely to cover the airway during sleep.

There is a large variation in the design of oral appliance and the choice of materials used. The first appliances were made of polymethyl methacrylate and were retained by wire clasps, but increasingly vacuum-formed blanks are used. As the first dental appliances were developed from functional appliances there were also devices which used traditional orthodontic attachments such as the Herbst rod and tube from the Herbst appliance and expansion screws for the Kleerway appliance. These appliances have the additional advantage that mandibular advancement can be titrated and allow the patient freedom of movement in vertical and lateral directions. Dental appliances will not be well tolerated by patients with temporomandibular joint dysfunction (Clark et al, 1996b). However mild joint problems may be lessened by the forward jaw position (Lyon et al, 1992).

Dental appliances can only be used for patients who are highly motivated, as the appliance may have to be worn during sleep for life, which is also true for CPAP.

Oral appliances may not always be effective, probably because of the combinations of different skeletal, soft tissue and functional factors that produce obstruction in the upper airway. Schmidt-Nowara et al (1995), and Schmidt-Nowara (1996), have reported that oral appliances are less effective when the respiratory distress index exceeds 40-50 events per hour.

This would suggest that oral appliances may be more suitable for snorers and mild to moderate OSA sufferers. Studies by Clark et al (1996b), Fleetham et al (1996) and Ferguson et al (1997) have compared oral appliances with CPAP and found that oral appliances were generally better tolerated than CPAP, although not as effective.

It is important that a sleep physician performs correct diagnosis before any treatment is undertaken. In some cases dental appliance therapy for mild to moderate OSA can be considered. Dental appliance treatment is simple, non-invasive, reversible, quiet and cost effective and may be the treatment of choice for simple snorers or for patients who are unable to tolerate CPAP or who are poor surgical risks.

Chapter 2

MATERIALS AND METHODS

2.1 A Preliminary Test Appliance

A series of test appliances was worn by the author, a 43 year old male who had been a snorer for five years according to his wife (the author was unaware of snoring). These appliances were a rigid mandibular positioner, a semi-flexible mandibular positioner, an adjustable mandibular positioner using a Hyrax expansion screw, and two commercially available anti-snoring devices. The author reported no daytime sleepiness or breathing problems, although he was overweight with a body mass index of 29. The only medical treatment had been a nasal inhaler, which was unsuccessful.

The first appliance was a mandibular positioning appliance similar to that described by Soll and George (1985). This consisted of a modified functional orthodontic appliance used to reposition the mandible in a open position of 4 mm (Figure 1.2). Clark et al (1996a) suggest that the mandible should be protruded by 50-75% of maximum, and should only be opened enough for the construction of the device. The appliance was an acrylic maxillary and mandibular splint retained by wrought stainless steel clasps. Labial and lingual wire connectors were used and there was a breathing space between the anterior teeth.

The author's wife reported that snoring was moderated to a level that did not disturb her sleep. However, there was pain in the temporomandibular joint upon awakening. This discomfort disappeared within an hour.

The author showed evidence of bruxism and he felt that the rigid material used in the design, which prevented any movement, contributed to the discomfort. Kobayashi et al (1984) suggested that bruxists had a significantly higher frequency of sleep apnoea.

It was felt that a more forward position might be more beneficial and a second appliance was constructed to a new registration. Luks et al (1996) suggested that a device that increases vertical dimension and protrudes the mandible may be more effective than one which modifies mandibular position in one dimension only. Although this appliance was successful, the appliance, with wrought wire retainers and labial wire connectors did require more time to construct.

The second appliance was constructed in a resilient polyvinyl acetate polyethylene (PVAc-PE), (Figures 2.1) which was transparent, physiologically harmless, insoluble in water, odour free and inactive (Erkoflex, E M Natt Ltd, London) and followed the design suggested by Jagger and Milward (1995) for the construction of a bimaxillary mouthguard used by sportsmen. This design was also similar to that described by Lyon et al (1992) for snoring and sleep apnoea.

The appliance was constructed in a more open protrusive position to ascertain whether this position would be of more benefit. The mandible was opened 7 mm in the inter-incisal region, with a forward position of approximately 75 per cent of maximum opening, (7 mm). The author reported no discomfort in this position. The appliance was constructed using a thermo-forming machine, (Drufomat, Dreve, Panadent, London) to provide upper and lower arch soft splints. The thickness of the blanks used was 4 mm. These splints covered all the maxillary and mandibular teeth and extended approximately 5 mm buccally, labially, and lingually to provide retention. The author had a full dentition.

The splints were finished and sealed together in the protrusive registration, on an articulator, using a heat gun with fusing pins, (Erkoflex 82, E M Natt Ltd, London). After forming, the thickness of the splint was about 2 mm but can be thinner depending on the shape and depth of the cast. This can result in thinning, particularly on the labial aspect of the splints. In order to compensate for thinning and provide a degree of rigidity for the anterior of the joined appliance the periphery of the upper and lower labial splints were restored to a thickness of 2 mm using the glue gun and fusing pins. This appliance proved to be successful in preventing snoring. The author's wife reported that the subject did not snore with the appliance. The author occasionally experienced mild discomfort of the TMJ on awakening on some occasions. However, this discomfort did not last more that 20 minutes.

The appliance with the Hyrax expansion screw (Figures 2.2, 2.3) was constructed using thermoformed disks in a combination of hard and soft material (Erkodent, E M Natt, London). This 3 mm material provided a hard outer shell with a softer inner material for comfort. This device was similar to the Kleerway appliance and allowed the jaws to be opened. An occlusal platform was incorporated in acrylic resin to allow the mandible to move in a more horizontal position if required. This appliance was also successful in reducing snoring but was not considered as effective as the softer type material and also required considerably more time to construct. The expansion screw and wires in the palate did not prove to be uncomfortable or restrict the tongue. Although this appliance allowed for mouth opening the author did not find it a significant advantage.

An alternative appliance was also tried by the author, this was an oral device called the Snorban. This consisted of a pre-formed, acrylic polymer blank which was softened in hot water and then moulded by the patient in their own mouth. This appliance was claimed by the manufacturer to be a mandibular positioning appliance. However, the author found it impossible to gain adequate retention for this appliance and found that the appliance could not be held in position without a conscious effort, which meant that it could not be worn during sleep.

Another prefabricated device, the Snorelezz, was used without success, as retention again proved difficult.

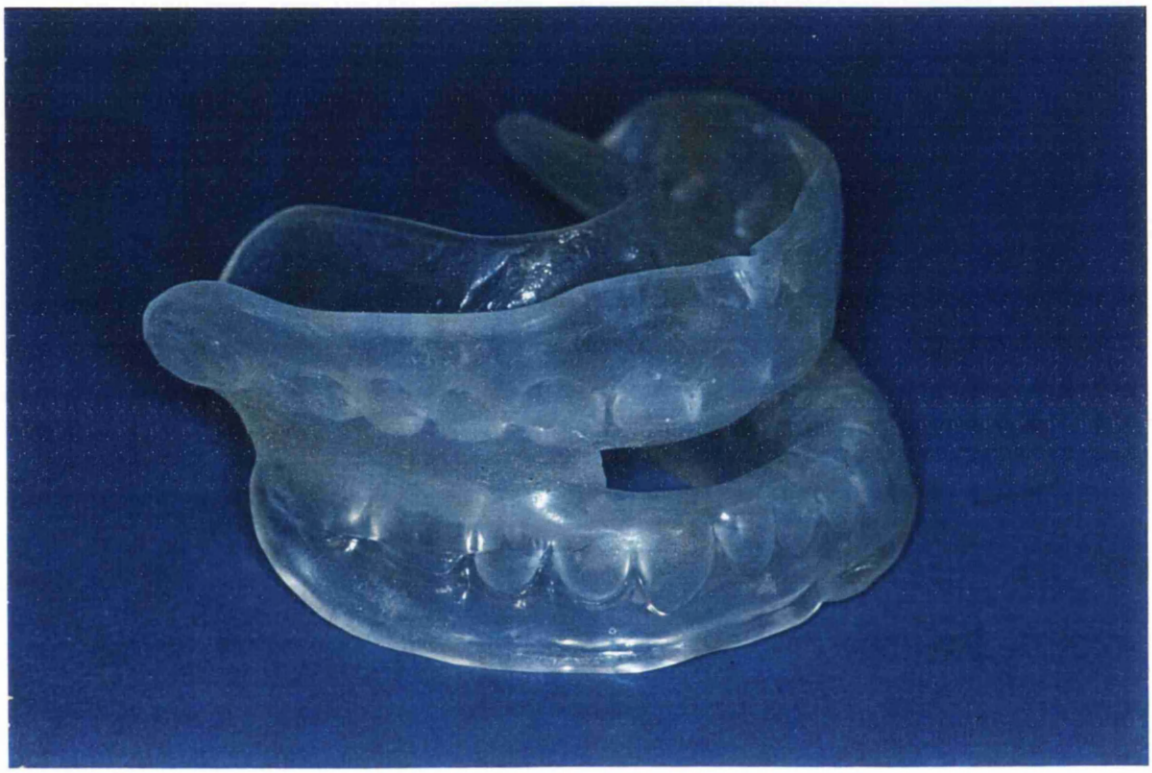

Figure 2.1 The semi-flexible mandibular advancement device (MAD).

In an attempt to improve retention, soft lining material was added to the appliance but it did not adhere to the device and the design of the device was too shallow to provide adequate retention.

During the course of this study a new material (also PVAc-PE) was introduced which although was still flexible was more rigid than previously available (Erkoflex 95, E M Natt Ltd, London). An appliance using this material was also used. The material was preferred as it provided better retention and did not have to be extended as far towards the vestibular sulcus.

2.2 Protocol for Patient Evaluation of a Mandibular Positioning Appliance

The project protocol was approved by the Ethics Committee of Glasgow Dental Hospital and School NHS Trust (Appendix C). The team used in our study consisted of a Consultant Physician, a Consultant Prosthodontist, and an Instructor in Dental Technology. Patients were referred from the Sleep Breathing Disorders Clinic at Glasgow Royal Infirmary to be treated with the PVAc-PE bimaxillary device. Patients were categorised as either simple snorers or snorers who also had symptoms of mild to moderate OSA. Some of the OSA patients had tried nasal mask CPAP but had been unable to tolerate this form of treatment. Other treatments that had also been tried by some patients were ENT surgery, most often treatment for a deviated septum, drug therapy (Protriptyline) and weight loss.

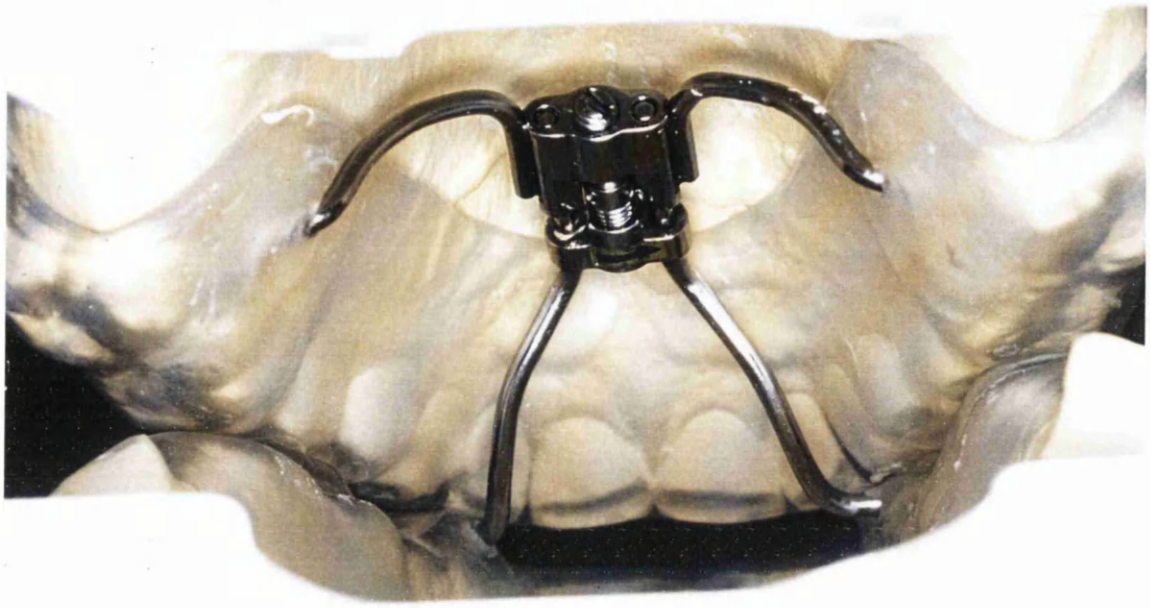

Figure 2.3 A Hyrax expansion screw rotated about 90^0 to produce an adjustable mandibular advancement device.

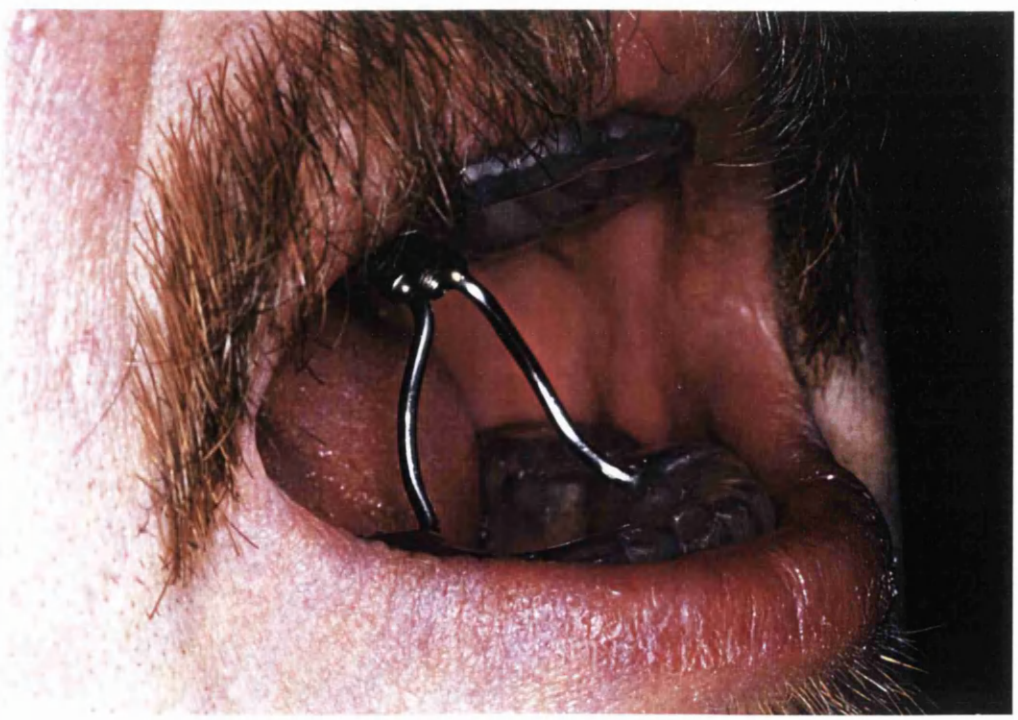

Figure 2.4 An intra-oral view with the Hyrax screw appliance allowing opening of the mandible.

All patients had undergone at least one limited sleep study. Sleep studies (mostly home based) comprised of assessment of respiratory variables that always included oronasal airflow and oxygen saturation monitoring. All traces were manually reviewed and graded accordingly into Normal (AHI< 5 per hour), Borderline (AHI 10-15 per hour and or RDI 5-15 per hour), Possible OSAS (AHI 15-20 per hour), Definite (AHI >25 per hour). The apnoea and hypopnoea index, calculated over the monitoring period, and desaturation data were combined on visual analysis of the trace to produce a respiratory distress index (RDI). Patients also completed the Epworth Sleepiness Scale, which consists of eight questions that ask how likely one is to doze off or fall asleep in everyday situations.

Patients were then referred to the Dental Hospital for an oral appliance.

A letter (see Appendix C) was sent with the patient's initial appointment asking that partners attended with the patient. On the initial visit to the Dental Hospital the nature of the study was explained to the patient and partner by the author and patients signed a formal consent form. An information sheet (see Appendix C) for patient and partner was also given at this interview. A questionnaire was given to the patients (A1, appendix C) and partner (B1 appendix C). Patients were asked if they were currently receiving dental treatment and if they had received treatment for TMJ problems.

There were three areas assessed by the questionnaires. Firstly, patient compliance with the device and its effect on their snoring as assessed by partners. Secondly, the effect on daytime sleepiness and the quality of sleep, again assessed by the partners, and thirdly, the effect on the partner's sleep quality.

A decision was made as to whether the patient had sufficient teeth to be able to wear the appliance. Patients had varying backgrounds and dental states and there was no set minimum number of teeth required. Impressions of upper and lower arches were taken, together with a protrusive jaw registration. The oral appliance was then constructed and fitted.

Patients received their appliance on the day of their first visit, although this was subsequently changed to receiving the appliance on the following day or two. The appliance was evaluated after 4 weeks by means of a second questionnaire for patient (A2, Appendix C) and partner (B2, Appendix C). Patients were subsequently re-evaluated at the Sleep Clinic when wearing the intra-oral appliance.

2.3 Impressions and jaw relationship

Impressions were taken in alginate using disposable stock trays, to provide full impressions of all teeth and vestibular sulcus depth.

The protrusive jaw relationship was established by first ascertaining the maximum amount of protrusion and then establishing a comfortable forward position of 50 to 75% of maximum. Impression compound was used to fix the position and also determine the amount of opening between upper and lower arches. The amount of opening was determined by the clinician as the minimum required, allowing protrusion, to provide enough space to construct the appliance. The total opening was partly determined by the overbite of each patient. Aluminium impregnated wax was placed over the impression compound and pressed over the labial and buccal surfaces of the teeth.

2.4 A Simple Measuring Tool

To enable the jaw position to be ascertained a simple measuring tool was constructed. It consisted of two tubes of stainless steel, of 3-mm diameter, soldered together. A handle was added to one of the tubes so that the tubes were on top of each other. The tubes were used in conjunction with a stainless steel rod on the lower tube. This device enabled the clinician to check how much mandibular advancement had been achieved. The patient's overjet was measured and then the patient was instructed to protrude their mandible as far forward as they could. This position was then measured to obtain the maximum protrusion (Figures 2.4).

2.5 Laboratory Construction Stages

Two sets of dental casts were produced from the impressions, one set on which the appliance was constructed and the other set mounted on an articulator in the protrusive position. Two sets of casts were required as the casts used in the thermoforming process were usually damaged during the finishing procedures.

1. The impressions were poured in dental stone. On setting, the impressions were carefully removed to avoid damage to the impressions and poured a second time. The first pour served as master casts that could be duplicated if modification to the appliance was necessary and new vacuum formed pieces were required. If the impressions could not be removed successfully then the casts were duplicated using reversible hydrocolloid.

2. The second pour served as the casts on which the appliance pieces were formed.

3. These casts were trimmed on a model trimmer to the required depth to ensure that when the appliance was formed the PVAc-PE blank would be of even thickness. This was important as failure to do this could result in thinning of the blank or failure to adequately form onto the cast. The amount that the formed piece extended into the sulcus depended on the number and arrangement of the teeth.

4. Disks of 4-mm PAVc-PE were heated for approximately two minutes and then vacuum formed (Drufomat, Panadent, London) onto the casts. The casts had been given an application of a plaster-separating medium. A thickness of 4mm was preferred to allow a measure of rigidity without the need to include metal wires. After forming, the thickness over the casts was approximately 2mm.

5. Following thermoforming, the individual pieces were trimmed to the required sulcus depth and then fitted to the mounted casts. The labial border was thickened using a glue gun with fusing pins to give an even thickness where required. This depended on the retention that that would be provided by each piece. The splints covered all the maxillary and mandibular teeth.

6. The first pour casts were mounted on an articulator using the wax and compound registration. An articulator with an incisal post was used to maintain the registered position. The amount of opening and mandibular advancement was measured on the articulator by measuring from fixed parts in the intercuspal position to the registered protrusive position. The amount of opening was approximately 5mm inter-incisally.

7. The upper and lower pieces were trimmed where necessary on the occlusal surface to leave a space of 2mm between the two splints for the joining material. The occlusal surfaces were left roughened to assist the joining of the fusing pins.

8. The upper and lower pieces were joined with a heat gun (Figure 2.8) using fusing pins (Erkoflex 82 or Erkoflex 95, E M Natt Ltd, London). The fusing pins were also PVAc-PE but were extruded from the gun in a viscous 3 mm thick rope. This was placed on the upper or lower piece and the articulator member closed while the material was soft. The glue gun also allowed edentulous areas to be easily filled.

The excess from the joined pieces was then finished using suitable trimmers for soft materials and polished using nylon disks (Lisko disk, E M Natt Ltd, London) ready for delivery to the patient. The finishing disks provided a smooth polished surface although a better finish can be achieved by flame polishing, either with a naked flame or with a dry air heat gun. However, care must be exercised that this process does not distort the appliance.

The upper and lower pieces were not joined anteriorly, which leaves a breathing space to allow patients to breathe through their mouth should their nasal passages be blocked. The laboratory time required to produce an appliance was approximately one hour and thirty minutes.

On delivery to the patient, appliances were adjusted for comfort and the patient was instructed in the handling and cleaning procedures. Patients were advised to clean the appliance each morning by rinsing in cold water and cleaning with a toothbrush.

Subjects were also advised to keep their appliance stored in cold water when not in use and that this should be changed daily. It was also recommended that the appliance should be carefully cleaned using detergent once per week using cold or tepid water. At the appliance delivery the maximum protrusion was measured and checked against the amount of protrusion for the registration using the measuring tool.

Patients were advised that they might experience some muscle discomfort initially and that they would experience an increase in saliva production but that both of these problems should subside in time.

The mounted casts of the patients were stored and duplicated when required to fabricate new pieces for the device.

2.6 Randomised Patient Allocation

The number of patients who received an appliance was 105. There were 89 men and 16 women with a mean age of 49 years (range 30-78 years).

The first 36 patients were randomly allocated into two groups with 18 patients in each group. Group A comprised of 14 men and 4 women, with 16 men and 2 women in group B. The patients and partners in A group were asked to complete pre-appliance questionnaires with the appliance being delivered that day. The subjects were reviewed after 4 weeks.

The patients in B group were asked to complete the pre-appliance questionnaires but did not receive the appliance until a further 4 weeks.

At their second visit, patients in B group were asked to complete questionnaires A1 and B1 again. The B group acted as a control for the study, as no treatment was given for 4 weeks. The questionnaires were used to establish that no change had occurred in their symptoms and also to test the reliability of the VAS scores

2.6.1 Patient questionnaire

There were separate questionnaires for patients and their partner (see Appendix C). The patient questionnaire asked personal details, name, sex, age, date of birth, occupation and height and weight. The height and weight enabled a body mass index (BMI) to be calculated for each patient, as obesity is a principle risk factor in snoring and obstructive sleep apnoea.

As alcohol and smoking are also identified as risk factors, questions were asked about smoking (quantity per day), and alcohol consumption (units per week). As well as personal details and habits, volunteers were asked questions on their quality of sleep. These were the numbers of hours slept, whether they felt refreshed on waking, and if they felt sleepy during the day. After wearing the appliance for four weeks the patients were asked to complete a post-appliance questionnaire. Visual analogue scales to record responses were used.

2.6.2 Partner Questionnaire

It was felt that the use of questionnaires must include a questionnaire for partners in addition to patients, to provide a subjective assessment of the effect of the appliance (Appendix C). Questions for partners included the level of the patient's snoring, in addition to how refreshed the patient seemed, and if they complained of daytime sleepiness. Partners were also asked questions on the quality of their own sleep. Visual analogue scales were used for these questions also.

2.6.3 Visual Analogue Scale Questions

In the preparation of the visual analogue scale (VAS) it was important to chose end phrases that were readily understood and that best defined the extreme limits of the responses. In the patient pre-appliance questionnaire (A1), the anchors to the question relating to their snoring were "Does not snore at all" and "Extremely loud". To the questions on whether they felt refreshed on wakening and if they felt sleepy during the day, the anchors were "Never" and "Always". The anchors to the question on their quality of sleep were "Awful" and "Excellent". In the post-appliance questionnaire (A2) on the question of comfort of the appliance, the anchors were; "Extremely comfortable" and "Totally uncomfortable". On satisfaction with the appliance the anchors were: "Extremely dissatisfied" and "Totally satisfied. In the pre-appliance partner questionnaire (B1) to the question: How loud does your partner snore? the anchors were: "Does not snore at all" and "Extremely loud".

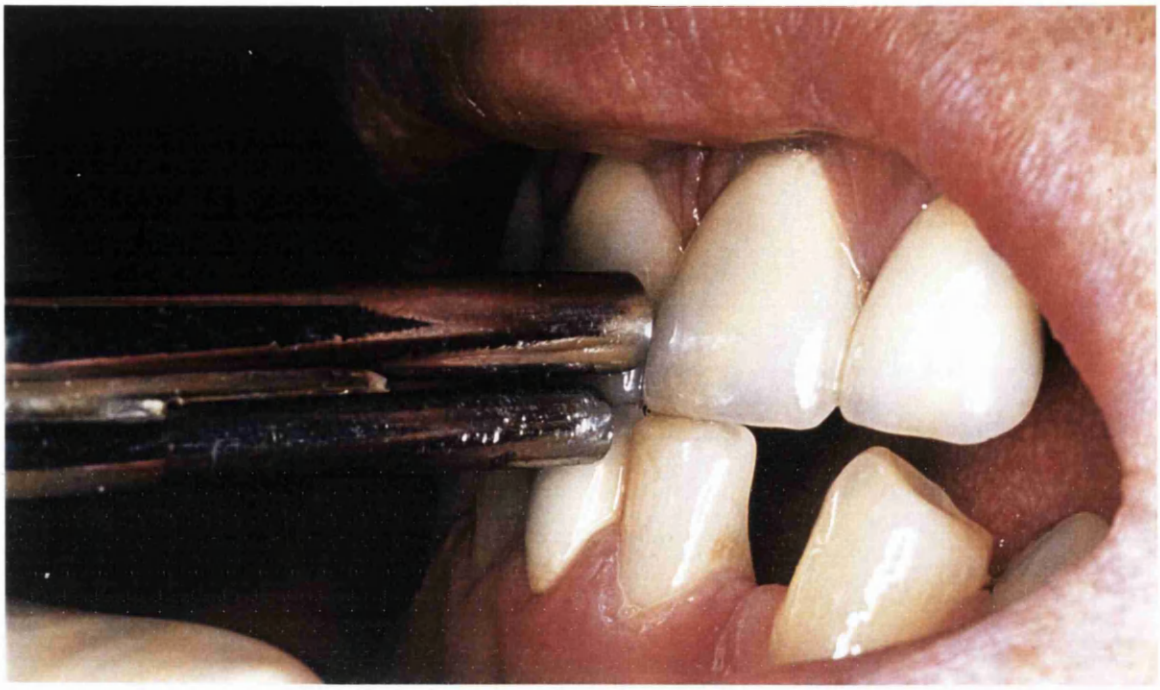

Figure 2.4 A Simple Measuring Tool.The patient's overjet in the intercuspal position was recorded with the tool and then the patient was instructed to protrude their mandible to the maximum and this position was measured.

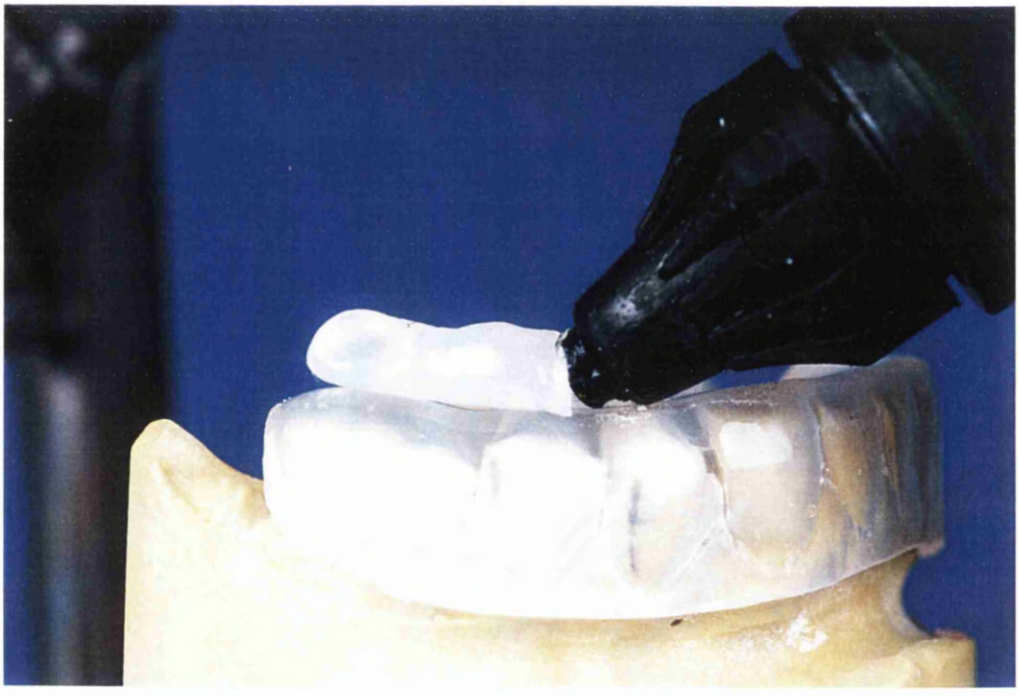

Figure 2.5 After thermoforming, the upper and lower pieces were trimmed and joined with fusing pins using a heat gun.

All the other questions had the anchors: "Never" and "Always", with the exception of the question: How would you rate the quality of your sleep, the anchors were: "Awful" and "Excellent".

2.7 Statistics

The possibility of bias towards each end of the scale in the data from the VAS scores leading to a deviation from a normal distribution was acknowledged and so the data were analysed using the Wilcoxon test for non-parametric scores (log transformation) before tests were applied. The transformed data from before and after fitting of the appliance were then subjected to paired t-tests to test for any significant difference. All tests were conducted at the 95% level of significance.

In addition to the VAS questions, there was the opportunity for the subjects and their partners to offer comments in pre-appliance and post appliance questionnaires.

2.8 Appliance Delivery

The appliances were constructed and delivered to the first group of patients on their first visit. The time taken to construct the appliance was approximately one hour thirty minutes. On delivery of the appliance the patients were shown insertion and removal. The majority of patients found it was best to insert the appliance on the upper arch and then bring their jaw forward and place their teeth in the lower part.

While the appliance was newly in place instructions were given on care and maintenance of the appliance in addition to possible side effects that they might experience, such as excess salivation and minor muscle and tooth discomfort initially. The time taken allowed the patients to determine if there was any discomfort which required adjustment. When the patients were satisfied with the fit of the appliance and were able to insert and remove the appliance satisfactorily an appointment was made to see them in four weeks.

2.8.1 Four Week Review

At the 4-week review, patients and their partners completed the second questionnaires (A2, B2), (Appendix). The patients and partners were asked to complete the questionnaires before being interviewed to avoid any bias to their responses. In the first group of patients there were a small number who had limited success with the appliance and on evaluating their jaw position it was felt that they could be registered in a more forward position. The majority of patients who had this done reported an improvement at their next appointment one week later.

2.8.2 Follow-up

Patients and partner were asked to attend the Dental Hospital at 12-week intervals up to one year. If a partner could not attend a questionnaire was sent with a stamped addressed envelope. A telephone survey was conducted in September 1998 of 25 patients who had worn the appliance for at least one-year to ask if they were continuing to wear the appliance.

CHAPTER 3

RESULTS

From September 1996 to March 1999 one hundred and five patients (89 male, 16 female) received the semi-flexible mandibular positioning appliance. The mean age was 49 years, (range 28-79), SD 10.7 with a mean body mass index (BMI) of 29 (range 20-46), SD 4.6.

After completing the four-week review, patients were seen at 12-week intervals up to 1 year (Table 1). A telephone survey was conducted in September 1998 at which time a possible 54 patients could have reached one year. The actual number who completed all reviews was 29. Patients and partners were asked to attend for reviews but some partners did not attend and questionnaires were given to patients with a stamped addressed envelope to be returned (Table A1, see Appendix A). Twelve patients did not have a partner. Results are presented up to 1-year review.

Number of weeks	Patient		%	Partner		%
	Actual	Possible		Actual	Possible	
4	93	105	89	76	83	91
16	53	89	59	42	79	53
28	36	72	50	30	62	48
40	31	66	47	23	56	41
52	29	59	49	25	51	49
104	26	13	50			

Table 1. The actual and possible number of patients and partners who attended review at 4 weeks and completed questionnaires at 12 week interval follow-up to 2 years.

A two-year follow-up was conducted by a telephone survey asking patients if they were still using the appliance (Table 1). Partners who did not complete a 4-week review were not included in the baseline figures.

3.1 Control group

The responses to all the questions given to the contol group, i.e. patients and partners who completed 2 baseline assessments 4 weeks apart (n=14), were very consistent, with no significant difference between the two sets of data (P = 0.46).

3.2 Review at 4-Weeks

Twelve patients (11 %) did not return for the 4 week review (Table 2). An attempt was made to contact these patients by telephone. One patient discontinued with the appliance because he found the appliance "unsightly", one stated that the appliance was uncomfortable to wear but did not return to have adjustments despite appointments being made, and four failed to respond to letters or reminders to attend their review appointments. Of these four, two were contacted by telephone but failed to attend and two could not be contacted by telephone. One patient contacted had been diagnosed as being depressed and did not wish to continue with the study.

Of the remaining 93 patients who completed the 4 week review, 81 (87%) were male and 12 (13%) female (Table 3). Twelve patients did not have a partner. Patients who could not wear the appliance at this review were referred back to the sleep clinic.

Patient	Telephone	New appointment	Reminder letter	Comment
90	no	yes	yes	failed to attend
50	yes	yes	yes	excess saliva made it difficult to wear
36	no	yes	yes	failed to attend
76	yes	yes (2)	yes	failed to attend - wearing appliance
27	yes	yes	yes	failed to attend - wearing appliance
92	no	yes (2)	yes	failed to attend
46				discontinued - appliance "unsightly"
43	yes	yes	yes	appliance needed adjustment
67	yes	yes (2)	yes	failed to attend - wearing appliance
3	no	yes	yes	failed to attend
62	yes	yes	yes	failed to attend - wearing appliance
47	yes			discontinued - depression

Table 2 The 12 patients who failed to complete 4-week review

Number of patients who completed questionnaire	93
Number of partners who completed questionnaire	76
Number of patients who did notcompleted questionnaire	6
Number of patients without partner	12

Table 3 The number of completed questionnaires at the 4-week review.

3.3 16-Week Review

At the next review at sixteen weeks, 53 patients out of a possible 89 (59%) attended (Table 4).

Number of patients completed questionnaire	53
Number of partners completed questionnaire	42
Number of partners who did not complete questionnaire	4
Number of patients without partner	7

Table 4. The number of completed questionnaires at the 16-week review.

Reasons for not continuing after the 4-week review were (Table A2, see Appendix A).

- 6 complained of hypersalivation
- 1 had surgery and achieved substantial weight loss
- 1 was hospitalised with a heart attack
- 1 found the appliance made no difference
- 1 preferred CPAP
- 1 no longer had a partner
- 1 experienced painful teeth
- 2 found the appliance uncomfortable to wear
- 8 did not return for review

3.4 28-Week Review

Thirty-six out of a possible sixty-two patients (58%) completed the 28-week review (Table 5). Reasons from the patients who discontinued at this stage included one patient who had separated from his/her partner and did not feel the need to continue with the appliance and five who were lost to follow-up.

Number of patients completed	36
Number of partners completed	30
Number of partners who did not complete	2
Number of patients without partner	4

Table 5. The number of returned questionnaires at the 28-week review.

3.5 40-Week Review

Thirty-one patients from a possible 66 (47%) completed questionnaires at 40-weeks (Table 6). There were five patients lost to follow-up at this stage.

Number of patients completed questionnaire	31
Number of partners completed questionnaire	23
Number of partners who did not complete questionnaire	3
Number of patients without partner	3

Table 6. The number of completed questionnaires at the 40-week review.

3.6 52-Week Review

The number of patients who wore the appliance during the study period for 52 weeks was 29 from a possible total of 59 (49%), (Table 7).

Number of patients completed questionnaires	29
Number of partners completed questionnaires	25
Number of partners who did not complete questionnaires	1
Number of patients without partner	4

Table 7. The number of completed questionnaires at the 52-week review.

3.7 Number of Teeth

The mean number of teeth in both arches was 22.3, SD 4.2 with the mean number of upper teeth 10.8, SD 2.7 and the mean number of lower teeth 11.5, SD 2.1.

The lowest number of teeth in the upper arch was four, and in the lower arch was five. No patient was excluded from the study due to lack of teeth.

3.8 Mandibular Position

In 93 of the patients the amount of mandibular advancement varied from 1 to 12 millimetres (Figure 3.1) with a mean of 6.2 mm, SD 1.9. In a number of patients (38) the device to measure maximum protrusion was used. There were 6 patients (16%) who were less than 50 % of their maximum protrusion, 24 (63%) who were between 50% to 75% of maximum and 8 (21%) who were at greater than 75 % of their maximum.

Ten patients from the first thirty-six reported that the appliance had made little or no difference. It was felt that in each case the mandible could be moved further forward and so another registration was taken and these patients were reassessed after two weeks. Of this group five reported an improvement.

The amount of opening of the jaw varied between 3 mm and 13 mm when measured on the casts on the articulator (Figure 3.2). The mean opening was 7 mm, SD 2.3 (N = 93) with a mean inter-incisal opening of 4 mm, SD 2.0. The amount of opening varied between patients depending on the amount of overbite and the arrangement of tilted or over-erupted posterior teeth, which in some patients precluded a more closed protrusive position.

3.9 The Use of a Control for the Visual Analogue Scales

In the patients who were randomly allocated to a control group, there was no significant difference in their responses to the questionnaires at the beginning and the end of the 4-week "waiting time" (P = 0.46, paired t-test).

3.10 Patient Responses to Questionnaires

3.10.1 Number of Days Appliance Worn

At the 4 week review of 93 patients the mean number of days the appliance was worn was 5.7, SD 1.8. At 16 weeks from 53 patients the mean was 5.6, SD 1.9; 28 weeks (36 patients) was 5.2, SD 2.2; at 40 weeks from (31 patients) was 5.1, SD 2.1 and at 52 weeks (29 patients) was 5.5, SD 2.0. (See Table 8).

	4 week	16 week	28 week	40 week	52 week
Number of days appliance worn	5.7 (n=93)	5.6 (n=53)	5.4 (n=36)	5.1 (n=31)	5.5 (n=29)

Table 8. The mean number of days the appliance was worn.

3.10.2 Comfort of Appliance

The mean VAS scores for comfort were 6.5, SD 2.5 at 4 weeks, 7.0, SD, 2.1 at 16 weeks, 7.2, SD 2.3 at 28 weeks, 7.3, SD 2.6 at 40 weeks and 7.5, SD 1.9 at 52 weeks (Table 9). The mean number increased the longer the appliance was worn as individuals who found the appliance uncomfortable to wear dropped out.

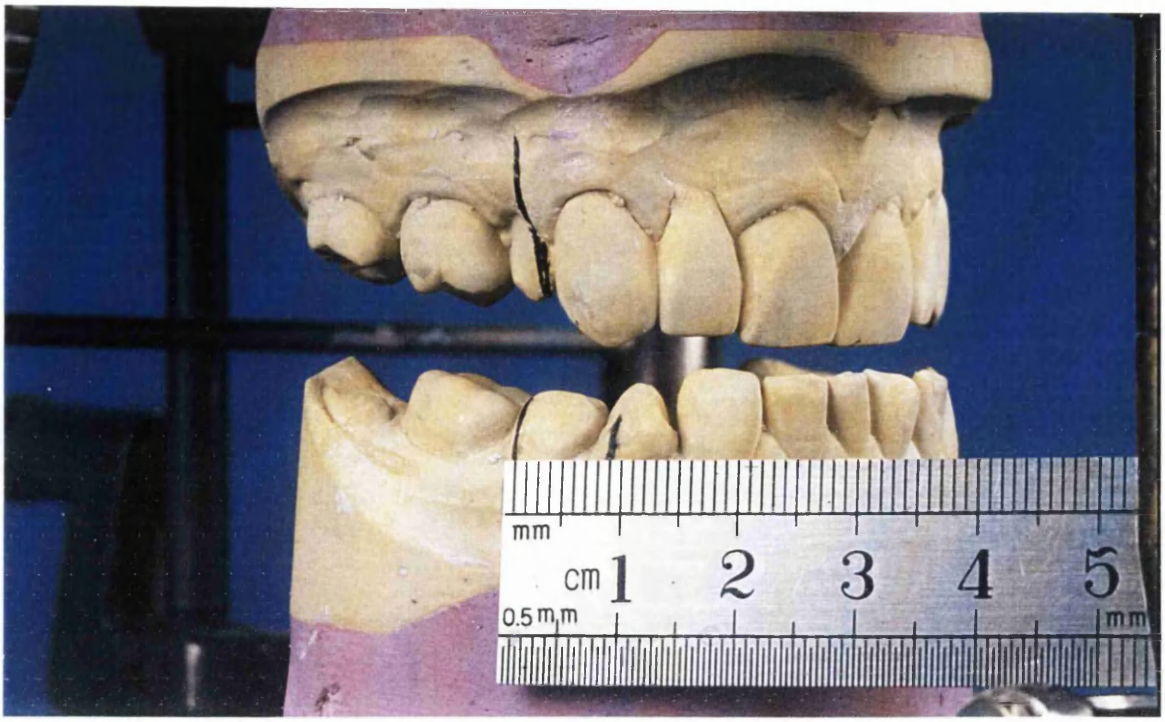

Figure 3.1 The mandibular advancement was measured on the mounted casts and compared with the maximum protrusion.

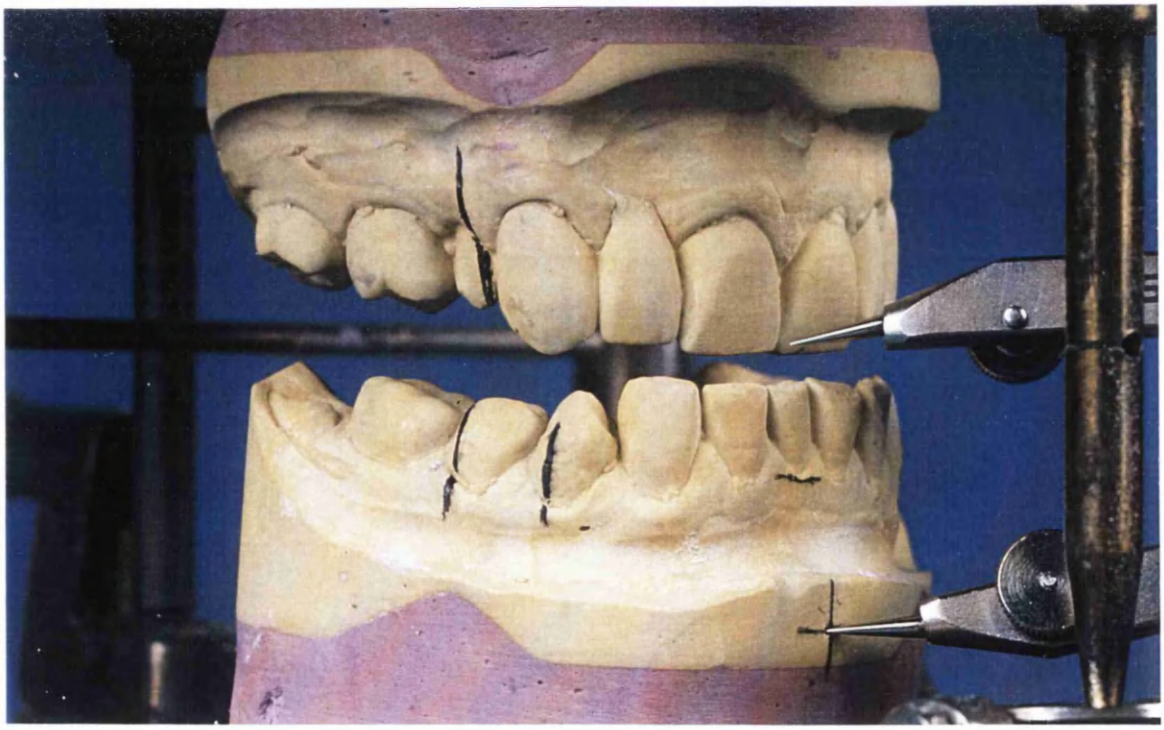

Figure 3.2 The amount of opening was also measured from the mounted casts, together with the inter-incisal opening.

	4 week	16 week	28 week	40 week	52 week
Comfort of appliance	6.5 (n=93)	7.0 (n=53)	7.2 (n=36)	7.3 (n=31)	7.5 (n=29)

Table 9. The patient's response to how comfortable the appliance was to wear.

3.10.3 Patient Satisfaction

Patient satisfaction for the appliance maintained a mean of between 7 and 8 from the VAS scores. This level was maintained throughout the 52-week period, which included appliance replacements when they were becoming less effective through wear. From interview at review stages it was clear that the fact that the device had to be worn each night also affected patient satisfaction. The mean VAS scores for satisfaction were, 7.2, SD 2.4 at 4 weeks, 8.1, SD 1.8 at 16 weeks, 7.9, SD 1.8 at 28 weeks, 7.6, SD 2.4 at 40 weeks and 7.9, SD 2.0 at 52 weeks (Table 10).

	4 week	16 week	28 week	40 week	52 week
Satisfaction with appliance	7.1 (n=92)	8.1 (n=53)	7.9 (n=36)	7.6 (n=31)	7.9 (n=29)

Table 10. The patients' response to how satisfied they were with the appliance. One patient did not complete this question.

3.10.4 State of Patient Refreshment Upon Wakening

Patients were asked how refreshed they felt on wakening. Before wearing the appliance the mean was 3.5, SD 2.4. At the 4 week review the mean was 5.9, SD 2.5 (Figure 3.3). These figures increased to 6.7, SD 2.4 at 16 weeks, 7.0, SD 2.3 at 28 weeks, 6.5, SD 2.9 at 40 weeks and 7.0, SD 2.1 at 52 weeks (Table 11). The differences between baseline and each review were statistically significant (Table 11).

	baseline	4 week	16 week	28 week	40 week	52 week
Refreshed on wakening	3.4 (n=93)	5.9 (n=93) p = 0.001	6.7 (n=53) p = 0.001	7.0 (n=36) p = 0.001	6.5 (n=31) p = 0.001	7.0 (n=29) p = 0.001

Table 11. How refreshed patients felt on wakening.

3.10.5 Daytime Sleepiness

Patients reported that daytime sleepiness had reduced from a mean of 6.1, SD 2.6 at baseline to 3.8, SD 2.4 after wearing the device for 4 weeks (Figure 3.4). The mean scores were further reduced at subsequent reviews to 2.6, SD 2.1 at 16 weeks, 3.9, SD 2.9 at 28 weeks, 3.4, SD 2.5 at 40 weeks and 3.1, SD 2.5 at 52 weeks (Table 12). The differences between baseline and each review were statistically significant (Table 12).

	baseline	4 week	16 week	28 week	40 week	52 week
Patient daytime sleepiness	6.1 (n=93)	3.8 (n=93) p = 0.001	3.7 (n=53) p = 0.001	2.5 (n=36) p = 0.001	3.9 (n=31) p = 0.001	3.1 (n=29) p = 0.001

Table 12. The VAS scores of the level of patient daytime sleepiness.

3.10.6 Quality of Sleep

Patients reported that their perceived quality of sleep had improved from a mean of 3.5, SD 2.2 at baseline before wearing the appliance to 6.3, SD 2.2 after wearing the appliance for 4 weeks (Table 13), (Figure 3.7). The differences between baseline and each review were statistically significant (Table 13).

	baseline	4 week	16 week	28 week	40 week	52 week
Patient quality of sleep	3.5 (n=88)	6.3 (n=93) p = 0.001	7.0 (n=53) p = 0.001	7.3 (n=36) p = 0.001	7.1 (n=31) p = 0.001	7.4 (n=29) p = 0.001

Table 13. The mean VAS scores of the patient perception of quality of sleep.

3.11 Partner Responses to Questionnaires

3.11.1 Partner Assessment of Difference Made by Appliance

In response to question C (Questionnaire B2, see Appendix); did the appliance make a difference to your partners snoring? The mean score at 4 weeks was 6.8, SD 2.8, at 16 weeks this had increased to 7.4, SD 2.1, 28 weeks 7.9, SD 1.7, 40 weeks 7.5, SD 2.6 and 52 weeks to 7.4, SD 2.2 (Table 14).

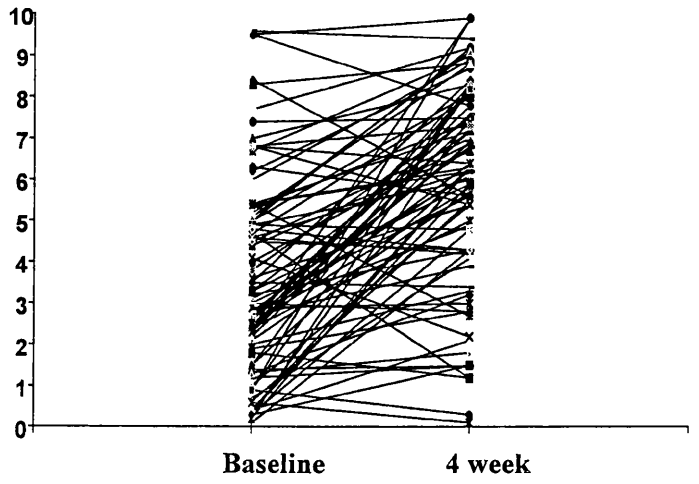

Figure 3.3 Patient respose to how refreshed they felt on wakening before wearing the appliance and after a 4-week period of use. Mean before wearing the device was 3.4, SD 2.4 and after 5.9, SD 2.5 (n = 93).

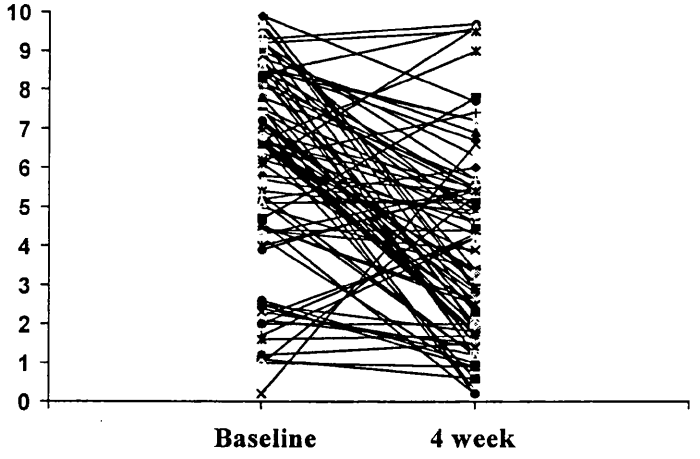

Figure 3.4 Patient response to their perceived level of daytime sleepiness before and after a 4-week period of wear with the appliance. The mean before use was 6.1, SD 2.6 (10 cm VAS) which reduced to 3.8, SD 2.4 (n = 93).

	4 week	16 week	28 week	40 week	52 week
Difference made by appliance	6.8 (n=76)	7.4 (n=42)	7.9 (n=30)	7.5 (n=23)	7.4 (n=25)

Table 14. The mean values from the partner VAS scores of the difference made by the appliance to patients snoring.

3.11.2 Partner Assessment of Snoring Reduction

The perception of partners to the patients level of snoring was reduced from a mean value of 8.5, SD 1.5 at baseline to 3.2, SD 2.7 at the 4-week review (Figure 3.5). At 16 weeks the mean score was 2.5, SD 2.0, at 28 weeks 2.3, SD 1.8, at 40 weeks 2.5, SD 2.4 and at 52 weeks 3.4, SD 2.4 (Table 14). There was a significant difference between baseline and each review, $p = 0.001$ (Table 15).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner perception of snoring	8.5 (n=76)	3.2 (n=76)	2.5 (n=42)	2.3 (n=30)	2.5 (n=23)	3.4 (n=25)
		p = 0.001	p = 0.001	p = 0.001	p = 0.001	p = 0.001

Table 15. The mean VAS scores of the partner perception of the patient's level of snoring.

3.11.3 Partner Perception of Level of Patient's Refreshment on Wakening.

Partners were asked if they thought that the patient seemed more refreshed on wakening after using the appliance. The mean score increased from 2.9, SD 2.6 at baseline to 6.2, SD 2.7 at 4 weeks (Figure 3.6) and increased beyond this figure at subsequent reviews to 7.1, SD 2.1 at 16 weeks, 6.9, SD 2.4 at 28 weeks, 6.2, SD 3.2 at 40 weeks and 6.6, SD 2.6 at 52 weeks (Table 16). There was a significant difference between values at baseline and at each review, $p = 0.001$, (paired t-test) (Table 16).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner perception of how refreshed patient seemed on wakening	2.9 (n=76)	6.2 (n=76) $p = 0.001$	7.1 (n=42) $p = 0.001$	6.9 (n=30) $p = 0.001$	6.2 (n=23) $p = 0.001$	6.6 (n=25) $p = 0.001$

Table 16. The mean VAS scores of the patient perception of how refreshed their partner seemed on wakening.

3.11.4 Partner Perception of Patient's Daytime Sleepiness

Partners were also asked their perception of the level of daytime sleepiness of the patient. The mean score at baseline was 7.2, SD 2.7, which was reduced to a mean score of 3.4, SD 2.3 at the 4-week review. At16 weeks the score was 2.3, SD 2.2, at 28 weeks 2.7, SD 2.5, at 40 weeks 3.2, SD 3.0 and at 52 weeks 2.9, SD 2.4 (Table 17). There was a significant difference between values at baseline and at each review, $p = 0.001$, (paired t-test) (Table 17).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner perception of level of patient daytime sleepiness	7.2 (n=76)	3.4 (n=76)	2.3 (n=42)	2.7 (n=30)	3.2 (n=23)	2.9 (n=25)
		p = 0.001	p = 0.001	p = 0.001	p = 0.001	p = 0.001

Table 17. The mean values from the VAS scores of partner perception of the level of daytime sleepiness of their partner.

3.11.5 Irritability on Wakening

In addition to the partner perception of patient refreshment on wakening, partners were asked to score the level of patients irritability on wakening as an indication of the quality of sleep of the patient. The mean score was 4.5, SD 3.1 at baseline, which reduced to 2.6, SD 2.8 at the 4-week review. The mean scores at subsequent reviews were: at 16 weeks 1.8, SD 1.7, 28 week 2.2, SD 2.2, 40 weeks 2.2, SD 2.3 and at 52 weeks 2.6, SD 2.6. A paired t-test was conducted at each review against the baseline score which showed that at 4 week, 16 week, 28 week and 52 week there was a significant difference ($p < 0.05$) but that at 40 week there was no significant difference ($p > 0.05$), (Table 18).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner perception of how irritable their partner was on wakening	4.5 (n=76)	2.6 (n=76)	1.8 (n=42)	2.2 (n=30)	2.2 (n=23)	2.7 (n=25)
		p = 0.001	p = 0.001	p = 0.004	p = 0.07	p = 0.04

Table 18. The mean values from the VAS scores of partner perception of patient irritability on wakening.

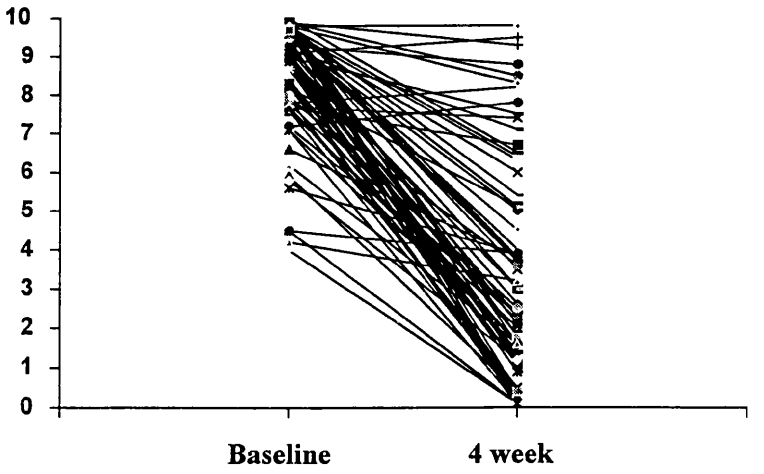

Figure 3.5 The partner response to the level of snoring before and after a 4-week period of use with the appliance. The mean before was 8.5, SD 1.5 (10 cm VAS) which reduced to 3.2, SD 2.7 (n = 76).

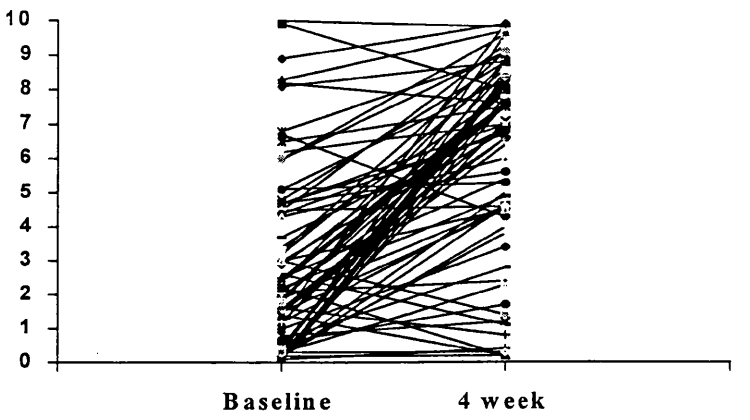

Figure 3.6 Partner perception of how refreshed patients were on wakening before and after a 4 week period of use with the appliance. The mean before was 2.9, SD 2.7 (10 cm VAS) which increased to 6.2, SD 3.2 (n = 76).

3.11.6 Tired on Wakening

As it was the sleep of the partner that was disturbed by the level of snoring, partners were asked on how tired they felt on wakening before and after the patient had worn the appliance. The mean VAS score at the baseline interview was 6.6, SD 2.7 which reduced to 3.4 SD 2.7 at the 4 week review and at subsequent reviews at 16 weeks to 2.9, SD 2.8, 28 weeks to 2.2, SD 2.0, 40 weeks to 2.7, SD 2.9 and 52 weeks to 2.5, SD 2.1 (Table 19).

There was a significant difference, P = 0.001, (paired t-test), (Table 19).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner response to tiredness on wakening	6.6 (n=76)	3.4 (n=76)	2.9 (n=42)	2.2 (n=30)	2.7 (n=23)	2.5 (n=25)
		p = 0.001	p = 0.001	p = 0.001	p = 0.001	p = 0.001

Table 19. The mean values from the VAS scores of partner perception of their tiredness on wakening.

3.11.7 Partner's Quality of Sleep

Partners reported that their own sleep quality had improved after the subjects wore the appliance, with a mean score at baseline of 3.0, SD 2.0 before which increased to 6.4, SD 2.5 (Figure 3.8) at the 4 week review which continued at subsequent reviews at 16 weeks of 6.9, SD 2.4, 28 weeks of 7.5, SD 1.9, 40 weeks of 7.0, SD 3.0 and 7.3, SD 2.0 at 52 weeks (Table 20). There was a significant difference between baseline values and those at each review, P = 0.001 (Table 20).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner response to their quality of sleep	3.0 (n=76)	6.4 (n=76)	6.9 (n=42)	7.5 (n=30)	7.0 (n=23)	7.3 (n=25)
		p = 0.001	p = 0.001	p = 0.001	p = 0.001	p = 0.001

Table 20. The mean values from the VAS scores of partner response of their quality of sleep.

3.11.8 Partner's Sleep Disruption Per Night

Partners were asked the number of times each night that the patients snoring disturbed them. The mean number at baseline was 5.1, SD 2.9, which reduced to 1.5, SD 1.8.

There was a significant difference between basline values and those at each review, P = 0.001(Table 21).

	baseline	4 week	16 week	28 week	40 week	52 week
Partner response number of times per night their sleep was disturbed	5.1 (n=76)	1.5 (n=76)	1.3 (n=42)	1.3 (n=30)	1.4 (n=23)	1.3 (n=25)
		p = 0.001	p = 0.001	p = 0.001	p = 0.001	p = 0.001

Table 21. The mean values from the VAS scores of partner response to number of times each night that their sleep was disturbed.

3.12 Replacement appliances

Two patients had teeth extracted and one patient had two new crowns that necessitated making new appliances. Two patients accidentally damaged their appliance with immersion in hot water and one patient in attempted self adjustments which resulted in the appliance not fitting. In three cases the patient's pet dog had chewed the appliance and in one case the appliance had been left behind while on holiday (Table A3, Appendix A).

Replacement of the appliance consisted of separating the two halves with a scalpel and replacing the defective half. Appliances needed to be replaced mostly between 28 and 40 weeks, although some patients continue to wear their original appliance for more than two years (Table A3, Appendix A).

3.13 Sleep Studies

All the patients in the study had reported socially disruptive snoring, with a number also reporting symptoms suggestive of sleep disordered breathing. Some patients had been attending the sleep clinic for more than two years and had undergone a series of treatments. The data presented is from 50 patients who were fitted with the intra-oral appliance during a 24-month period from September 1996. However, there were 7 who did not have a partner and so the data is presented for 43 patients, 34 males and 9 females (mean age 48 years, range 31 -67 years) who did have regular sleep partners. Paired sleep studies are available for 33 patients (Table A4, Appendix A).

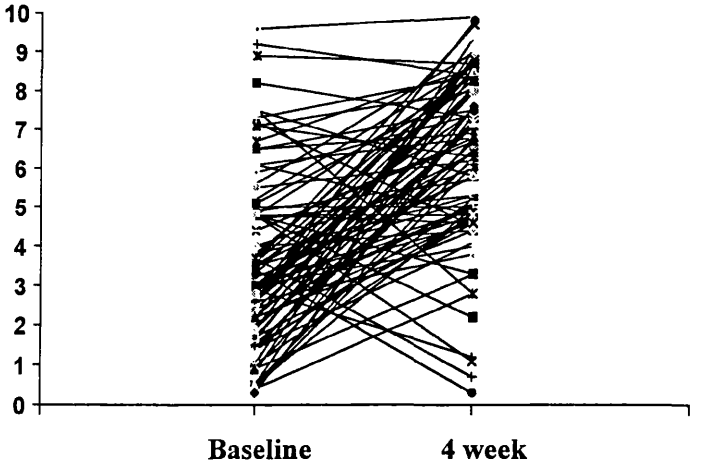

Figure 3.7 Patient perception of their quality of sleep before and after a 4-week period of use with the appliance. The mean before was 3.5, SD 2.2 (10 cm VAS) which increased to 6.3, SD 2.2 (n = 93).

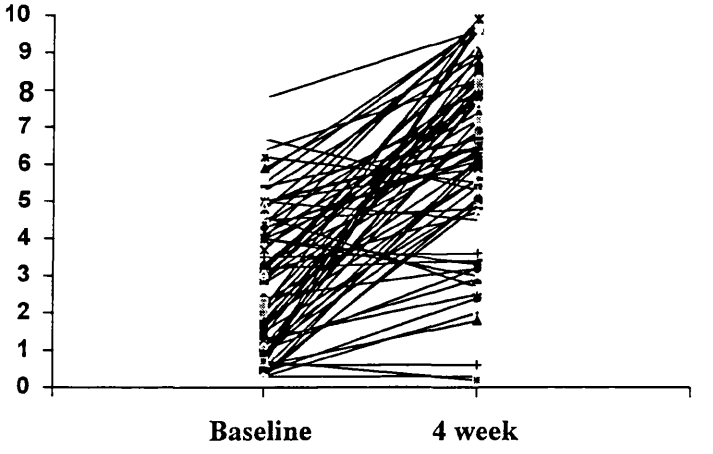

Figure 3.8 Partner perception of their own quality of sleep before and after their partners wore the appliance for 4 weeks. Mean before use was 3.0, SD 2.0 (10 cm VAS) which increased to 6.4, SD 2.5 (n = 76).

Chapter 4

DISCUSSION

For the purposes of statistical analysis the patients who did not return for the 4-week review were counted as failures. It is possible that if the device was successful, there are some patients who would not bother to return for review simply because their problem has been solved. Also, there are some patients who are not prepared to wear the device each night, even though it may successfully eliminate the snoring, and therefore they do not return for review.

The number of days per week that the appliance was worn tended to decrease at each subsequent review. Patients settled into a pattern that suited their individual needs. For some patients snoring increased on nights when they consumed alcohol and so the device tended to be used more at the weekend when they were more likely to take alcohol. Shift workers would not use the appliance if they were not sleeping with their partners. Two patients who had OSA returned to using their CPAP machine after the initial 4-week period and only used the appliance when travelling because it was convenient and portable. Although the appliance reduced snoring for both patients, they did not feel as refreshed as with CPAP.

The number of patients lost to follow-up increased at each review period, as might be expected.

Follow-up by the sleep clinic indicated that a few patients had discontinued using the device because of discomfort to their teeth or facial muscles. Other patients reported at the sleep clinic that they continued to use the device but simply did not return to the Dental Hospital for review.

Retention of the appliance varied between patients depending on the number, shape and position of teeth. Retention of the appliance was good even in situations were there were only a few teeth present. Patients presenting with bounded edentulous spaces often had better retention. Retention was less in individuals where there were bilateral or unilateral distal extension edentulous areas, particularly where there was good retention in the opposing arch. Patients with no teeth missing sometimes also presented problems with retention because of short crown height. The appropriate extension of the device varied depending on the number and arrangement of the teeth and on the amount of opening and protrusion of the mandible. From the summer of 1998 a more rigid flexible material became available (Erkoflex 95, E M Natt Ltd, England) and this was subsequently used in less retentive situations.

During the period of the study there were only three patients who reported TMJ discomfort. One patient reported discomfort after two weeks and two patients after four weeks. In each case the jaw relationship was checked and re-recorded if necessary. The casts were then split and re-joined as previously described.

In each case the patient reported that the discomfort did not re-occur. The appliance was well tolerated by the majority of patients. Minor adjustments were made to improve comfort for a few patients. Side effects included uncomfortable teeth, uncomfortable jaw muscles and excessive salivation, particularly in the first two weeks. Although some patients did find the appliance uncomfortable to wear, particularly with hypersalivation, they were prepared to tolerate this discomfort.

The criteria for measuring success were by the subjective reports of patients and their partners, mostly by means of VAS scores. Patients who found that the appliance had reduced their snoring but was not comfortable to wear produced a low score in terms of satisfaction. However, it was clear that this appliance has been effective in reducing snoring across a broad range of subjects. The reduction in satisfaction recorded at 52 weeks may be explained by the fact that more appliances needed to be replaced at this stage because of reduced retention.

Patients who used the appliance reported that they felt more refreshed on wakening and less tired during the day, probably because there was less restriction in the upper airway. Partners also reported that they were less tired and had a better quality of sleep, for obvious reasons. Couples reported that their relationships had improved because of the fact that they were no longer being wakened during the night and did not have to resort to moving to another room to get some sleep.

Patients and partners who had previously been reluctant to stay with friends or invite friends to stay were now able to do so. More than one patient reported that the appliance had changed their life, that they could concentrate better, their performance at work had improved and they were less tired and had more energy during the day.

The use of mandibular advancement devices has been shown in previous studies to provide an alternative to existing forms of treatment for snoring and sleep apnoea.

This study has shown that a simple, one piece, non-adjustable mandibular advancement device can be used successfully in managing snoring and mild to moderate obstructive sleep apnoea. This study has also shown that there is no prerequisite for number of teeth or type of jaw relationship required and that is is suitable for a broad range of patients. As shown in other studies, the device was successsful in patients who could not tolerate nasal CPAP or who had no success with other treatments.

Appliances were replaced when patients said that it was no longer effective because either one or both parts lacked retention. Appliances were also replaced if patients had teeth extracted or other dental work done. The longevity of the appliance depended to some extent on the care taken of the appliance and the patient's dentition.

Although the mandibular advancement device was successful in reducing or eliminating snoring in 90 out of 93 (96.7%) patients, half the patients in the study were not wearing the device at one year. When offering this treatment to patients it is important to inform them that they have to wear the appliance each night for it to work and this means a possible lifetime of use.

There were patients and partners who reported subjective success but follow-up sleep studies showed that their results were worse with the appliance. Although not all follow-up sleep studies have been completed at this time, out of 33 patients who had follow-up sleep studies there were 3 (9%) whose symptoms became worse. This may be because of the downward rotation of the mandible which occurs when the device is in place or it may be due to a natural progression of their OSA.

The question of whether a dentist should provide these appliances for patients with primary snoring without sleep clinic diagnosis needs to be addressed. In view of the finding of worsening of sleep study variables in a small number of patients, it would seem unwise for dentists to do so. Dentist would at least need to understand the problem of OSA, be aware of the significance of daytime sleepiness and be aware of the possibility of worsening OSA. Overnight pulse oximetry is the minumum investigation that should be performed to exclude OSA.

The question of what constitutes success is important, as no recording of the noise level of snoring was conducted in this study. The subjective response of the partner was considered appropriate because if the partner is happy then that is really all that matters, the objective recording of noise level seems superfluous.

The type of appliance used in this study would appear to be a good first choice in the treatment of primary snoring and also snoring with mild OSA. The appliance has the advantage of being quick and inexpensive to make in the laboratory, is well-accepted, effective and remains effective for at least 9-12 months. It is very cheap to re-make if necessary. However, this type of one-piece appliance may not be suitable for some patients and these might benefit from an adjustable device of the type which permits mouth opening.

The number of patients who have been referred from the sleep clinic continues to increase, as data shows that for a substantial number of patients, especially those with primary snoring, this therapy is successful. Those patients with mild to moderately severe OSA who cannot tolerate CPAP may also prefer dental appliance therapy.

Chapter 5

CONCLUSIONS

- This mandibular advancement device is successful in the control of snoring and OSA and should be considered as the treatment of choice for primary snoring.
- A minimum of four teeth in each arch are required for treatment success with an intra-oral appliance for snoring and OSA
- This mandibular advancement device should be effective for at least nine months before requiring replacement.
- Patients who could not tolerate CPAP were able to use the mandibular advancement device.

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Appendix A

			4 week		16 week		28 week		40 week		52 week	
Patient	**B**	**R**	**Pt**	**Pr**	**Pt**	**Pr**	**Pt**	**Pr**	**Pt**	**Pr**	**Pt**	**Pr**
1.			*	*	*	*	*	*	*	*	*	*
2.	*	*	*	*	*	*	*	*	*	*	*	*
3.												
4.	*	*	*	*	*	*	*	*	*	*	*	
5.	*		*		*							
6.	*	*	*	*								
7.			*	*								
8.			*	*	*	*	*	*	*	*	*	*
9.	*	*	*	*	*	*	*	*	*	*	*	*
10.			*	*	*	*			*	*	*	*
11.	*	*	*	*	*	*	*	*	*	*	*	*
12.			*		*		*		*		*	
13.			*									
14.			*		*							
15.	*	*	*	*								
16.	*	*	*	*	*	*						
17.			*	*			*	*				
18.			*	*	*	*	*	*			*	*
19.	*		*	*	*		*		*		*	*
20.	*	*	*	*			*	*	*	*	*	*
21.			*	*	*	*	*		*	*	*	*
22.	*	*	*	*	*	*	*	*	*	*	*	*
23.			*	*								
24.			*	*			*	*	*	*	*	*
25.			*	*								
26.			*	*	*	*	*	*	*		*	*
27.												
28.			*	*								
29.			*									
30.	*	*	*	*	*	*	*	*	*	*	*	*
31.	*	*	*	*					*	*		
32.			*	*	*	*	*	*	*	*	*	*
33.	*	*	*	*								
34.	*	*	*	*	*	*	*	*	*	*	*	*
35.			*	*	*	*	*	*	*	*		
36.												
37.			*	*	*	*	*	*	*	*	*	*
38.			*	*	*	*	*		*	*	*	*
39.			*									
40.			*									
41.			*	*								
42.			*	*	*	*	*	*	*	*	*	*
43.												
44.			*	*	*	*	*	*	*	*	*	*
45.			*		*		*		*		*	
46.												
47.												
48.			*	*	*	*	*	*	*		*	*
49.			*	*	*	*	*	*	*	*	*	*
50.												
51.			*	*	*	*	*	*			*	*
52.			*		*		*		*		*	

Table A1. Completed questionnaires from patients and partners in chronological order 1-52. B = Baseline, R = Repeat baseline, Pt = patient, Pr = partner. Patients in bold type did not have a partner.

Patient			4 week Pt	4 week Pr	16 week Pt	16 week Pr	28 week Pt	28 week Pr	40 week Pt	40 week Pr	52 week Pt	52 week Pr
53.			*	*	*							
54.			*	*	*	*	*	*	*	*	*	*
55.			*	*	*	*						
56.			*	*								
57.			*		*							
58.			*	*								
59.			*	*	*	*	*	*	*	*	*	*
60.			*	*	*	*						
61.			*	*								
62.												
63.			*									
64.			*	*								
65.			*	*	*	*	*	*	*	*		
66.			*		*		*		*			
67.												
68.			*	*	*	*	*	*				
69.			*	*	*	*	*	*				
70.			*	*	*	*	*	*				
71.			*	*	*	*						
72.			*	*	*	*	*	*				
73.			*	*								
74.			*	*	*	*						
75.			*	*	*	*						
76.												
77.			*	*								
78.			*	*								
79.			*	*	*	*						
80.			*									
81.			*	*	*							
82.			*	*	*	*						
83.			*	*	*	*						
84.			*	*	*	*						
85.			*	*								
86.			*	*	*	*						
87.			*	*	*	*						
88.			*	*	*	*						
89.			*	*	*	*						
90.												
91.			*	*								
92.												
93.			*	*								
94.			*									
95.			*									
96.			*									
97.			*									
98.			*	*								
99.			*	*								
100.			*	*								
101.			*	*								
102.			*	*								
103.			*	*								
104.			*	*								
105.			*	*								

Table A1 (continued). Patient 53-105. The 105 patients (partners) completed review questionnaires. B = Baseline, R = Repeat baseline, Pt = patient, Pr = partner. Patients in bold type did not have a partner.

Patient	Reason for non-continuance
6	Could not tolerate appliance- hypersalivation
7	Could not tolerate appliance- hypersalivation
13	Could not tolerate appliance- hypersalivation
15	Discontinued - ENT operation and weight loss
23	Appliance made no difference
25	Hospitalised - heart attack
28	Failed to attend - good response at 4 week
29	No partner
33	Could not tolerate appliance- hypersalivation
39	Failed to attend - good response at 4 week
40	Could not tolerate appliance- hypersalivation
41	Failed to attend - good response at 4 week
56	Discontinued - appliance "a nuisance" to wear
58	Discomfort due to pressure on teeth
61	Preferred CPAP
63	Failed to attend - good response at 4 week
64	Appliance uncomfortable to wear
73	Failed to attend - good response at 4 week
77	Failed to attend - good response at 4 week
80	Could not tolerate appliance- hypersalivation
85	Failed to attend - good response at 4 week
89	Failed to attend - good response at 4 week

Table A2. Reasons for not continuing after 4-week review

Patient	Time in weeks	Upper	Lower	New appliance.	Comment
1	36		1		Loose
4	8	1			Loose
	36			1	Loose
	95			1	Loose
9	40		1		Loose
	52			1	Loose
10	36			1	Loose
11	24			1	Dental treatment, teeth extracted
	48			1	Loose
17	36			1	Appliance lost
21	64			1	Dental treatment, new crowns
24	26	1			Loose
	38			1	Loose
	87			1	Dental treatment, teeth extracted
30	100			1	Loose
31	80			1	Loose
32	59				Patient damage (boiling water)
34	6			1	Dog chewed appliance
	36			1	Patient damage (self adjustment)
37	63			1	Loose
38	30		1		Loose
	64			1	Loose
	79		1		Loose
42	92			1	Loose
44	80			1	Loose
48	76			1	Patient damage (boiling water)
55	8		1		Loose
59	42			1	Dog chewed appliance
71	8			1	Dog chewed appliance

Table A3. The frequency of replacement appliances.

Name	Age	Sex	Other reported symptoms	Epworth Score= >10	Previous Therapy	Sleep Study 1	Sleep Study 2	Change
1.	65	F	Y			Negative	-	
2.	45	F	Y			B	N	Improved
3.	50			12	CPAP trial	B	-	-
4.	41					P	N	Improved
5.	46					P	D	Worsened
6.	61		Y	15		D	D	Static
7.	63					P	N	Improved
8.	59					N	N	Static
9.	50				U3P/CPAP	N	N	Static
10.	55			10		-	N	Static
11.	41	F		13	CPAP/Oxygen	D	-	-
12.	30	F		18		P	N	Improved
13.	47					B	N	Improved
14.	45		Y	24	CPAP Trial	B	P	Worsened
15.	49					D	N	Improved
16.	55			10	CPAP Trial	N	N	Static
17.	50		Y	14	ENT/CPAP	P	P	Static
18.	39	F		12	ENT/CPAP	B	B	Static
19.	40					N	N	Static
20.	36			16		N	N	Static
21.	47		Y	11		D	P	Improved
22.	60			22		-	-	-
23.	45			17		N	N	Static
24.	47					P	-	-
25.	42					B	N	Improved
26.	52			12		N	-	-
27.	39		Y	11		N	N	Static
28.	57		Y	21	ENT/CPAP	P	B	Improved
29.	48					B	N	Improved
30.	43		Y		CPAP	P	-	-
31.	43				ENT	P	D	Worsened
32.	49	F	Y	14		N	N	Static
33.	30	F		13		B	-	-
34.	46				CPAP Trial	D	P	Improved
35.	43	F	Y	11	CPAP	D	P	Improved
36.	45	F				B	B	Static
37.	61			12	CPAP Trial	B	-	-
38.	47		Y	16	CPAP Trial	B	N	Improved
39.	53			12		N	N	Static
40.	46			10		N	N	Static
41	33		Y	15	CPAP	N	-	-
42.	33			10	ENT	B	N	Improved
43.	67				ENT	B	N	Improved

Table A4. Patient characteristics and sleep study profiles. ENT - procedures other than U3P, usually correction of deviated nasal septum. CPAP Trial - short home trial (2 Weeks) for assessing snoring reduction. CPAP - formal appraisal of CPAP for sleep apnoea suspects.

N - Normal (AHI. <5/hr), B - Borderline (AHI. 10-15/hr or RDI 5-15/hr), P - Possible OSAS (AHI. 15-25/hr), D - Definite (AHI >25/hr).

Appendix B Assessment by Questionnaire

The Epworth Sleepiness Scale

Name:_____

Today's date:_____Your age (years)_____

Your sex (male = M; female = F):_____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired ? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected *you. Use of the following scale to choose the most* appropriate number for each situation.

0 = would *never* doze
1 = *slight* chance of dozing
2 = *moderate* chance of dozing
3 = *high* chance of dozing

Situation	**Chance of dozing**
Sitting and reading	----------
Watching TV	----------
Sitting, inactive in a public place (e.g. a theatre or a meeting)	----------
As a passenger in a car for an hour without a break	----------
Lying down to rest in the afternoon when circumstances permit	----------
Sitting and talking to someone	----------
Sitting quietly after a lunch without alcohol	----------
In a car, while stopped for a few minutes in traffic	----------

B1. ***The Epworth Sleepiness Scale.*** Individuals are asked a series of questions related to the likelihood of their falling asleep in various circumstances. The likelihood is scored from 0-3 in each of 8 situations giving a total possible score of 24. A score of 16 or above is considered high.

BASIC NORDIC SLEEP QUESTIONNAIRE

QUESTION 1 Do you snore while sleeping (ask other people)?
Response alternatives: never or less than once per month
less than one day per week
on 1-2 days per week
on 3-5 days per week
daily or almost daily

QUESTION 2 How do you snore (ask other people about the quality of your snoring)?
Response alternatives: I don't snore
My snoring sounds regular, and it is of low voice
It sounds regular, but rather loud
It sounds regular, but it is very loud (other people hear me in the next room)
I snore very loudly and intermittently (there are silent breathing pauses when snoring is not heard and at times very loud snorts with gasping)

QUESTION 3 Have you noticed breathing pauses (sleep apnoea) during sleep (have other people noticed that you have pauses in respiration when you sleep)?
Response alternatives: never or less than once per month
less than one day per week
on 1-2 days per week
on 3-5 days per week
daily or almost daily

QUESTION 4 If you snore at least one to two times per week, how many years have you been snoring (ask other people if you don't know)?
Response: The answer is: "I have been snoring for about_____years."
"I was about _____ years old when I started to snore."

B2. ***Basic Nordic Sleep Questionnaire.*** Questionnaire used by the Scandinavian Sleep Research Society, Partinen et al (1988).

Predictors and prevalence of obstructive sleep apnoea and snoring.

Height
Weight
Neck circumference,
Arterial oxygen saturation (SaO_2),
Sapirometric values.

Alcohol consumption
Categories 1-4: <10g/day, 10-39g/day, 40-70g/day, >70g/day

Cigarette consumption
Categories 1-4: nil, 1-5/day, 6-15/day, >15/day

Nasal stuffiness e.g. hayfever, previous nasal damage or surgery.
Previous adentonsillectomy.
Use of sedative or hypnotic drugs.
Regular use of other drugs.

Subjects asked about snoring (partner present)
Occupation

B3. Questionnaire used by Stradling and Crosby (1991).

Questionnaire for Sleep Apnoea and/or Snoring

NAME_____ DATE_____

1. How long have you been aware of your snoring?
2. Has it caused problems for relatives or friends?
3. Have you been told your breathing stops while asleep?
4. Have you been told you move around a lot while asleep?
5. About how many times per night do you wake up?
6. Do you have any difficulty falling asleep at night?
7. How many hours of sleep a night do you get?
8. Do you most often wake up feeling refreshed?
9. Do you often wake up with a headache?
10. Will a small amount of alcohol give you a headache?
11. Do you feel sleepy during the day frequently? occasionally? seldom? Never?
12. What other doctors have you seen about your snoring or sleep apnoea?
13. Have you had a sleep lab study?
14. Do you have any difficulty breathing through your nose?
15. Have you gained weight recently? About how much?
16. Present body weight? Height? ft. inches
17. What professional advice or treatment have you received about your snoring or sleep apnoea?_____

Signature Date

(A positive response to questions 3, 4, 9, 10, 11 may have OSAS)

B4. Questionnaire used by George (1993). It was suggested that positive response to questions 3, 4, 9, 10, 11 may have OSAS.

APPENDIX C PATIENT DOCUMENTATION

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron Glasgow Dental Hospital and School
Dr Mervyn F. Lyons Glasgow Dental Hospital and School
Dr Stephen Banham Glasgow Royal Infirmary

Patient questionnaire for snoring and/or sleep apnoea

(Before Appliance)

Title: Dr, Mr, Mrs, Ms, Miss. Delete as appropriate.

NAME:_____DATE:

Address:_____

_____**Reference No.**

_____

_____

Telephone (Daytime)_____Home_____

Date of Birth: SEX: M. F.

Marital Status:_____
Occupation: _____

Please tick a box, where provided.

A. How long have you been aware of your snoring? _____Years.

B. How loud do you think you snore? (from what other people tell you).
On the scale below, indicate with a single mark:

|_____|
Do not snore at all — Extremely loud

C. Has it caused problems for relatives or friends ?_____

_____

_____

C1. Pre-appliance patient questionnaire A1 (Page 1).

1. How many hours of sleep a night do you get?_____

2. Do you wake up feeling refreshed?
On the scale below, indicate with a single mark:

|_____|
Never Always

3. Do you feel sleepy during the day?
On the scale below, indicate with a single mark:

|_____|
Never Always

4. Present body weight _____st____lbs. Height ___ft.____inches

(office use) BMI_____

5. Do you smoke YES NO Cigarettes Cigar Pipe

1-5 per day 6-15 per day more than 15 per day

6. Do you drink alcohol YES NO
Alcohol consumption: In units
A leaflet from the Scottish Council on Alcohol is provided to assist you.

Average units per week _____

7. How would you rate the quality of your sleep?
On the scale below, indicate with a single mark:

|_____|
Awful Excellent

C1 (continued). Pre-appliance patient questionnaire A1 (Page 2).

COMMENTS

---------- ----------

Signature of patient

Date

Thank you for your co-operation

C1 (continued). Pre-appliance patient questionnaire A1 (Page 3).

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron Glasgow Dental Hospital and School
Dr Mervyn F. Lyons Glasgow Dental Hospital and School
Dr Stephen W. Banham Glasgow Royal Infirmary

Partner questionnaire for snoring and/or sleep apnoea

(Before Appliance)

Patient Name_____ **Reference No.**

NAME:_____**DATE:**

Address:_____

_____ Reference No.

_____

_____

Please tick a box, where provided.

A. How long have you been aware of your partner snoring? _____Years.

B. How loud does your partner snore?
On the scale below, indicate with a single mark:

|_____|
Does not snore at all — Extremely loud

C. Has your partners snoring caused problems for relatives or friends?

_____

_____

_____

_____

_____

_____

C2. Pre- appliance partner questionnaire B1 (Page 1).

1. Does your partner wake up feeling refreshed?
On the scale below, indicate with a single mark:

Never |_____| Always

2. Is your partner irritable upon wakening?
On the scale below, indicate with a single mark:

Never |_____| Always

3. Does your partner complain of daytime sleepiness?
On the scale below, indicate with a single mark:

Never |_____| Always

The following questions relate to your sleep.

4. Is your sleep disrupted by your partners snoring? YES

NO

If yes, on average how many times per night? _____

5. Do you feel tired upon wakening?
On the scale below, indicate with a single mark:

Never |_____| Always

6. How would you rate the quality of your sleep?
On the scale below, indicate with a single mark:

Awful |_____| Excellent

C2 (continued). Pre- appliance partner questionnaire B1 (Page 2).

COMMENTS

---------- ----------

Signature of partner Date

Thank you for your co-operation

C2 (continued). Pre- appliance partner questionnaire B1 (Page 3).

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron Glasgow Dental Hospital and School
Dr Mervyn F. Lyons Glasgow Dental Hospital and School
Dr Stephen W. Banham Glasgow Royal Infirmary

Patient questionnaire for snoring and/or sleep apnoea

(After appliance)

Evaluation of Dental Appliance

NAME:_____DATE:

Address:_____

_____ Reference No.

_____

_____

Please note when answering, that questions relate only to the last 4 weeks.

Please tick a box, where appropriate.

A. How often do you wear the appliance?

1 day per week
2 days per week
3 days per week
4 days per week
5 days per week
6 days per week
7 days per week

B. How comfortable is the appliance to wear?
On the scale below, indicate with a single mark:

|_____|
Extremely uncomfortable — Totally comfortable

C. Did the appliance make a difference to your snoring?
On the scale below, indicate with a single mark:

|_____|
None at all — Entirely eliminated snoring

C3. Post-appliance patient questionnaire A2 (Page 1).

D. How satisfied are you with the appliance?
On the scale below, indicate with a single mark:

|_____|

Extremely dissatisfied — Totally satisfied

E. Were there any side effects from wearing the appliance:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

C3 (continued). Post-appliance partner questionnaire A2 (Page 2).

1. How many hours of sleep a night do you get? _____

2. Do you **now** wake up feeling refreshed?
On the scale below, indicate with a single mark:

|_____|

Never Always

3. Do you **now** feel sleepy during the day?
On the scale below, indicate with a single mark:

|_____|

Never Always

4. Present body weight____st____lbs Height____ft._____inches

(office use) BMI_____

5. Do you smoke? YES NO Cigarettes Cigar Pipe

1-4 per day 6-15 per day more than 15 per day

6. Do you drink alcohol: YES NO

Alcohol consumption: In units
A leaflet from the Scottish Council on Alcohol is provided to assist you.

Average units per week _____

7. How would you rate the quality of your sleep **now**?
On the scale below, indicate with a single mark:

|_____|

Awful Excellent

C3 (continued). Post-appliance patient questionnaire A2 (Page 3).

COMMENTS

_____

_____

_____

_____

_____

_____

_____

_____

Signature of patient

Date

Thank you for your co-operation

C3 (continued). Post-appliance patient questionnaire A2 (Page 4).

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron Glasgow Dental Hospital and School
Dr Mervyn F. Lyons Glasgow Dental Hospital and School
Dr Stephen W. Banham Glasgow Royal Infirmary

Partner questionnaire for snoring and/or sleep apnoea

(After appliance)

Patient Name_____ Reference No.

Treatment date: weeks

NAME:_____**DATE:**

Address:_____

_____ Reference No.

_____

_____

Please note when answering, that questions relate only to the last 4 weeks.

Please tick a box, where provided.

A. Have you noticed a difference in your partner's snoring **now** with the appliance?
On the scale below, indicate with a single mark:

|_____|

None at all — Entirely eliminated snoring

B. How loud does your partner snore **now**?
On the scale below, indicate with a single mark:

|_____|

Does not snore at all — Extremely loud

C4. Post- appliance partner questionnaire B2 (Page 1).

1. Does your partner **now** wake up feeling refreshed?
On the scale below, indicate with a single mark:

|_____|

Never Always

2. Is your partner irritable **now** upon wakening?
On the scale below, indicate with a single mark:

|_____|

Never Always

3. Does your partner **now** complain of daytime sleepiness?
On the scale below, indicate with a single mark:

|_____|

Never Always

The following questions relate to your sleep.

4. Is your sleep **now** disrupted by your partners snoring? YES NO

If yes, on average how many times per night? _____

5. Do you **now** feel tired upon wakening?
On the scale below, indicate with a single mark:

|_____|

Never Always

6. How would you rate the quality of your sleep **now?**
On the scale below, indicate with a single mark:

|_____|

Awful Excellent

C4 (continued). Post- appliance partner questionnaire B2 (Page2).

COMMENTS

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

---------- ----------

Signature of partner Date

Thank you for your co-operation.

C4 (continued). Post-appliance partner questionnaire B2 (Page 3).

Questionnaire A1

A. How long have you been snoring?
appliance?
Years

B. How badly do you think you snore?
to (From what other people tell you)
Does not snore at all - Extremely loud

C. Has this caused problems for relatives or friends?
now?
Comment

1. How many hours sleep do you get?
you

2. Do you wake up feeling refreshed?
refreshed?

Never - Always

3. Do you feel sleepy during the day?
day?

Never - Always

4. Present body weight? **BMI**

5. Do you smoke?

Yes/No - Cigarettes, Cigar, Pipe - 1-5, 6-15, >15/day

6. Do you drink alcohol?

Yes/No Units/week

7. How would you rate the quality of your sleep?

Awful - Excellent

Comments

Questionnaire A2

A. How often do you wear the

1 day, 2 days/week, 3 days/week, 4 days/week
5 days /week, 6 days/week, 7 days/week

B. How comfortable is the appliance
wear?
Extremely uncomfortable- totally comfortable

C. How badly do you think you snore

(from what other people tell you)
Do not snore at all - Extremely loud

D. How satisfied are you with
the appliance?
Extremely dissatisfied - Totally satisfied

E. Were there any side effects from
wearing the appliance?
Comment

1. How many hours sleep a night do
get?

2. Do you <u>now</u> wake up feeling

3. D you <u>now</u> feel sleepy during the

4. Present body weight? **BMI**

5. Do you smoke?

6. Do you drink alcohol?

7. How would rate the quality of your
sleep <u>now</u>?

Comments

C5. Summary of Questionnaires A1 and A2 (Patient)

Questionnaire B1

A. How long have you been aware of your partner's snoring?
Years

B. How loud does your partner snore?
now?

Does not snore at all - Extremely loud

C. Has your partner's snoring caused problems for relatives or friend?
Comments

1. Does your partner wake up feeling refreshed?
feeling

Never - Always

2. Is your partner irritable upon wakening?

Never - Always

3. Does your partner complain of daytime sleepiness?

Never - Always

4. Is your sleep disturbed by your partners snoring?

Yes/No **If yes, times /night**

5. Do you feel tired upon wakening?
wakening?

Never - Always

6. How would you rate the quality of your sleep?
your

Awful - Excellent

Comments

Questionnaire B2

A. Have you noticed a difference in your partner's snoring now with the appliance ?
None at all - Entirely eliminated snoring

B. How loud does your partner snore

1. Does your partner **now** wake up refreshed?

2. Is your partner irritable **now** upon wakening ?

3. Does your partner **now** complain of daytime sleepiness?

4. Is your sleep **now** disturbed by your partner's snoring?

5. Do you **now** feel tired upon

6. How would you rate the quality of sleep **now**?

Comments

C6. Summary of questionnaires B1 and B2 (Partner)

APPLICATION TO GLASGOW DENTAL HOSPITAL ETHICS COMMITTEE:

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron	Glasgow Dental Hospital and School
Dr Mervyn F. Lyons	Glasgow Dental Hospital and School
Dr Stephen W. Banham	Glasgow Royal Infirmary

LOCATION

Unit of Prosthodontics, Glasgow Dental Hospital and School

DATE

27 October 1996

PRINCIPAL INVESTIGATOR - Donald A. Cameron

SUPERVISOR - Mervyn F. Lyons

SUPERVISOR - Stephen W. Banham

INTRODUCTION

It has been shown that dental devices can be of value in the treatment of snoring and obstructive sleep apnoea. Snoring may affect 20% of the adult population and is a primary symptom of Obstructive Sleep Apnoea Syndrome, a condition where the airway is narrowed or blocked, obstructing breathing while sleeping. During the apnoeic episodes, oxygen levels in the blood drop and the subject resumes breathing with gasps or snorts. This pattern can be repeated many times during the night. This leads to poor sleep, snoring, daytime sleepiness, impaired cognitive function and an increased risk of cardiovascular disease. Treatments for this condition includes the use of a nasal mask (Nasal Continuous Positive Airway Pressure). This is worn while the subject is asleep and acts as a pneumatic splint to blow air and keeps the airway open. Surgery has also been used to remove excess tissues in the throat to prevent obstruction and reduce the vibration of tissues.
Unfortunately CPAP is a very obtrusive method of treatment, and dental devices are much less obtrusive. It is thought that dental devices may have a useful role to play in patients who are unsuitable for surgery and would therefore be committed to long term CPAP. We have developed a polyvinyl acetate-polyethylene bimaxillary splint and wish to investigate the effectiveness of this device in a carefully designed and well-documented trial.

AIMS

To obtain reliable data on the efficacy of the bimaxillary splint in various categories of patients, and to further develop this device as may be indicated by experience.

METHODS

A large group (in excess of 20) of patients will be referred from Glasgow Royal Infirmary with symptoms of Snoring and Obstructive Sleep Apnoea. The patients will be clinically evaluated, including sleep studies, at Glasgow Royal Infirmary before referral. The subjects in the study will be patients with mild to moderate sleep apnoea. The patients will be randomly allocated into two groups with one group acting as a control. At the Dental Hospital, the A group will be asked to complete a questionnaire. A jaw registration and impressions will be taken and a bimaxillary splint will then be made. The A group will receive their appliance that day. They will wear the appliance for four weeks after which time they will return to the Dental Hospital to complete a second questionnaire. The B group patients will also be asked to complete the questionnaire, a jaw registration and impressions will be taken. The B group will be given their appliance after a 4 week period when they will be asked to complete they same questionnaire as before. The B group will wear the appliance for four weeks and complete the second questionnaire. Patients will be asked to attend the Dental Hospital with their partners who will also complete questionnaires before the treatment and after the four-week period. An evaluation of the appliance will be made after six months, with an evaluation also at Glasgow Royal Infirmary.

EVALUATION

A pre-and post-appliance polysomnography investigation will be conducted on each patient at the Glasgow royal Infirmary and questionnaires for patient and partner will be completed at the Glasgow Dental Hospital.

INFORMATION ON SUBJECTS AND ANALYSIS OF DATA

Information on subjects will be recorded on paper and kept confidential. Analysis of recordings and data will be done on a PC, and code numbers will identify subjects only.

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

INVESTIGATORS

Mr Donald A. Cameron	Glasgow Dental Hospital and School
Dr Mervyn F. Lyons	Glasgow Dental Hospital and School
Dr Stephen W. Banham	Glasgow Royal Infirmary

INFORMATION SHEET FOR VOLUNTEERS

The results of your assessment have confirmed the presence of a sleep breathing disorder. The spectrum ranges from disruptive snoring through to obstructive sleep apnoea syndrome. Treatments for these conditions range from simple dietary measures through to specialised ENT surgical procedures. The range of treatments appropriate to your own condition will have been discussed with Dr Banham.
Currently all forms of treatment have some limitation and a new form of treatment has been developed in association with the Glasgow Dental School. This is a new appliance consisting of an individually measured and constructed mouthguard which when placed in the mouth slightly alters the shape of the jaw and increases the air channel at the back of the throat. Various versions of this device have been studied principally in North America, and show encouraging results. We would like you to help in assessing this locally developed appliance. A half day session at the Dental Hospital is required for the necessary measurements and to mould the plastic material to your own individualised "gumshield". The only reported side-effect of this approach is of some initial jaw discomfort.

At the Dental Hospital you will be asked to fill in a questionnaire at the start of your treatment and at a follow-up appointment after 4 weeks. There will be a further recall appointment 6 months from the treatment.

The sequence of the treatment will be:

1. Evaluation and sleep test at Glasgow Royal Infirmary.

2. Referral to Glasgow Dental Hospital and School where impressions will be taken for the construction of the appliance if you have sufficient teeth. There will be a questionnaire for you at this appointment. There will be an appointment for the patient at 4 weeks after delivery of the appliance when you will be asked to fill in a second questionnaire. There are also questionnaires at these stages for your partner. It would greatly assist the study if your partner accompanied you to fill in their questionnaire.

3. An evaluation and sleep test at Glasgow Royal Infirmary at 6 months from the treatment date.

Patients will be required to sign a consent form at the beginning of treatment.

Your general practitioner will be informed of participation in the study. Information will be recorded on paper and kept confidential. Analysis of recordings and data will be done on a computer, and code numbers will identify subjects only.

No information will be disclosed without the permission of the patient to any other party in a manner that would reveal their identity.

Appliance Maintenance

When not in use the appliance should be cleaned with warm water, soap and a soft brush. It can be stored in water or a mouthwash solution.
Immersion in **hot** water can result in distortion of the appliance and should be avoided.

If you have any questions or comments regarding the appliance, please do not hesitate to contact Mr Cameron (telephone: 0141 211 9622) or Dr Lyons (telephone : 0141 211 9625). Outwith office hours Mr Cameron can be contacted on (01698 428162).

CONSENT FORM:

THE MANAGEMENT OF SNORING AND OBSTRUCTIVE SLEEP APNOEA WITH AN INTRAORAL DEVICE

I,_____of_____

_____

freely and voluntarily agree to participate in the clinical research study named above.

The nature and purpose of the study has been explained to me by _____.

I have had the opportunity to ask questions and I fully understand what is proposed.

I recognise that I am free to withdraw my consent at any time without prejudice to me.

I have been assured that the information obtained from me will not be disclosed without my permission to any other party in a manner which will reveal my identity.

Volunteers signature

DATE:_____

I confirm that I have explained the nature and purpose of the clinical research study and the procedure in respect of which consent has been given by the above named.

D. A. Cameron M. F. Lyons

DATE:_____

C10. Volunteer consent form.

UNIVERSITY
of
GLASGOW

Telephone for appointments: 0141 211 9634
(Please ask for Dr Lyons' nurse)

Date:

Dear

You have been referred to this Unit by Dr Banham, Glasgow Royal Infirmary, for the fitting of a device to help reduce your snoring. This device is a new design and so we are recording detailos of your snoring problem very carefully by questionnaire in order to measure the effectiveness of the device. It is very important that your spouse/partner comes with you for your first appointment so that we can obtain a complete picture of your problem, and so your co-operation in this regard would be greatly appreciated. If this is not convenient on the date we have sent you, would you please telephone for an alternative appointment.

Would you please note that this device requires natural teeth to hold it in place, so if you wear full dentures we cannot help you. Please telephone us to clarify if you are in doubt.

Yours sincerely.

Dr M.F.Lyons

C11. Letter sent with initial appointment from the Dental Hospital.

GLASGOW DENTAL HOSPITAL AND SCHOOL
NHS TRUST
378 SAUCHIEHALL STREET, GLASGOW G2 3JZ
TELEPHONE: 0141-211 9600 FAX: 0141-211 9800

HAC/MMCC/03

22 July 1996

Mr Donald Cameron
Dental Instructor
Teaching Laboratory
Floor 2

Dear Mr Cameron

Area Dental Ethics Committee

Protocol: The management of snoring and obstructive sleep apnoea with an intra-oral device.

I write to inform you that your protocol for a clinical research project has now been approved by the Area Dental Ethics Committee subject to

a) The protocol should state that subjects will have mild or moderate sleep apnoea or snoring which has not responded to standard treatment.

b) The patient questionnaire should be submitted.

c) The investigator will comply with the requirements of the Data Protection Act.

d) General practitioners will be informed of patients in the study.

e) The Information Sheet should have a contact home telephone number.

f) There should also be an information sheet for partners.

g) The protocol and information sheet should make clear the sequence of events in the investigation, ie sleep test, construction of appliance, questionnaires at 1, 4, 12 weeks and 6 months, sleep test.

The Committee would be grateful if you would inform them of the results of your project and any ethical problems encountered when the project is complete.

Yours sincerely

H A Critchlow
Chairman
Area Dental Ethics Committee