The Management of Sleep-Related Breathing Disorders Utilising Mandibular Repositioning Splints.

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DECLARATION

This thesis is the original work of the author, with the exception of the generous help and guidance acknowledged in the text.

Signed:

Date: 5. 3. 2006

iii. ABSTRACT

This prospective cross sectional cohort study examined management of sleep related breathing disorders with mandibular repositioning splints (MRS).

Three aspects were examined;

1. The relationship between severity of sleep related breathing disorders and lateral cephalometric radiograph values.
2. Patients' perspectives on treatment of sleep disordered breathing with a mandibular repositioning splint.
3. Comparison of treatment success with severity of sleep disordered breathing and patients anatomical dimensions.

One hundred and twenty one lateral cephalometric radiographs were traced under uniform conditions and a series of 56 landmarks identified, from which 48 angular and linear measurements were made.

Significant differences were seen when comparisons of these measurements with the severity of sleep related breathing disorders were investigated.

Body Mass Index, the Maxillary-Mandibular Plane angle and the pharyngeal dimension increased significantly in some subjects as Epworth Sleepiness Score (ESS) increased in severity. Overjet, lower lip length, and the distance from the Hyoid bone to B point on the mandible increased significantly in some subjects as OSAHS, as measured by the Apnoea/Hypopnoea Index (AHI), increased in severity. The Hyoid bone was found to rotate counter clockwise as severity of AHI increased, as a result the distance between the most anterior superior point on Hyoid bone and the maxillary plane was seen to decrease as severity of AHI increased.

Investigation of patients and sleeping partners perspectives on treatment was undertaken with the use of a questionnaire based study. ESS score for both patients and partners decreased significantly after treatment, but the mean decrease was not clinically significant.

Fifty four out of 121 subjects were compliant with treatment; various minor side effects were commonly reported.

Twenty out of 53 (37.7%) sleeping partners felt that their partners' daytime sleepiness was improved or much improved and 37 out of 53 (69.8%) sleeping partners felt that their partners' snoring was improved or much improved. Twenty three out of 53 (43.3%) sleeping partners felt that their partners' breathing pauses during sleep had improved or much improved

Thirty three (64%) sleeping partners reported their own sleep to be improved since their partner's treatment.

No correlation was found between AHI and ESS score.

No predictors for success or failure of treatment were found.

In conclusion, some radiographic anatomical features show significant differences when examined in subjects with increasing severity of AHI and ESS score. These features could be used for the identification of patients with severe sleep related breathing disorders.

The Logit equation derived from the findings of this study could also be a useful clinical tool in assessment of a patient's likelihood of suffering from a severe sleep related breathing disorder.

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1. INTRODUCTION

Obstructive Sleep Apnoea/ Hypopnoea Syndrome (OSAHS) was described as early as 360 BC, by Aelianus and was highlighted again in the Victorian era by Charles Dickens in the Pickwick Papers (Aelianus 1666, Dickens 1837).

Dickens, who was an acute observer of the human condition, vividly described the clinical features of OSAHS when he characterised the "fat boy", highlighted by the red arrow in figure 1; "Joe was obese, excessively sleepy, snored loudly and suffered from heart failure."

Figure 1: Pickwickian syndrome. "The Posthumous Papers of the Pickwick Club" (Charles Dickens, 1837)

William Osler coined the term "Pickwickian", referring to obese, hypersomnolent patients, and in 1936 Kerr and Lagen noted that a significant cardiocirculatory problem could develop in such patients leading to cor pulmonale and eventual cardiac failure (Osler 1918, Kerr and Lagen 1936).

In the early 1980's sleep clinics in the UK first began to treat substantial numbers of OSAHS patients, with the condition receiving increased recognition over recent years, due to the multi-system complications associated with the syndrome and its high prevalence in the adult population (Young et al. 1993).

OSAHS is part of a broader range of respiratory control disorders associated with sleep, known collectively as sleep-related breathing disorders.

This thesis aims to explore the management of sleep-related breathing disorders with Mandibular Repositioning Appliances.

2. LITERATURE REVIEW

2.1 DEFINITION

OSAHS is a well recognised clinical disorder in which there is repeated narrowing and collapse of the upper airway during sleep, causing cessation of breathing to occur in the presence of inspiratory effort (Guilleminault 1985, Battagel 1996). It is a potentially life threatening disorder.

2.2 AETIOLOGY

The aetiology of OSAHS is complex and remains incompletely understood, the predisposing factors and origin are still under debate (Pracharktam et al. 1996). It is thought to arise from a combination of anatomical and pathophysiological factors, which predispose to narrowing of the upper airway (Johal and Battagel 1999).

Anatomical aberration of the pharyngeal airway, with or without neurogenic failure, with consequent loss of the patency of the pharyngeal airway during sleep, are currently the two most common theories regarding the origin of the syndrome (Pracharktam et al. 1996).

Genetic link

It is at present unclear whether OSAHS can be inherited. OSAHS has also been reported to have a genetic link, but this may result from an association with obesity. Douglas in 1993 carried out a study to identify a possible genetic link (Douglas et al. 1993). He examined twenty OSAHS patients who were not obese and found that there was an increased frequency of abnormal breathing during sleep in the relatives of non-obese patients with OSAHS. He concluded that it was difficult to prove a genetic link.

Involved factors

Factors that tend to enhance the degree of upper airway narrowing with sleep onset are those that narrow the physical dimension of the pharynx or dynamically overload the airway sufficiently to overwhelm the pharyngeal dilators as pharyngeal tone decreases.

Residual tonsils, retrognathia or external pressure from neck obesity will cause structural narrowing of the pharynx (Davies and Stradling 1990). A smaller diameter in the pharynx means that the normal withdrawal of dilator tone will produce a significantly greater increase in pharyngeal airway resistance.

With the onset of sleep all skeletal muscle loses tone. This is necessary in order to sleep comfortably, particularly within the parameters of the rapid eye movement phase. The pharyngeal muscles that dilate and maintain patency in the upper airway share in the general loss of muscle tone, with the result that even in a non-snoring individual there is a narrowing of the airway and an increased airway resistance (Stradling 1995).

This narrowing at sleep onset varies considerably between individuals and in some subjects will result in the pharyngeal walls approximating sufficiently to generate snoring. Further narrowing engenders complete collapse, and although the degree of narrowing is a continuous variable the onset of snoring and of complete collapse are clearly two stages. The point of onset of apnoea is dramatic and initially was believed to be the only pathological event (Guilleminault 1985).

Neck obesity will also load the pharyngeal muscles, which may be able to maintain patency of the airway whilst the patient is awake, but fail when muscle tone is withdrawn upon sleep onset. Concurrence of more than one of these factors such as obesity and retrognathia or tonsillar hypertrophy may be particularly potent in provoking sleep related collapse of the upper airway (Stradling 1995).

2.3 CLINICAL FEATURES

The main morphological feature is narrowing of the upper airway during sleep, which is associated with snoring and excessive daytime sleepiness (Young et al. 1993). These obstructive episodes may occur at various levels from the nasopharynx down to the base of tongue and the hypopharynx. They lead to hypoxaemia, increased ventilatory effort, brief arousal from sleep, daytime sleepiness and the possibility of cardiovascular disease.

OSAHS occurs most commonly during rapid eye movement (REM) sleep (Douglas and Polo 1994). The dilator muscles of the upper airway, (geniohyoid, genioglossus and tensor veli palatini), lose their tone and are therefore unable to offset the negative pressure of inspiration which draws the base of tongue, including the epiglottis and soft palate, posteriorly against the pharyngeal walls.

Nasal Obstruction

In the "normal" individual the nose is the primary route for breathing during wakefulness, and more specifically during sleep (Gleeson et al. 1986). The nose, especially the lumin, accounts for around half of the respiratory resistance to airflow, and a marked increase in nasal resistance can be seen in subjects with acute or chronic rhinitis when they lie supine. Unilateral disease such as nasal polyps or deviated septum may also cause increased resistance (Lavie et al. 1982). Nasal occlusion in normal subjects leads to an increase in the number of apnoeic episodes, sleep arousals and awakenings (Surat et al. 1986). An increase in the frequency of apnoeas and hypopnoeas is also seen in patients with seasonal allergic rhinitis (McNicholas 1982).

Obstruction of this primary route for somnolent breathing can have profound effects on the individual. In the growing child obstruction of the upper airway may lead to excessive vertical facial development. The soft-tissue stretch hypothesis, postulates that an increased cranio-cervical angulation is triggered by airway obstruction (Solow and Kreiborg 1977).

Head Position

Natural Head Position was defined by Solow and Tallgren in 1971. First the body is positioned in the orthoposition, the intention position from standing to walking. The subject then orientates the head in the proprioceptive self-balance position and subsequently, by means of a mirror suspended in front of them, orientates the head in to the mirror position. After the subject has positioned the head and neck complex into this position the ear rods can be gently inserted into the external meatus in order that the head posture is stabilised during exposure. This method is highly reproducible and allows superimposition on serial radiographs.

Positioning of the head and neck affects pharyngeal patency and neck flexion is capable of producing a considerable increase in pharyngeal resistance during wakefulness and under anaesthesia. This is readily demonstrated on placing a patient into the recovery position, or by observing an anaesthetist performing the head-tilt-chin-lift as a patient first becomes unconscious during anaesthesia.

Varying head position between flexion and extension can cause significant variation in the size of the retroglossal space and hyoid position on lateral cephalometry (Davies and Stradling 1990).

Solow in 1993 found that OSAHS patients have extremely large cranio-cervical angles and felt that this was due to a physiological adaptation aiming to maintain airway patency by extending the neck. His findings were corroborated by Tangugsorn in 1995 and Ozbek in 1998.

This increase in cranio-cervical angle results in an extended, forward, natural head posture when compared with controls. This may be attributed to the compromised morphology or physiology of the airway in OSAHS patients, which persists when patients are awake.

2.4 CLINICAL SYMPTOMS

Obstructive Sleep Apnoea is characterised by a constellation of signs and symptoms related to arterial oxygen desaturation and sleep fragmentation caused by pharyngeal obstructions during sleep (Strohl et al. 1994).

Symptoms suffered by patients can be categorised into those which are nocturnal, diurnal or medical.

2.4.1 Nocturnal Symptoms

Snoring

Snoring is a common affliction affecting people of all ages but particularly middle-aged and elderly men or women who are overweight (Schmidt-Nowara et al 1995).

It was until recently a symptom that was poorly understood and as a result often treated inappropriately. It is a distressing symptom, not only for the patient but also to people in the vicinity. It is more common in the obese, the male, the over 40 year olds and alcohol imbibers. The cause is partial airway obstruction during inspiration, which causes vibration of soft tissues in the oropharynx (Maran 1996).

Most individuals with OSAHS snore; however not all individuals who snore have OSAHS (Friedlander et al. 2000).

The majority of individuals who make snoring sounds whilst sleeping do so because the uvula and or the posterior border of the soft palate is excessively lax and vibrates as air passes over them during normal respiration.

Snoring, whether directly associated with OSAHS or of a benign nature may be so pronounced that a partner may be unable to share the room. Socially this is such a problem that the noise of loud snoring has been cited on several occasions as a reason for divorce (Heath 1993).

Choking and Restlessness

Patients can complain they awaken suddenly with a feeling of choking or gagging. These patients may be awakened before the obstructive episode has ceased. Restlessness and abnormal motor activity, such as leg jerking or clonus is not uncommon (Douglas et al. 1993).

Nocturia

Increased abdominal pressure associated with respiratory efforts against an obstructed upper airway has been suggested as a mechanism for the nocturia suffered by some patients (Timms 1990).

2.4.2 Diurnal Symptoms

Daytime Sleepiness

One of the main indications for treatment is subjective daytime sleepiness; this can result in the OSAHS patient falling asleep at unexpected and inappropriate moments, such as whilst talking or eating, or whilst stopped in a car at traffic lights. Sufferers may only be able to stay awake when constantly stimulated.

In Britain, the daytime sleepiness associated with OSAHS has been shown to be linked to an increased use of medical resource (Fleetham 1997). Impaired vigilance and driving performance have also been recognised in a Leicestershire Police Force study which noted that around 20% of accidents on motorways in Leicestershire County were caused by motorist falling asleep (Semple and Gibson 1993). Alarmingly, 24% of patients with OSAHS have been reported to fall asleep whilst driving at least on a weekly basis (Terran-Santos 1999). Thus clinicians in the UK are required to advise patients with OSAHS that they should not drive until effective treatment has been established for them (Taylor 1995).

Studies in Europe have shown that OSAHS associated daytime sleepiness leads to motorway and work related accidents costing European Nations the equivalent of billions of pounds-sterling each year in medical costs and lost productivity (Terran-Santos 1999).

Fatigue

Often the sleep these patients have is described as unrefreshing and the patient awakes still feeling tired. This is thought to be due to a lack of REM sleep time and several awakenings during the night due to apnoeic events.

Morning Headaches

Diminished Libido/ Impotence

Decrease in Cognitive Performance

Impaired memory and concentration, often due to tiredness are commonly reported by patients.

Mood Disorders

Sleep fragmentation and cerebral haemodynamic changes, secondary to apnoea, may lead to personality change, with bursts of jealousy, suspicion, anxiety and bouts of deep depression (Guilleminault 1985).

Poor Performance in the Work Place

Whilst not all these symptoms may be observed in one individual, frequently several will be present.

2.4.3 Medical Symptoms

Recurrent sleep disruption causes disabling nocturnal and diurnal symptoms, but also a range of potentially life threatening medical symptoms. Recurrent exposure to apnoeic initiated hypoxaemia, hypercarbia, increased catecholamine production and sympathetic activity with resultant surges in systolic blood pressure are known to be associated with:

Sustained Hypertension

Systemic and pulmonary arterial pressures are affected by OSAHS. Pressures rise with each episode, returning to control levels when ventilation resumes. When apnoeic episodes occur in rapid succession, however, values increase in a stepwise fashion so that systemic diastolic may reach values as high as 130-160 mmHg (Stradling 1989).

Blood pressure always peaks when breathing resumes and in a patient with repetitive apnoea these cyclical changes can lead to serious systemic and pulmonary hypertension. In studies of hypertension and snoring it has been shown that when other risk factors such as obesity are eliminated, snoring correlates significantly with high blood pressure. Nocturnal hypoxaemia if prolonged can cause hypertension and cardiac problems (Guilleminault 1985).

Coronary Artery Atherosclerosis and Ischaemic Stroke

The atherosclerotic process is accelerated in patients with OSAHS due to the combined effects of hypertension, hypoxaemia and increased sympathetic activity (Fleetham 1997, Jennum at al. 1992). This exacerbates arrhythmias, nocturnal angina, myocardial ischaemia and infarction, particularly in patients who have pre-existing cardiac disease (Fleetham 1997). Patients with OSAHS have been estimated to suffer cerebrovascular accidents at three to six times the rate of controls (Friedlander et al. 1999). Atherosclerosis of the cervical portion of the carotid artery has been suggested as a possible cause for these strokes. Calcified lesions are found typically in the region of the third and fourth cervical vertebrae. Atheromas are visible on a lateral cephalometric radiograph with a reported prevalence of 21.3% in OSAHS patients (Friedlander et al. 1999). It has also been observed that a third of patients with OSAHS also have type 2 diabetes mellitus, which further accelerates the process of atherosclerosis (Friedlander et al. 1999).

Psychological Disorders

There is increasing recognition of a link between OSAHS and depression. Changes in REM sleep pattern are a feature of depressive illness.

2.5 PATHOPHYSIOLOGY

The periods of obstructed airflow typically last between 10 and 30 seconds, resulting in a repetitive asphyxia, which is a fall in blood oxygen level or hypoxaemia. This is followed by a rise in blood carbon dioxide or hypercarbia and a transient hypertension and bradycardia, typically with a heart rate of less than 60 beats per minute.

These surges in systolic blood pressure of approximately 20 to 40 mm Hg are precipitated by a hypoxaemia induced rise in catecholamine production and sympathetic nervous output, which causes constriction in vascular smooth muscles (Stradling 1989). Increased but frustrated respiratory effort also contributes to the transient hypertension (Stradling 1989).

Bradycardia is also contributed to by the hypoxaemia and results from the carotid body stimulation of the vagus nerve (Heath 1993). Powerful efforts to inspire against the closed upper airway continue, but breathing resumes only when the subject transiently awakens, resulting in sleep fragmentation. The patient is often unaware of this awakening and this arousal restores the tone of the musculature surrounding the pharynx, allowing a gasp followed by breathing without obstruction. Upon opening of the airway, cardiovascular and pulmonary derangements are rectified. Even when the airway is open, partial obstruction often occurs and results in loud, irregular snoring sounds caused by air rushing through the narrow passage and stimulating the soft palate, uvula, throat walls and tongue to vibrate. However, once the patient is asleep again the obstruction rapidly recurs and the cycle may repeat many times throughout the sleep cycle.

These pathophysiological processes underlying the upper airway closure form the basis of treatment for OSAHS, which aim to raise pharyngeal pressure above closing pressure or decrease the closing pressure or increase upper airway muscle activity (Kuna and Sant'Ambrogio 1991).

2.6 PREVALENCE

OSAHS is a potentially life threatening breathing disorder. Estimates of the prevalence are dependant on the age and sex of subjects studied as well as the definition and method of diagnosis used by the study (Taylor 1995).

OSAHS has a suggested prevalence of 2% in the general population, with an increasing prevalence seen in middle-aged, overweight male subjects and with a corresponding lower incidence in women. The most recent, comprehensive studies carried out by Young et al in 1993, suggest that 4% of middle aged men (aged from 30-60 years) and 2% of middle aged women suffer from OSAHS.

Guilleminuault reported in 1985 that 70% of adult sufferers of OSAHS also snored as children. Epidemiological studies of habitually snoring children suggest a prevalence of 7 to 12% (Ali et al. 1993, 1994). Children who snore are reported to be mouth breathers or restless sleepers, have excessive daytime sleepiness, are hyperactive, have poor hearing and may present with a bilateral crossbite (McDonald 1995, Caroll et al. 1995). Although snoring has been reported to be a common finding in children, only a small subgroup of these habitually snoring children have OSAHS.

Common clinical findings in adults include mild-moderate obesity, with a Body Mass Index (BMI) greater than 29kg/m^2. A neck circumference greater than 42.5 cm is relevant as subcutaneous masses externally compress the pharynx. Excess fat deposition in the palate, tongue and pharynx, are often seen and intrapharyngeal visceral fat masses have been shown to narrow the airway (Friedlander et al. 2000, McDonald 1995).

Also at risk are individuals with small posteriorly positioned maxillae, micrognathia and retrognathia. The tongue, which may be enlarged, has a tendency to have reduced functional space or a relative macroglossia, thus forcing it posteriorly toward the pharyngeal wall and superiorly above the plane of occlusion. The soft palate, which is usually enlarged and elongated, is positioned posteriorly, adjacent to the pharyngeal wall. The uvula is also usually obscured during phonation as it lies below the base of the posteriorly/ superiorly positioned tongue (Battagel and L'Estrange 1996).

Alcohol, particularly when ingested close to sleep, increases the number of obstructive events and prolongs their duration. Central nervous system depressant drugs, independent of their type, taken close to sleep, have a similar effect.

Partial sleep deprivation, including shift work, may impact on certain subjects, as may respiratory allergies, time spent above an altitude of 1,500 meters and environmental factors such as smoking or the working environment i.e. dust and conditions leading to silicosis or asbestosis.

2.7 DIAGNOSIS

The diagnosis of OSAHS is established following a comprehensive history, which should explore the patients' and the sleeping partners' account of the symptoms and include comment upon choking attacks, nocturnal or morning headaches, gastro-oesophageal reflex, nocturia, impotence, involuntary limb movements, poor memory, concentration, unrefreshing sleep and mood changes. Although this extensive list of symptoms is important, snoring and daytime sleepiness are the key symptoms in OSAHS.

The history is supported by the use of questionnaires such as the Epworth Sleepiness Scale which is used to assess daytime sleepiness (Johns 1991).

Lateral Cephalometry is also an established tool in the investigation of the airway in OSAHS subjects both for diagnostic purposes and to monitor the changes in the airway response to mandibular protrusion (Lowe et al. 1986, Johal and Battagel 1999, Schmidt-Nowara et al. 1995). It has been demonstrated that posture has a significant effect on the upper airway dimensions and as a consequence the use of supine rather that traditional upright radiographs has been reported to be more meaningful (Johal and Battagel 1999).

A full ear nose and throat examination is undertaken and awake video nasopharyngoscopy can also be used, a procedure carried out under local anaesthetic in which the patient is asked to perform a reverse Valsalva manoeuvre i.e. to take a deep inspiration with a closed nose and mouth to allow location of the site of airway collapse, base of tongue, pharyngeal walls or soft palate.

Body Mass Index calculation is also performed. BMI is determined from the patient's weight and height.

$$\text{BMI} = \frac{\text{weight (kg)}}{\text{height}^2\,(\text{m})}$$

2.7.1 Polysomnography

Multichannel overnight polysomnography remains the gold standard diagnostic tool and is regarded as the definitive investigation for the diagnosis of OSAHS, as it permits the physician to distinguish between simple snoring and true OSAHS.

An overnight sleep study is conducted in a laboratory with computerised recording equipment; many parameters are recorded such as:

Neurophysiological recordings monitor sleep stage and arousals.

Electroencephalography

Electromyography - measuring submental muscle tone

Electrooculography - measuring eye movements

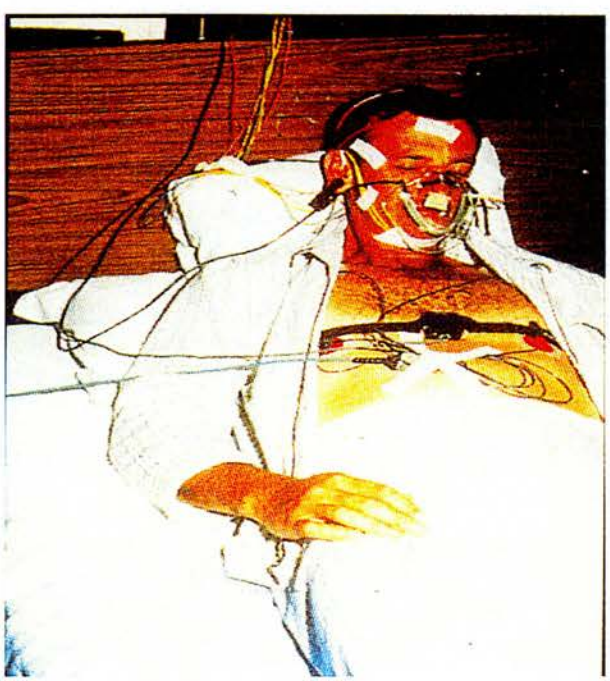
Respiratory tests - measure oxygen intake via oronasal flow, rib cage and abdominal wall motion and arterial oxyhaemoglobin saturation

Throat microphone detects snoring sounds

Cardiological tests to document secondary cardiovascular changes i.e. electrocardiograph, ECG and blood pressure.

Some institutions have initiated the use of a portable sleep monitoring device for home use by patients, which is highly cost effective as it does not require an overnight stay in hospital or the presence of technical staff throughout the night. It also has the added benefit of the patient sleeping in a familiar environment and the possibility therefore, of a more accurate recording of a typical night's sleep (Friedlander et al. 2000).

Figure 2: Patient undergoing polysomnography



2.7.2 Epworth Sleepiness Scale

This is a simple self-administered questionnaire, which is shown to provide a measurement of the subject's general level of daytime sleepiness (Johns 1991). It was first developed by Murray Johns at the Sleep Disorders Unit of the Epworth Hospital in Melbourne, Australia in 1991 and is shown in Appendix 1.

It has many advantages over the alternatives for determining daytime sleepiness, such as the **Maintenance of Wakefulness** (MWT), in which the time taken to onset of sleep is measured with the subject sitting in a dimly lit, warm quiet room trying to stay awake. The **Multiple Sleep Latency Test** (MSLT) is based on the premise that the sleepier the subject the quicker he will fall asleep when encouraged to do so by lying down in an unstimulating environment.

The MSLT has shown reasonably high test-retest reliability over periods of months in normal subjects (Johns 1991). Assuming that this same reliability is true for patients with OSAHS, the MSLT was considered the standard method for measuring their daytime sleepiness. However these methods are time consuming, expensive and inefficient to perform on a patient group.

Other tests have been suggested based on pupillometry, or cerebral evoked potentials and even prolonged psychomotor performance tests, but these test have proved unreliable and inconsistent in different subjects, as well as being expensive and time consuming to perform (Johns 1991).

The Epworth Scale is designed to measure sleep propensity in a simple, standardised way, and was derived from observations about the nature and occurrence of daytime sleep and sleepiness. For example, some people who suffer from excessive daytime sleepiness keep themselves busy and choose not to lie down and sleep, thereby purposely avoiding daytime sleep. However, others who may be bored, with spare time or who are socially withdrawn, but not sleepy, choose to lie down and sleep during the day.

Around 50% of healthy medical students usually sleep during the day at least once in an average week, and among a cohort of 22-year-old French army recruits, 19% reported sleeping during the day, regularly or occasionally, but only 5% complained of daytime sleepiness, hence the frequency or length of sleep during the day probably does not provide a useful measure of sleepiness (Johns 1991).

Sleepy people often describe how they doze inadvertently whilst engaged in activities that require low levels of stimulation, relative immobility and relaxation,

such as sitting and watching television. The Epworth Scale refers to eight such activities or situations, some known to be very soporific and others less so.

The Epworth scale attempts to compensate for the fact that people have different daily routines, some facilitating and others inhibiting daytime sleep. The Epworth scale does not ask how frequently the subject falls asleep whilst watching television, as that would depend on how frequently he watched television as much as his sleepiness. Instead the subject is asked to rate his sleepiness, on a scale of 0-3, the chances of dozing when watching television.

One question asks how likely the subject is to doze off while lying down to rest in the afternoon when circumstances permit. It was felt that normal people probably would and that sleepy people certainly would tend to doze in that situation. Never to do so would indicate an unusually low level of sleepiness as described by some insomniacs. Other situations are included in the questionnaire as it is believed that only the most sleepy people would doze in them, such as whilst sitting and talking to someone and in a car while stopped for a few minutes in traffic. These extremes act to control the questionnaire.

Epworth Sleepiness Score

The numbers reported in the eight situations are added together with a maximum possible score of 24. ESS has proved capable of distinguishing individuals and diagnostic groups over the whole range of daytime sleepiness (Johns 1991).

Johns showed that a questionnaire based scale as brief and simple as the Epworth can give a valid measure of sleep propensity in adults. He showed that the ESS significantly distinguished groups of patients who are known from other investigations to have differences in their levels of sleepiness, as measured by MSLT. The ESS was significantly correlated with sleep latency measured during the day with MSLT's and at night with polysomnography. There was also a significant positive correlation between the sleep latency at night and during the day in the same subject.

An ESS greater than 15 is indicative of a high level of daytime sleepiness, and is usually encountered in patients with moderate or severe OSAHS. However a high ESS alone is not diagnostic of a particular sleep disorder, any more than a sleep latency of 5 minutes would be in a MSLT.

The Epworth scale does not distinguish the nature of long term physiological or pathological processes that produce a particular level of sleep propensity. More searching investigations, including overnight polysomnography are required for that.

The Epworth scale assumes that subjects can remember whether they have dozed or not during the day in various situations. Johns in 1991, showed that most patients can give meaningful self reports about this aspect of their behaviour and that their ESS provide a measurement of their general level of daytime sleepiness, from low to very high levels. This has not been shown previously by any other published questionnaire system (Johns 1991).

2.7.3 Apnoea Hypopnoea Index (AHI)

This is used by many clinicians to confirm diagnosis and to quantify the severity of illness. The AHI is calculated by adding the number of apnoeas, which is the cessation of breathing for 10 seconds or more, to the number of hypopnoeas, defined as the reduction in tidal volume by more than 50% of the baseline measurement for more than 10 seconds, accompanied by a 3% or greater fall in oxygen saturation or arousal from sleep, and dividing it by the number of hours slept.

$$\text{AHI} = \frac{\text{Total Apnoeas} + \text{Total Hypopnoeas}}{\text{Number of hours slept}}$$

Mild OSAHS is defined as an AHI of 5-20 events per hour of sleep, with an AHI of over 15 being clinically significant. Moderate OSAHS is indicated by an AHI of 20-40 events per hour of sleep and severe as an AHI of greater than 40.

2.8 MANAGEMENT

In the early 1980's, when sleep clinics in the UK first began to treat substantial numbers of OSAHS patients, the main indication for their treatment was subjective daytime sleepiness, as assessed by the Epworth Scale (Johns 1991).

In recognition of the multifactorial nature of OSAHS, current management strategies focus around a multidisciplinary approach to treatment, involving a respiratory physician, an ENT surgeon and an orthodontist. This combined approach to treatment makes use of the following recognised treatment modalities:

- Weight loss
- Cessation or reduction of smoking
- Cessation or reduction of alcohol or drug intake
- Surgery
- CPAP
- Oral Devices

2.8.1 Weight Loss

If a patient presents with a Body Mass Index higher than 30 he or she may be classified as obese (Popoola 2004). It is known that increased BMI exacerbates snoring and OSAHS, therefore patients who are obese are advised to lose weight both as a first stage in treatment for their condition but also as a general health precaution (Partinen 1988).

Battagel and Johal showed in 2000 that all OSAHS patients exhibit some anatomical basis for their condition, and that this is compounded by soft tissue factors in obese patients (Battagel and Johal 2000). This study failed however to demonstrate any significant correlation between severity of OSAHS and obesity, possibly due to the small numbers of patients involved in the study. Other studies have demonstrated a positive significant correlation between AHI and BMI or neck circumference, but further work is required in this area to confirm the nature of the relationship between BMI, severity of OSAHS and cephalometric anomalies (Partinen 1988, Davies and Stradling 1990, Hoffstein 1992).

One possible explanation for the relationship between obesity and OSAHS is narrowing of the airway due to increased fat deposition in the pharyngeal walls of obese patients. Magnetic Resonance Imaging can highlight areas of increased fatty deposition surrounding the collapsible segment of the pharynx in OSAHS patients.

The amount of detected fatty deposit has been shown to correlate significantly with AHI (Shelton et al. 1993).

The upper airway may also be narrowed in obese patients due to external compression by superficial fat in the neck, explaining the finding that increased neck circumference correlates closely with OSAHS (Davies and Stradling 1990, Stradling 1995). Loss of fat surrounding the airway allows it to dilate more fully. Permanent weight loss for OSAHS patients is more difficult than for the general population as they have a lowered basal metabolic rate (Friedlander et al. 2000).

Ferguson showed in 1995 that there is a spectrum of upper airway soft tissue and craniofacial abnormalities among OSAHS patients, including obese patients with increased upper airway soft tissue structures, non-obese patients with abnormal craniofacial structure and an intermediate group of patients with abnormalities in both craniofacial structure and upper airway soft tissue structure.

2.8.2 Alcohol and Drug Use

Alcohol is a Central Nervous System depressant and will contribute to the hypotonicity of the muscles of the pharynx, soft palate and tongue, relaxing the upper airway and permitting collapse, especially significantly if taken before sleep.

Benzodiazepines, narcotics and barbiturates cause relaxation of the musculature and therefore increase the likelihood or severity of snoring and OSAHS. In some circumstances Benzodiazepines are prescribed specifically for relief of muscle spasm. A side effect of this treatment is to further relax any postural reflexes, including those of the muscles in the pharynx (Smith et al. 1983).

Protriptyline, a non-tricyclic antidepressant, may be associated with a mild reduction in apnoeic episodes. It is thought that this occurs as a result of its REM sleep suppressant effects, or by augmentation of upper airway muscle tone (Smith et al. 1983).

If OSAHS patients are using any of these substances it may be possible to substitute for an alternative, in order to relieve the compounding effect they have on the patients sleep disorder.

2.8.3 Training

Techniques such as a golf ball in the back of the OSAHS patients' pyjamas or a firm pillow behind the patient have been advocated by some clinicians to prevent sleeping on the back. Cartwright et al in 1985, trained 10 OSAHS patients to avoid sleeping on their backs by wearing a gravity-activated alarm, which woke the patients up should they lie on their back for longer than 15 seconds. They found that the number of apnoeic and hypopnoeic events were significantly reduced. However the device itself initially caused awakenings and difficulty in obtaining a comfortable sleeping position.

2.8.4 Surgery

Surgical treatment of OSAHS aims to correct obstruction of the airway or bypass it. Current surgical options are:

1. Nasal surgery if there is an obvious cause such as a polyp or alar collapse
2. UPPP, uvulopalatopharyngyoplasty
3. LAUP, Laser assisted uvulopalatoplasty
4. Tracheostomy
5. Orthognathic surgery

For many years bypassing the obstruction via a tracheostomy was the only effective treatment option for OSAHS. Permanent tracheostomy virtually always leads to a rapid improvement in daytime sleepiness and reversal of cardiopulmonary abnormalities in a few days (Djupesland 1987).

However, permanent tracheostomy is associated with psychosocial problems and potential complications and has generally been replaced by the UPPP procedure, uvulopalatopharyngyoplasty.

UPPP

Initially described by Ikematsu in 1964, it was described as a surgical alternative to tracheostomy in selected OSAHS patients. Principally the technique removes redundant tissue in the posterior nasopharynx and thus enlarges the oropharynx and reduces the degree of obstruction during apnoea.

UPPP can give some relief, particularly if the respiratory obstruction can be documented as occurring in the retro palatal area. The tonsils, the pillars, the uvula and a rim of soft palate are removed with a scalpel under general anaesthesia. The patients have a great deal of pain for a week, and regurgitation of fluids and hypernasal speech for 2 weeks (Maran 1996). Unfortunately symptoms tend to recur, with a success rate around 50% (Petri et al. 1994).

LAUP

A less radical resculpting of the soft palate can be performed using a surgical carbon dioxide laser or laser assisted uvulopalatoplasty, LAUP. The laser incorporates a special attachment to protect the posterior pharyngeal wall, and the operation takes place under local anaesthesia and intravenous sedation in a day surgery unit.

Both procedures are associated with significant postoperative discomfort and may result in palatal incompetence with nasal regurgitation on swallowing and nasal speech (Maran 1996).

Orthognathic Surgery

If the respiratory obstruction is discovered to be occurring at the base of the tongue and the patient is retrognathic the entire mandibular alveolus may be advanced and repositioned into a class one occlusion.

Because the tongue is attached to the lower jaw at the genial tubercles the anterior movement of the alveolus is accompanied by anterior movement of the tongue, away from the posterior pharyngeal wall. The tongue can be drawn even further anteriorly by performing a genioplasty. Positioning the chin forwards advances the attached geniohyoid and genioglossus muscles thereby repositioning the hyoid bone and the base of tongue anteriorly (Battagel 1996).

If the patient is not retrognathic and the respiratory obstruction is discovered to be at the base of tongue and soft palate, simultaneous surgical advancement of the maxilla and mandible is indicated. The maxilla is arbitrarily advanced 10-12 mm and the mandible advanced an appropriate distance to maintain class one occlusal contact. An advancement genioplasty can also be performed at this time if required. The results of this surgery while not always aesthetic do appear to ameliorate OSAHS in most instances (Waite et al. 1995).

Patients who have had soft palate and jaw surgery but who remain with severe symptomatic OSAHS may require a permanent tracheostomy to breathe at night. During the day however, the tracheal stoma may be obturated so as not to interfere with the activities of daily living. Currently patients tend to receive surgery for OSAHS as a last resort, if they are unable to comply with CPAP, tolerate an intra-oral device or if larger movements (6-12mm), of the tongue are required to move it anteriorly away from the posterior pharyngeal wall. This widely held view is based upon the increasing amount of literature demonstrating the limited efficacy and risks of UPPP (Wilhelmsson et al 1999).

2.8.5 Continuous Positive Airway Pressure (CPAP)

Nasally applied CPAP is highly effective and has become the major non-surgical, long term form of treatment, the so called gold standard (Sullivan et al. 1991, Grunstein 1995). It was estimated that in 1993 over 100,000 nasal CPAP units were sold worldwide, creating a health expenditure of around 100 million US Dollars for the equipment alone (Australian Health Technology Advisory Committee.1996).

Mechanism of Action

The original experiments were based on the concept that closure of the oropharynx was the result of an imbalance in the forces that normally kept the airway open.

A low pressure blower delivers a continuous stream of air into a sealed nasal mask that the patient wears whilst sleeping (Figure 3). The positive pressure pneumatically splints the airway open by preventing the soft palate and tongue from collapsing against the pharyngeal walls, while permitting periodic expiration. There is no reflex increase in upper airways muscle activity (Grunstein 1995).

Figure 3: Patient using CPAP

CPAP corrects arterial oxyhaemoglobin desaturation, eliminates carbon dioxide retention, restores the normal drive to breathe, stabilises blood pressure and permits unfragmented sleep. CPAP can also reduce the patients' sleepiness and improves their cognitive performance and mood. The Oxford Healthy Life survey found a marked improvement in self reported physical, mental and social domains of OSAHS patients who were treated with CPAP therapy (Friedlander et al. 2000).

The findings of the Australian National Health Medical Research Council are consistent with those of the Oxford survey and in addition show that CPAP is highly cost effective (Australian Health Technology Advisory Committee.1996). The report notes that individuals who successfully use CPAP gain an average of 5.5 quality adjusted life years (QALYS) at an approximate cost of £2000 per QALY gained. (£11,000)

Compliance

Unfortunately long term compliance with CPAP has been shown to be difficult for some patients with only 66% patients using the device long term and many using it only for limited hours during sleep (Walker-Engstrom et al. 2000). A study carried out by Engleman in 1994 estimated that long term compliance with CPAP was between 60 and 70%.

Complications

Side effects related to CPAP are mostly minor and the long term effect is discontinuation or reduced usage of CPAP. The most common complaint, expressed by 46% of patients, was nocturnal awakenings (Hoffstein 1992). Common side effects, approximately 30-50% of patients, include; dryness, burning sensations and congestion of the nasal mucosa, claustrophobia, machine noise and less intimacy with bed partner (Caroll 1995, Grunstein 1995).

Patients with a class II malocclusion are almost uniformly uncomfortable with the fit of the mask and often fail to use it as prescribed.

Several factors are associated with improved compliance, including the simplicity of the regime, family support, patients' perception that their disease is serious, belief that the proposed therapy will be effective, patient understanding of the rationale of treatment, provision of details of the treatment planned and a close patient-clinician relationship, including close clinical supervision of therapy (Grunstein 1995).

One of the great advantages of nasal CPAP is that it is immediately effective in relieving OSAHS. It may also be used on a trial basis and withdrawn if not tolerated, in contrast to a surgical option.

2.8.6 Oral Devices

Dentists use oral devices for many purposes; including the correction of various types of occlusal disorder. They have been considered as a treatment for mandibular deficiency and upper airway obstruction for many years, the earliest report being by Robin in 1934. Oral appliances of various designs have been proposed and are used increasingly in the treatment of snoring and mild to moderate sleep apnoea (Figure 4).

The techniques used often modify the position of the mandible. The extent of this mandibular positioning is limited by the temporo-mandibular joint and the pterygoid muscles. Oral appliances offer an attractive alternative for both Clinician and Patient in cases of snoring or OSAHS, where the alternatives are unsatisfactory or more complex, for example surgery or CPAP.

As a consequence of the limitations of CPAP, and increasing success rates reported with intra oral devices, the use of intra-oral mandibular advancement devices has been investigated by a number of workers, including a Task Force of the Standards of Practice Committee of the American Sleep Disorders Association (Schmidt-Nowara et al.1995, Battagel and L'Estrange 1996, Shadaba et al. 2000).

The Royal College of Physicians of England in a publication on the subject of OSAHS has acknowledged the participation of Dentists in the management of patients with this disorder (Gibson 1998). They report that there is an increasing amount of evidence that intra-oral devices are useful in the management of patients with mild to moderate OSAHS.

The RCP based its recommendation on the results of studies which have shown that oral appliances improve symptoms; overnight breathing patterns can reduce the AHI by more than 50%, improve both the arterial oxygen saturation and sleep quality in approximately 50% of patients with OSAHS (Ferguson et al. 1996, Schmidt-Nowara et al. 1995).

Mechanism of Action

These appliances aim to modify the position of the upper airway structures, either by increasing the size of the airway or by reducing its collapsibility. This is effected by drawing the tongue and soft palate forwards, and so maintaining the patency of the airway during sleep. Devices such as the palate lifter or the tongue retainer (Figure 5) have been used in the past (Cartwright 1982). The most widely used device, however is the mandibular repositioning splint (Figure 4).

Mandibular advancement appliances have been demonstrated, using cephalometric radiographs, to increase various upper airway dimensions in patients when they are awake (Bonham 1988, Schmidt-Nowara et al. 1995, Evelof 1994). These studies indicate that dental devices produce complex changes in the shape and function of the upper airway that may positively influence airway patency during sleep.

However, these studies may have limitations as the observations were made in patients who were awake, and the appliances are constructed to be worn in the sleeping patient.

Figure 4: Mandibular Repositioning Splint

Mandibular Positioning

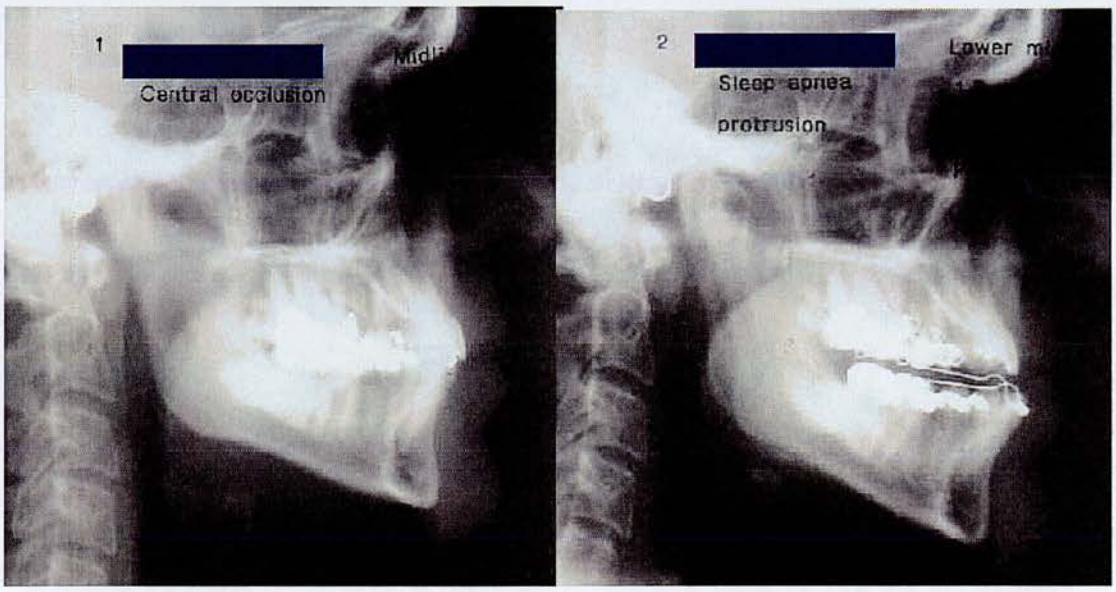
Removable mandibular repositioning devices are constructed so that the lower jaw is positioned between 2 and 5mm anteriorly, which is usually between 50% and 100% of the patient's maximum protrusive distance, therefore advancing the tongue passively due to its attachment to the genial tubercles.

Friedlander et al. 2000, Johal and Battagel 1999 and Clark et al. 1996 have suggested, based on their clinical experience, that the optimum distance for forward positioning of the mandible should be around 75% of the subject's maximum protrusion, to a position which is comfortable for the patient. Clarke et al. 1996 further quantified this movement as being 7mm or more in order to gain the maximum reduction in AHI.

These movements enlarge the airway and reduce the likelihood that the tongue or soft palate will collapse against the posterior pharyngeal wall when the patient inspires during sleep.

Figure 5 demonstrates the radiographic appearance of a patient wearing a mandibular repositioning splint, which can be compared to a radiograph of the same patient in centric occlusion on the left.

Figure 5: Radiographic Appearance With and Without Appliance.



Design

There are major design differences in the numerous devices available and these differences impact on success and compliance rates.

Construction requires dental impressions, bite registration and fabrication by a dental laboratory. Some devices are available in prefabricated form, as a thermoplastic material which can be moulded to fit the patients' teeth.

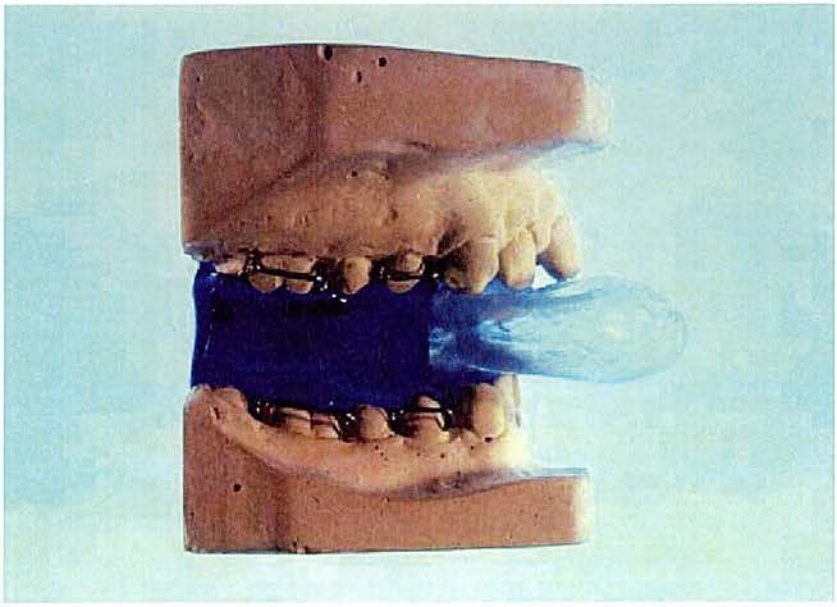
Devices can be produced as either a one or two piece appliance. A fixed or one piece appliance positions the mandible anterior to the maxilla and may be retained by the use of clasps, acrylic or thermoplastic polymer. Anterior breathing holes can be added to allow oral respiration for those with restricted nasal airflow.

Non-fixed or two piece devices, where there is a separate appliance for each arch, positions the mandible anteriorly and is secured to the maxilla by the use of thermo-plastic buttons, inter arch elastics or a buccal tube and rod. The two piece appliance affords the patient greater control by permitting lateral mandibular movement.

Most intraoral devices are designed to relieve snoring or sleep apnoea and advance the mandible i.e. the Snorebuster (Figure 4) and the Herbst, but there is a second class of intra oral appliance, the tongue retainer (Figure 6). This appliance aims to keep the tongue in an anterior position during sleep. The tongue is secured by means of negative pressure in a soft plastic bulb. A flange, which fits between the lips and teeth, holds the device and tongue anteriorly in the oral cavity. This device will produce some modification in mandibular posture, mainly by downward rotation.

With all oral appliances proper fitting and adjustment is important and a professional society of dentists interested in sleep disorders has issued recommendations for the implementation of oral appliance therapy (Lowe et al. 1994). The potential for worsening of the airway function should be recognised as a few patients may suffer worse Apnoea-Hypopnoea frequencies after treatment (Cartwright 1982).

Figure 6: Tongue Retainer



Complications

Side effects with treatment are usually mild and improve with time. Initial adverse side effects associated with intra oral devices may prevent early acceptance of the device. Transient discomfort in the muscles of mastication for a brief time after awakening is commonly reported with the initial use of oral appliance, as is excess salivation (Schmidt-Nowara et al. 1995, Heath 1993). Later complications may include TMJ discomfort and changes in occlusion. All these symptoms have been reported as reasons for discontinuing treatment.

Efficacy of MRS in the Treatment of Snoring

Many published clinical studies in which snoring has been assessed, using a variety of different devices and based on reports of patients or sleep partners, show improvements in symptoms for a significant proportion of patients (Schmidt-Nowara et al. 1995). In Johal and Battagel study (1999), 76% of subjects reported an improvement in snoring and daytime sleepiness.

Possible mechanisms for the improvement in snoring include an increase in oropharyngeal and hypopharyngeal dimensions with associated reduction in turbulent airflow in the region or an increase in pharyngeal wall tone (Sullivan et al. 1981).

Efficacy of MRS in the Treatment of OSAHS

In a review of 21 publications undertaken by the American Sleep Disorders Association in 1995, the mean AHI with mandibular repositioning splint treatment appeared to reduce from 47 to 19 (Schmidt-Nowara et al. 1995).

This study however has the following limitations:

1. It consists entirely of case series, with relatively small sample sizes
2. It lacks randomised controlled studies
3. The descriptions of the patients, their selection criteria and the study methods used were varied and incomplete.

Since this publication a number of prospective randomised controlled trials have reported on the use of mandibular repositioning appliances in OSAHS (Ferguson et al. 1996, Clark et al. 1996, Bloch et al. 2000, Mehta et al. 2001).

Two studies (Ferguson et al. 1996 and Clark et al. 1996) compared MRS with CPAP and concluded that the MRS achieved substantial success in reducing AHI, but was less effective than CPAP. The compliance rate in both studies was similar with the

patients reporting that they strongly preferred treatment with the splint. Both these studies have limitations in that no power calculation is reported and the sample sizes are low.

Bloch et al. (2000) reported the results of a randomized, controlled crossover trial of two oral appliances for sleep apnoea with different designs and found that the AHI reduced from 22.6 to 8.7 with a two piece appliance and to 7.9 with a single piece appliance. Patients reported that they preferred the one piece appliance due to its simplicity. This trial however reports on a small sample size and compares one appliance with another failing to use a control.

A randomised controlled study of an MRS for Obstructive Sleep Apnoea was reported in 2001 by Mehta et al, who found subjective improvements in symptoms were reported in 96% of patients. He also reported significant improvements in patients using MRS in AHI, minimum oxyhaemoglobin saturation and in arousal index with a third of patients having their OSAHS completely controlled by this treatment. It was also found that this treatment improved the patients sleep architecture, with redistribution to more REM sleep and less NREM sleep.

Mehta et al's study design however, allowed the patients to elect to use an MRS rather than the conventionally advocated CPAP, which may have led to sample bias.

In summary, despite the considerable variation in design of MRS appliances the clinical effects seen are consistent with OSAHS improving in the majority of subjects. All reports discovered in the Literature Review show a significant improvement in average AHI when wearing an appliance. Studies also suggest that the greatest success is to be found in mild to moderate cases of OSAHS.

Compliance

"Compliance" is a complicated term involving a number of factors. It is important to recognise that 40-50% of patients do not use medication as prescribed, and that compliance is not associated with age, sex, education, economic status, or disease characteristics (Grunstein 1995).To improve compliance patients must receive initial written instruction regarding the use of their device in order to produce the best compliance rates (Schmidt-Nowara et al. 1995).

Data on long term compliance with mandibular repositioning splints are limited in number, with a range from 52 to 100% compliance being reported in the literature (Schmidt-Nowara et al. 1995, Ferguson et al. 1996, Clark et al. 1996, Shadaba and Battagel 2000).

Management Decisions

In the treatment of OSAHS, no currently available treatment provides the ideal combination of a high rate of success and patient acceptance without complications. Nasal CPAP has become the gold standard treatment due to its efficacy, but patient acceptance and compliance are significant problems (Engleman et al. 1994). Tracheostomy is the only other treatment with an efficacy comparable to CPAP, but given the broad range of alternatives few patients choose a treatment option requiring a permanent prosthesis in the neck.

Oral appliances are effective, therapy is relatively inexpensive and may be withdrawn at any point. It has also been found to have a better success rate than soft tissue surgery (Wilhelmsson 1999). Compared to protriptylene, the principle medication used for OSAHS, oral appliances are more effective and the side effects more tolerable (Schmidt-Nowara et al.).When compared to weight loss the effect of oral appliances is realised more quickly and the rate of success higher.

Hence oral appliances although producing a lower rate of AHI reduction can offer a viable alternative to CPAP. The combination of side effects, complications, reversibility and cost compares favourably with any other treatment for mild to moderate OSAHS. Oral Appliance therapy for snoring and or OSAHS is simple, reversible, portable, quiet and cost effective and may be used in patients who are unable to tolerate CPAP or are a poor surgical risk.

2.9 THE ROLE OF UPPER AIRWAY ANATOMY AND PHYSIOLOGY IN OSAHS

The upper airway comprises of both rigid and flexible structures. The structures allow for multiple functions to occur within the same space such as swallowing, vocalising and breathing. Breathing is the sole function which must be maintained during sleep.

The Nose

The bony nasal components, the septum, inferior turbinates and hard palate aid in maintaining patency during inspiration and expiration. These nasal bones are covered with a highly vascular mucosa that may swell to narrow or even occlude the nasal passages. Decreased nasal patency may contribute to OSAHS in several ways (Hudgel 1992).

1. Nasal obstruction with the mouth closed may result in an obstructed airway, which then results in arousal.
2. Nasal congestion may induce mouth breathing, which leads to posterior displacement of the mandible and anterior pharyngeal structures, producing hypo-pharyngeal narrowing.
3. Nasal congestion causes a large inspiratory pressure drop across the nose, which leads to a high subatmospheric pressure at locations within the potentially collapsible pharynx.

In the contribution of nasal pathology to OSAHS, nasal decongestion should be part of a therapeutic program for OSAHS if a patient exhibits nasal symptoms (Hudgel 1992). Repair of a deviated nasal septum may not help in the treatment of OSAHS, as this procedure does not decrease total nasal resistance. Its failure to relieve patients' symptoms of OSAHS confirms the relatively minor role that septal deviation plays in the aetiology of OSAHS (Hudgel 1992).

The Pharynx

The pharynx is composed of three segments:

1. **Nasopharynx:** Extends from the posterior aspect of the nasal turbinates to the horizontal plane of the soft palate. Its patency can be compromised by local mass lesions, scarring secondary to surgery, underdevelopment of local bony structures and palatal and uvular hypertrophy and oedema.
2. **Oropharynx:** The airway lies between the soft palate and the posterior base of tongue, its patency can be compromised by palatine tonsil hypertrophy or inflammation, palatal or uvular enlargement and macroglossia.
3. **Hypopharynx:** Extends from the base of tongue to the larynx, its patency can be compromised by macroglossia, retrognathia and posterior or superior displacement of the hyoid bone and surrounding structures

Normally the upper airway narrows during sleep. This change has been identified by measurement of total respiratory system resistance or specific upper airway resistance (Hudgel 1988). Upper airway resistance increases approximately two to three times in transition from wakefulness to non-rapid eye movement (NREM) sleep (Hudgel 1988). It has also been found that the average resistance is no higher in REM than in non-REM sleep, although the airway calibre is more variable during REM sleep. The same investigation by Hudgel in 1988 also revealed that the site of narrowing is in isolated areas rather than along the whole length of the pharynx. This finding of isolated loci of narrowing simulates the pattern of upper airway collapse seen in OSAHS. Measurements taken of differential pressures across the palate and hypopharynx also revealed that approximately 50% of OSAHS patients regularly obstruct at the level of the palate and 50% below the level of the palate in the hypopharynx. The area of collapse was an average of only $1cm^2$, again suggesting that the site of obstruction is rather specific and may be due to the airway being structurally narrower at these sites. Late in the apnoeic episode the obstruction extends inferiorly down the airway from its specific loci, due to the increased inspiratory effort generated by the chest wall muscles leading to a rise in suction pressure.

2.10 CEPHALOMETRIC ANALYSIS IN OSAHS

Cephalometric radiography, although having the limitations of any two dimensional image of a three dimensional (3D) object, has many advantages for imaging in patients with sleep-related breathing disorders. It has low cost, is widely available and is less invasive than other techniques of imaging.

Computerised Tomography (CT) and magnetic resonance imaging (MRI) scans can provide both transverse and sagittal measurements of airway dimension, but these scans cannot be justified routinely in patient assessment as they are time consuming, are prohibitively expensive for routine use and the equipment may often be difficult to access, CT also requires relatively high doses of radiation (Lowe et al 1986).

Cephalometric radiography is usually performed in the upright position and is used routinely in the diagnosis and treatment of OSAHS (Bacon 1989, Lowe 1994). In addition to providing information about the bony tissues, cephalometric radiographs may reveal information about soft tissue structures in the oropharyngeal passage. Cephalometric analysis has also been shown to be a valuable tool in the presurgical evaluation of OSAHS patients (Lyberg 1989).

A limitation of cephalometric analysis relevant to this study may be the effect on cephalometric measurements of a change in posture (Lowe et al 1986, Yildrim et al 1991, Battagel et al 2002).

Battagel et al. in 2002 analysed the radiographic changes that occurred in the airway and surrounding structures when subjects with sleep disordered breathing moved from the upright to the supine position. They found that when moving from the upright to the supine the antero-posterior dimensions of the oropharyngeal airway decreased at all levels, with a concomitant reduction in cross-sectional area. The narrowing was most severe behind the soft palate, where the minimum airway reduced by approximately 40 per cent. They found that there were no differences between the non-apnoeic snorers and the OSA subjects in any of the postural changes recorded.

Some caution must therefore be exercised when relating results of upright cephalometry as used in this study, to events occurring during sleep in the supine position. Despite this controversy the upright cephalometric radiograph remains the most popular clinical tool in the assessment of upper airway size for diagnostic and therapeutic purposes (Pracharktam et al 1994).

Classification

It has been demonstrated that patients with OSAHS show different anatomical features upon radiological examination than patients who do not suffer the condition (Lowe 1986).

Severity of OSAHS can be considered as a continuum of signs and symptoms from mild to severe. A clinical need exists to quantify the structural components and identify morphological characteristics which distinguish patients with or who are predisposed to severe disease from those with simple snoring.

Historically, Jamieson et al. published the first large scale systematic cephalometric analysis of OSAHS patients in 1986. They examined one hundred and fifty five OSAHS patients' radiographs and a control group of forty one adult orthodontic patients. They found commonly that there was retro positioning of the mandible, cranial base flexure with the nasion-sella-basion angle more acute than expected. The hyoid bone was also displaced to a lower position than normal and the length of the soft palate was increased.

Several studies have attempted since to identify and utilise these anatomical features to classify OSAHS patients.

Bacon et al. in 1989 used cephalometric variables in a stepwise discriminant analysis to classify forty three male subjects with OSAHS and forty male dental students. The four cephalometric variables that entered the discriminant model were soft palate length, sagittal dimension of upper face, anterior cranial base length, and lower face height. By using these four variables he was able to correctly classify 93% of the study population.

However, this model did not include age or weight which are known to play an important role in developing OSAHS. The control group consisted of male dental students who were not matched in age to the experimental group and the study lacked randomisation.

Pracharktam et al. in 1996 carried out a similar study in which age and weight were included in the discriminant function and were able to correctly classify 82% of the OSAHS patients and 87% of snoring patients. They also found that variables related to the soft tissues, hyoid bone to mandibular plane, BMI and soft palate length had the highest predictive value, and suggested that cephalometric measurements could be used to identify subjects with and without OSAHS.

Tsuchiya et al. carried out a cluster analysis of 84 adult males with OSAHS in 1992 and found that there were two distinct subgroups of OSAHS:

i.) Patients with a high AHI and low BMI ratio had proclined mandibular incisors, retruded mandibles and a skeletal open bite tendency, i.e. they had skeletal deformities contributing to their OSAHS which may respond well to mandibular advancement procedures.

ii.) Patients with low AHI and high BMI ratio had inferiorly placed hyoid bones and large soft palates, i.e. they had soft tissue abnormalities which may respond well to weight loss measures or surgical techniques.

The verification of cephalometric variables which may predict the anatomical risks associated with OSAHS may impact on both the diagnosis and treatment, facilitating treatment decisions.

Anatomical Differences

Since the work of Bacon et al. (1989), further research has been carried out confirming a series of anatomical differences between OSAHS sufferers and "normality". This research will be considered in chronological order.

Lowe et al. (1986) demonstrated by examining CT reconstructions of tongue and airway in 25 OSAHS sufferers, that the majority of subjects displayed a single oropharyngeal constriction and that 6 of the subjects demonstrated two constrictions, one in the oropharynx and one in the hypopharynx. He also showed that subjects with severe OSAHS tended to have larger tongue surface areas and smaller airway surface area.

It must be borne in mind that the subjects involved in this study were not randomly selected and the results not compared to any control group.

Djupesland et al. (1987) studied the cephalometric oropharyngeal soft tissue profiles of 25 OSAHS patients and 10 controls. They reported that the length of the soft palate was significantly longer and thicker in the OSAHS group and the distance of close contact of the tongue and soft palate was also longer. The hyoid bone was more inferiorly positioned, giving the tongue a more upright appearance with more tongue tissue at the hypopharyngeal level. The oro and nasopharyngeal airway space were also significantly reduced anteroposteriorly.

Based on the findings of this cephalometric study a modified UPPP surgical technique was developed for the treatment of OSAHS.

Lyberg et al. (1989) studied 25 oropharyngeal soft tissue profiles of OSAHS patients and 10 controls by cephalometric analysis. He found that the length of soft palate was significantly longer and that there was a longer distance of close contact between the tongue and soft palate in OSAHS patients. The area of soft palate was also larger in OSAHS patients and occupied a greater proportion of the pharyngeal area, which was found to be reduced in anteroposterior dimensions at the nasopharyngeal, velopharyngeal and hypopharyngeal levels in OSAHS patients. The tongue was also found to be more inferiorly positioned in these patients, giving the tongue a more upright position with more of the tongue tissue at the hypopharyngeal level than was found in the control group.

However, this study reports cephalometric analysis in 25 OSAHS middle aged patients who were not randomly selected and who were compared to a control group of students who were not age matched to the experimental group, in fact the age ranges of the two groups had no cross over.

Tangugsorn et al. (1995) found in a comprehensive cephalometric analysis of 100 male patients with OSAHS and 36 male controls that there were several significant differences in morphology between the control and experimental groups.

1. Cranio-cervical facial skeletal differences

The OSAHS group in Tangugsorn et al's study had a shorter cranial base length, shorter maxillary length but with normal height, maxillo-mandibular retrognathia, 47% had mandibular retrognathia, an increased anterior lower facial height and increased mandibular plane angle, reduced size of bony pharynx, inferiorly positioned hyoid bone at C4-C6 level and a deviated head posture with larger cranio-cervical angle.

2. Uvulo-glossopharyngeal differences

The OSAHS group had increased length, thickness and area of soft palate, which held a more upright position and occupied more pharyngeal area. The contact length between soft palate and tongue was increased twofold; the tongue was larger, despite being a similar length and height and took up more oral area. There were also decreased sagittal dimensions of nasopharynx, velopharynx and minimum distance between base of tongue and posterior pharyngeal wall.

However to criticise the methodology, the possibility of errors being introduced could have been reduced by digitising the radiographs directly from the radiograph rather than by hand tracing first and then digitising. This introduces the possibility of errors at two points when tracing and again when digitising.

Battagel and L'Estrange (1996) studied the cephalometric morphology of patients with Obstructive Sleep Apnoea in a well designed, prospective study of 59 dentate Caucasian males. Where 35 subjects had proven OSAHS and 24 served as controls, with no history of respiratory disease. They found no differences in conventional Cephalometric variables between the two groups. But found that there were significant reductions in the lengths of mandibular body, cranial base and cranial base angle in OSAHS subjects. The width of the oropharynx was also significantly narrower in this group, especially in the post palatal region. The area of the soft palate was increased although that of the tongue was not. Intermaxillary space was decreased and the area in which the tongue had to function was smaller in OSAHS subjects than in controls. Discriminant analysis then demonstrated 100% discrimination between the OSAHS and normal subjects.

Battagel et al. (2000) carried out a prospective, controlled cephalometric comparison between 115 dentate male, Caucasian subjects with snoring and Obstructive Sleep Apnoea. They showed significant inter-group differences in cranial base angle and mandibular body length, showing that in the OSAHS and snoring groups anatomical differences place the entire facial complex closer to the cervical spine. They also found that both snorers and OSAHS subjects exhibited narrower airways and reduced oropharyngeal areas and shorter thicker soft palates with larger tongues than the controls. The comparison of the two sleep disorder groups showed no difference in any other skeletal or dental variables. In the OSAHS group however the soft palate was larger and thicker, both lingual and oropharyngeal areas were increased and the hyoid was further from the mandibular plane than in the snoring group. She felt that the dento-skeletal patterns of the snorers resembled those of the OSAHS group, but with differences in soft tissue and hyoid orientation, and that the Cephalometric morphology associated with snoring supports the idea that snoring is part of a continuum between normality and OSAHS.

Liu et al. (2000) examined the effects of a mandibular repositioner on OSAHS. The study was carried out on 22 OSAHS patients, a small group. It was found that appliance wear decreased AHI in 21 out of 22 patients and that a significant linear correlation was found between the reduction in AHI and specific craniofacial skeletal structures. Subjects with a smaller reduction in AHI tended to have shorter anterior cranial bases, steeper mandibular planes and smaller upper to lower facial height ratios.

However the patients were not randomly selected to take part in this study; they were selected to have Class II division 1 malocclusions. This should be borne in mind when considering the results of this study and OSAHS patients with other malocclusions.

Pracharktam et al. (1996) summarise the major differences between OSAHS sufferers and "normality" seen on lateral cephalometric radiographs when they state that," Lateral cephalometric radiographs of patients with suspected OSAHS usually demonstrate a retropositioned maxilla and mandible, a shortened cranial base, an inferiorly placed hyoid bone, an enlarged soft palate and tongue and a narrowed posterior airway space."

Head Posture

It has been proposed that head posture may be related to OSAHS. Solow et al. (1993), examined head posture on lateral cephalometric radiographs from 50 male OSAHS sufferers. They found that the cranio-cervical angle was extremely large, exceeding his control sample by 1-2 standard deviations. They proposed that this large cranio-cervical angle in OSAHS patients was a physiological adaptation aiming to maintain airway patency, whilst the head and visual axis is kept in its natural relationship to the true vertical. They also suggested that monitoring of the cranio-cervical angle may be useful in assessing the effect of various treatment modalities.

Ozbek et al. in 1998 also demonstrated a significant relationship between head posture and OSAHS. They showed that cranio-cervical extension (CCE) and a forward head posture in OSAHS patients were correlated with a higher disease severity. The patients also had longer, larger tongues, a lower hyoid bone position in relation to the mandibular plane, smaller nasopharyngeal and larger hypopharyngeal cross sectional areas, and a higher BMI. They concluded that a CCE with a forward head posture is more likely to be seen in severe and obese OSAHS patients with the morphological characteristics described.

2.11 PATIENT SATISFACTION

When any treatment is provided by a health care professional it is important to take into consideration how that care is viewed and valued by the patient. Historically in the development of health care there have been periods where consideration of the patients' wishes has been so paramount that it has inhibited the development of scientific medicine, as was the case in the eighteenth century (Fitzpatrick 1997).

However, in the first half of the twentieth century medicine became so concerned by biomedical and technological aspects of disease that the opposite extreme was reached, that of the frequent neglect of patients' wishes and preferences. In recent times health care systems have sought to achieve balance in their services, which aim to be effective and scientifically evidence based but at the same time sensitive to patients.

Maxwell (1984) identified six dimensions we should judge the quality of a modern health service by;

1. Access
2. Relevance to need
3. Effectiveness
4. Equity
5. Efficiency
6. Social acceptability

The final dimension, social acceptability encompasses patient satisfaction. It is clear that in today's society these six desirable properties are often traded off against one another. The drive for efficiency in a complex modern hospital seeking to provide cost effective services to large numbers of patients may jeopardise satisfaction at the level of the individual patient. For this reason it is especially important to assess the impact that services have in terms of patient satisfaction as well as health outcomes.

Patient satisfaction has become the subject of investigation in the health care systems of Europe and North America for a variety of reasons. It is an important indicator of the quality of health care and for this reason purchasers, providers and planners of health care services constantly seek to obtain patients' views on the quality of care and to use that information in the continuous process of monitoring and improving care.

In the United Kingdom this approach received momentum from the Griffiths report on NHS management, which criticised the NHS for failing to obtain and act upon systematic feedback from its customers (Griffiths 1983). Further impetus was provided by a 1989 White paper and by documents of the NHS Management Executive such as Local Voices in 1992, which both made assessment of patient's views a priority.

In the USA these ideas have been more extensively developed so that consumer reports are now published ranking health care plans according to patients' views.

The most important reason for measuring patient satisfaction is the increasing amount of evidence which indicates the contribution it makes to other outcomes that are of great importance to purchasers and providers of health care (Griffiths 1983).

It is known that satisfied and dissatisfied patients behave differently (Hudak and Wright 2000). Studies have demonstrated that patients who are dissatisfied are more likely not to return for further care (Orton et al. 1991). Dissatisfied patients are also less likely to comply with treatment regimes, maintain a relationship with a specific provider, participate in their own treatment and cooperate with health care providers by disclosing important medical information (Hudak and Wright 2000). There is also a range of evidence that links lower levels of patient satisfaction with poorer health outcomes (Hall and Dornan 1990).

Measuring Patient Satisfaction

There is currently a strong climate of opinion which seeks patient's involvement in assessing the quality of care. Patients' views must be obtained by a measurable, feasible and defensible method in order to monitor the quality of services.

Three distinct approaches exist to assess patients' views of health care. Two approaches use fixed choice questionnaires and the third uses in-depth interviews to generate qualitative or quantitative data. This research reported by this thesis required the use of the questionnaire approach only. Questionnaires may be used which focus upon specific questions or they may focus upon scale scores.

1. Questionnaire focussing upon specific questions

In the UK there is a traditional use of survey research which carefully samples nationally representative respondents' views and experiences of primary care and hospital services. This method is particularly associated with the work of Ann Cartwright, who has given much research attention to obtaining accurate estimates of views by obtaining representative samples with high response rates (Cartwright 1988). The questionnaires are carefully piloted to eliminate ambiguous or difficult questions. The emphasis is placed upon asking patients in as precise and comprehensible way as possible about their experiences in the course of their care.

Such surveys have influential effects on health policy, providing representative response on how commonly specific problems occur in hospitals or general practice. The same questionnaire surveys can be used to achieve international comparisons of the quality of hospital care in different systems.

2. Questionnaire focussing upon scale scores

The second approach when using questionnaires to measure patient satisfaction derives from psychometric approaches to the measurement of human subjective states. This approach is based upon the idea that no single item is likely to assess an individual's view or attitude towards a phenomenon. Instead a number of deliberately chosen items together will provide a better approximation of underlying views. The advantages of this system are that greater attention can be given to estimating reliably the true underlying views of patients and that finer gradations of score can be achieved when multiple items are combined, increasing sensitivity to differences of experience. The disadvantages are the time consuming nature of this approach which may be beyond the resources of many survey users. The scale scores also provide a less intuitive result for audiences of surveys than the distribution of answers to single questions.

Methods of Data Collection

Most patient satisfaction questionnaires, with fixed choice format can be completed by respondents without the involvement of an interviewer; this means that they can be sent by post. There are several advantages to this method of data collection and it would appear on balance that there are few circumstances when a well designed postal questionnaire cannot produce accurate results and a good response rate (Table 1) (Fitzpatrick 1997).

Table 1: Advantages of self-completed versus interview based questionnaires

Self-Completed	Interview Based
Standardisation of task	Sensitivity to patients' concerns
Anonymity	Flexibility in covering topics
No interviewer bias	Rapport
Low cost of data collection	Clarification of ambiguities
Less need for trained staff	Respondent adherence to task

A case for the use of in-depth interviews in the realm of patient satisfaction research is made when qualitative data is required. There is an argument that structured patient questionnaires have produced a distorted impression of how patients view health care, and that only in-depth interviews will uncover dissatisfaction and the grounds for such negative responses (Williams 1994).

Methodological Problems

There are a number of methodological problems that arise commonly in the design of studies where patient satisfaction is the primary concern. They may not jeopardise the investigation but can, if ignored lead to misleading results.

Positive Skew

Hall and Dornan's meta-analysis of studies showed that if scores are standardised to a range of 0-100, the mean level of satisfaction score across studies is 76 (Hall and Dornan 1988). This is very positively skewed data; the vast majority of patients select positive responses in surveys about patient satisfaction. It is hard to distinguish whether this is due to high quality of care or to the negative values that surround the discussion of doctors, nurses and medicine, which patients may feel inhibits more critical comment (Fitzpatrick 1997).

Effects of health status and psychological well being

A number of studies have associated poorer health status and dissatisfaction with health care (Fitzpatrick 1997). It appears difficult however to arrive at the real reason for this. Patients with poorer health may attribute this to their quality of care, even when this is unwarranted and at the other extreme there may be real differences in the quality of care that lead to dissatisfaction and poorer health status.

Influence of demographic variables

Responses to patient satisfaction questionnaires may reflect generalised attitudes to health rather than the actual experiences of treatment. Variations in satisfaction levels may reflect patients' characteristics rather than the service being evaluated. Hall and Dornan (1988) found that across studies age appears to be the most consistent variable to have this affect; with older patients usually expressing more positive satisfaction. Demographic variables need to be compensated for when interpreting results of questionnaires.

Patient Satisfaction with Treatment for OSAHS with a Mandibular Repositioning Splint

Patient satisfaction in patients suffering from OSAHS has been investigated predominantly using questionnaires of the type which focus on specific questions.

For example, Shadaba et al. in 2000 evaluated retrospectively by postal questionnaire the Herbst mandibular advancement splint used in the management of patients with sleep related breathing disorders. They had a 74% response rate to their questionnaire and found that 82% of the splints were worn and 88% of the patients found the device to be effective. 70% of subjects wore their devices regularly averaging 6.2 nights per week wear, with 45% of individuals wearing their appliance every night.

They found that the long term side effects were minimal, but a large majority of patients experienced one or more side effects during the first few days of splint wear. Dry mouth was found to be the most common complaint.

This study examined a large number of subjects retrospectively and it was evident that their group had worn their appliance for varying amounts of time, from 18 months to a few weeks, a potential source of bias. The questionnaire also relies on the patients perceptions of treatment, which do not necessarily correlate with actual clinical findings, i.e. improvements in ESS. The results did highlight that this splint is effective in treatment of habitual snoring, mild to moderate OSAHS and for those patients unable to tolerate CPAP.

Information such as this is considered a way of including patients' perspectives in the planning and assessment of services (Hudak and Wright 2000). The study of patient satisfaction is a relatively new field and the use of satisfaction measures has surged in popularity in the past three decades. However there is not a consensus of opinion about the optimal way to capture the patients' perspective. There is a requirement for further research in methods of assessment to ensure that patients' views are consistently and appropriately assessed in the evaluation of health care.

There is also a need for the recognition of what satisfaction measures can reasonably show us about patients' perceptions of health care.

3. AIMS

This thesis will examine the following areas:

1. The relationship between severity of sleep related breathing disorders and lateral cephalometric radiograph values.
2. Patients' perspectives on treatment of sleep disordered breathing with a mandibular repositioning splint.
3. Comparison of treatment success with severity of sleep disordered breathing and patients anatomical dimensions.

4. MATERIALS AND METHODS

4.1 Subjects

Orthodontic patients attending the orthodontic departments of Victoria Hospital, Kirkcaldy and Edinburgh Dental Institute under the care of one Consultant Orthodontist were recruited consecutively as referred, between October 2001 and July 2002.

In the cephalometric study, the patients were adult, dentate, Caucasians with a history of snoring or sleep apnoea confirmed by polysomnography and without a history of respiratory disease or having previously undergone surgery to reduce the size of their soft palates.

In the patient satisfaction survey, all of the patient responses were analysed. No patients were excluded as it was felt important to gather data from all patients undergoing treatment, including the edentulous.

4.2 Data Collection

Anthropometric data collected included age, gender and Body Mass Index (BMI). The Apnoea/Hypopnoea Index (AHI) was recorded from patients who had attended the Edinburgh Sleep Centre for overnight sleep study. Each subject and sleeping partner completed the Epworth Sleepiness Scale (ESS) at their initial visit.

4.3 Appliance

The MRS used in this study consisted of two vacuum formed mouthguards providing complete occlusal coverage (Figure 4). They were constructed from Kombiplast hard/soft (Dreve, Frankfurt, Germany), a bi-laminate ethylene-methylacrylate/polystyrene material which has a soft fitting surface and harder resilient outer layer. The two units were sealed in protrusion. Retention was by engagement of undercuts by the flexible material.

The appliances were fabricated by a specialist orthodontic technician on stone models articulated with the use of a wax occlusal record. Occlusal records were obtained using softened pink wax and a Projet bite fork (Orthocare, Bradford, UK). All MRS were individually manufactured and custom fitted to produce 75% of the maximal comfortable mandibular protrusion and 2-4mm inter-incisal clearance. Patients received both written and verbal instructions regarding the use of their device at their initial visit and again when fitting the device a week later.

4.4 Radiography

Standardised lateral cephalometric radiographs are taken as part of the normal protocol for initial evaluation of the OSAHS patients in the Orthodontic department. All the radiographs used in this study were taken by the same radiographer and machine, (Siemens Orthophos CD. ®. Siemens, Inc., Germany), with intensifying screens and motorised adjustable grid. The KVP (peak kilo voltage) was adjusted to optimise the contrast of both hard and soft tissues. The subject was standing with the median plane parallel to the film with the maximum intercuspation of teeth and lips in light contact and in natural head position looking into a mirror (Solow and Tallgren 1971).

First the body is positioned in the orthoposition, from walking to standing. Then the subject orientates the head in the proprioceptive self-balance position and subsequently, by means of a mirror suspended in front of them orientates the head in to the mirror position. After the subject has placed the head and neck complex into this position, ear rods can be gently inserted into the external meatus in order that the head posture is stabilised during exposure. This method is highly reproducible and allows superimposition on serial radiographs.

4.5 Cephalometric Analysis

One operator carried out all tracings manually under identical conditions and each radiograph was taped onto an illuminated viewing box in a darkened room. Images were traced onto high quality acetate paper with a hard pencil (4H) and orientated with the Maxillary plane to the horizontal. Patient names were masked in order to eliminate possible bias, with radiographs traced in random order, achieved by using numbered cards drawn from sealed envelopes.

Fifty-six dental, skeletal and oropharyngeal landmarks were identified. (Tables 2-5) (Figures 7 and 8) Following this, forty-eight measurements (Tables 6-9) were made in a randomised sequence to a tolerance of 0.5 millimetres. These measurements would allow the comparison of head posture, hyoid bone position, facial profile, pharyngeal dimensions and skeletal morphology to be compared with increasing severity of OSAHS.

A pilot study series of 10 calibration tracings were undertaken before the study commenced in order to familiarise the operator with the procedure of landmark identification.

4.6 Method Error

An evaluation of method error was undertaken by performing duplicate tracings of 25 radiographic films drawn at random from the main series. The tracings were made on separate occasions, under identical conditions, in random order one month apart.

Systematic error was tested for as described by Houston and was found to be within an acceptable range after Bonferroni correction, which decreases the chances of a false positive result due to performing multiple statistical tests on a data set (Houston 1983, Bland and Altman 1995).

The tracings were then assessed for random errors by plotting on a scatter graph; this demonstrated a high reproducibility of measurement.

Random error was determined as described by Dahlberg in 1940. Errors ranged from 0.12mm for lower lip thickness to 2.69mm for the distance Gonion to Menton (Error Evaluation, Appendix 3 on CD). Errors tended to be larger for measurements that were less precise in their definition, or in areas where landmarks were difficult to define, i.e. the tip of the soft palate. The random error was very small indeed; the error variance did not exceed 3 percent of the total variance for any of the measurements made in the study.

STANDARD CEPHALOMETRIC POINTS RECORDED

Table 2: Hard Tissue Points

POINT	DEFINITION
Point A	Subspinale- the most posterior point on the profile of the maxilla between ANS and alveolar crest
ANS	Anterior Nasal Spine
Art	Articulare- the intersection of posterior border of neck of mandibular condyle and lower margin of posterior cranial base
Point B	Supramentale-most posterior point on profile of mandible, between chin point and alveolar crest
Ba	Basion-most posterior inferior point on the clivus (basiocciput)
G	Gonion-most posterior inferior point on angle of mandible
L1A	Lower incisor apex
L1T	Lower incisor tip
Me	Menton-lowermost point of mandibular symphysis in the midline
N	Nasion-most anterior point on the frontonasal suture
Or	Orbitale-most inferior point on margin of orbit
PNS	Posterior Nasal Spine
Pog	Pogonion-most anterior point on bony chin
Po	Porion-uppermost outermost point on bony external auditory meatus
S	Sella turcica-midpoint of sella turcica
U1A	Upper incisor apex
U1T	Upper incisor tip

Table 3: Soft Tissue Points

POINT	DEFINITION
N tip	Tip of nose
Li	Labrale inferioris-most prominent point on soft tissue outline lower lip
LL	Lowest point on upper lip
Ls	Labrale superioris-most prominent point on soft tissue outline upper lip
Si	Sulcus inferioris- deepest point of concavity on soft tissue outline of lower lip
STMe	Soft Tissue Menton
STN	Soft Tissue Nasion
Ss	Sulcus superioris-deepest point of concavity on soft tissue outline of upper lip
STPog	Soft Tissue Pogonion
UL	Highest point on lower lip

Table 4: Additional Definitions

	DEFINITION
FH	Frankfort Horizontal- line joining Orbitale with Porion
NSL	Maxillary plane-Line connecting Nasion with Sella turcica
OPT	Odontoid Process Tangent, through CV2ip and CV2tg
CVT	Cervical Vertebra Tangent, through CV4ip and CV2tg
NL	Line connecting ANS with PNS
Mandibular plane	Line joining Menton and Gonion
Aesthetic line	Line joining N tip and STPog

Table 5: Additional Points Relating to Cervical Vertebrae, Oropharynx, Epiglottis, Soft Palate and Tongue.

POINT	DEFINITION
CV2tg	Constructed tangent point, on dorsal contour of odontoid process of 2nd cervical vertebra, to a line from CV2ip
CV2ip	Most posterior inferior point of corpus of 2nd cervical vertebra
CV4ip	Most posterior inferior point of corpus of 4th cervical vertebra
H_1	$Hyoid_1$-most ant and sup point on hyoid
H_2	$Hyoid_2$-most inferior point of the hyoid bone
3	The point on the posterior pharyngeal wall at the same horizontal level as point 9
4	The point of intersection of the occlusal plane with the posterior pharyngeal wall
5	The point on the posterior pharyngeal wall at the same horizontal level as the lower incisor tip
6	The point on the posterior pharyngeal wall at the same horizontal level as the most posterior point on the soft palate (point11)
7	The point on the posterior pharyngeal wall at the same horizontal level as the tip of the soft palate (point 12)
8	The point on the posterior pharyngeal wall at the same horizontal level as the most posterior point on the tongue contour (point 13)
9	Most postero-superior point on the soft palate
10	The point on the posterior aspect of the soft palate at the same horizontal level as the lower incisor tip.
11	The most posterior point on the contour of the soft palate
12	The tip of the soft palate (uvula)
13	The most posterior point on the contour of the tongue

Table 6: Skeletal and Dental Measurements

VARIABLE	DEFINITION
Cranial Base	
BaSN (deg)	Cranial base angle, formed by a line constructed between Ba to S, and NSL
S-N (mm)	Linear distance between point S and N
Maxilla	
SNA (deg)	Angle between NSL and a line constructed from A-N
Point A-S (mm)	Vertical distance between A and S
Mandible	
SNB (deg)	Angle between NSL and a line constructed from B-N
Gonial angle (deg)	Angle between lines used to construct Gonion
Gonion-Menton (mm)	Linear distance between G and M
Gonion-Point B (mm)	Linear distance between G and B
Point B-S (mm)	Vertical distance between B and S
Intermaxillary	
ANB (deg)	Angle between lines constructed from A-N and B-N
MMPA (deg)	Angle between the maxillary and mandibular planes
Upper anterior face height (mm)	Vertical distance between N and ANS
Lower anterior face height (mm)	Vertical distance between ANS and Me
Lower anterior face height (%)	% LFH forms of total Face Height
Intermaxillary space length (mm)	Linear distance between the posterior pharyngeal wall (Pt 4) and the lower incisor at the level of the occlusal plane.
Dental	
1/1 to max plane (deg)	Angle between a line through the upper incisor tip and apex and the maxillary plane
1/1to mandibular plane (deg	Angle between a line through the lower incisor tip and apex and the mandibular plane
Overjet (mm)	Horizontal overlap of upper and lower incisors
Overbite (mm)	Vertical overlap of upper and lower incisors

Table 7: Hyoid Bone Measurements (mm)

VARIABLE	DEFINITION
H1-ANS	Linear distance between H1 and ANS
H1-B	Linear distance between H1 and Point B
H1-NL	Linear distance along a perpendicular from H1 to Maxillary plane
H1-(Me-G)	Linear distance along a perpendicular from H1 to Mandibular plane
H2-ANS	Linear distance between H1 and ANS
H2-B	Linear distance between H1 and Point B
H2-NL	Linear distance along a perpendicular from H2 to the Maxillary plane
H2-(Me-G)	Linear distance along a perpendicular from H2 to the Mandibular plane

Table 8: Head Posture Measurements (Degrees)

VARIABLE	DEFINITION
FH/NSL	Angle between Frankfort Horizontal and Sella-Nasion lines
NL/NSL	Angle between Nasal and Sella-Nasion lines
CVT/NSL	Angle between Cervical Vertebra Tangent and the Sella-Nasion line
FH/CVT	Angle between Frankfort Horizontal and Cervical Vertebra Tangent
NL/CVT	Angle between Nasal and Cervical Vertebra Tangent
OPT/NSL	Angle between Odontoid Process Tangent and Sella-Nasion line
OPT/CVT	Angle between Odontoid Process and Cervical Vertebra Tangent
FH/OPT	Angle between Frankfort Horizontal and Odontoid Process Tangent

Table 9: Measurements Relating to Lips, Spine, Hyoid, Pharynx, Soft Palate and Tongue.

VARIABLE	DEFINITION
Soft Tissue	
Upper lip thickness (mm)	Linear distance between Point A and Ss
Upper lip length (mm)	Vertical distance between LL and subnasale
Ls to aesthetic line (mm)	Linear distance between Ls and aesthetic line
Lower lip thickness (mm)	Linear distance between Point B and Si
Lower lip length (mm)	Vertical distance between STMe and UL
Li to aesthetic line (mm)	Linear distance between Li and aesthetic line
Oral & Pharyngeal	
Palatal angle (deg)	Angle between ANS-PNS-Point 12
Pharynx: retro-palatal 1(mm)	Linear distance between Points 3-9
Pharynx: retro-palatal 2(mm)	Linear distance between Points 5-10
Pharynx: retro-palatal 3(mm)	Linear distance between Points 6-11
Pharynx: retro-palatal 4(mm)	Linear distance between Points 7-12
Pharynx: retro-lingual (mm)	Linear distance between Points 8-13
PNS-tip of soft palate (mm)	Linear distance between PNS-Point12

Figure 7: Hard Tissue Points

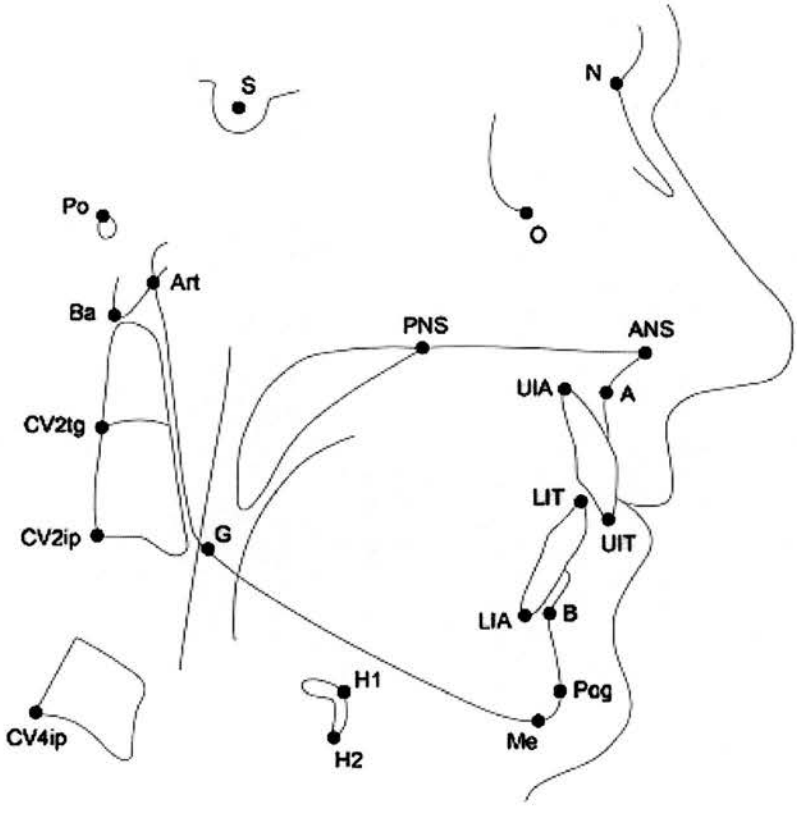
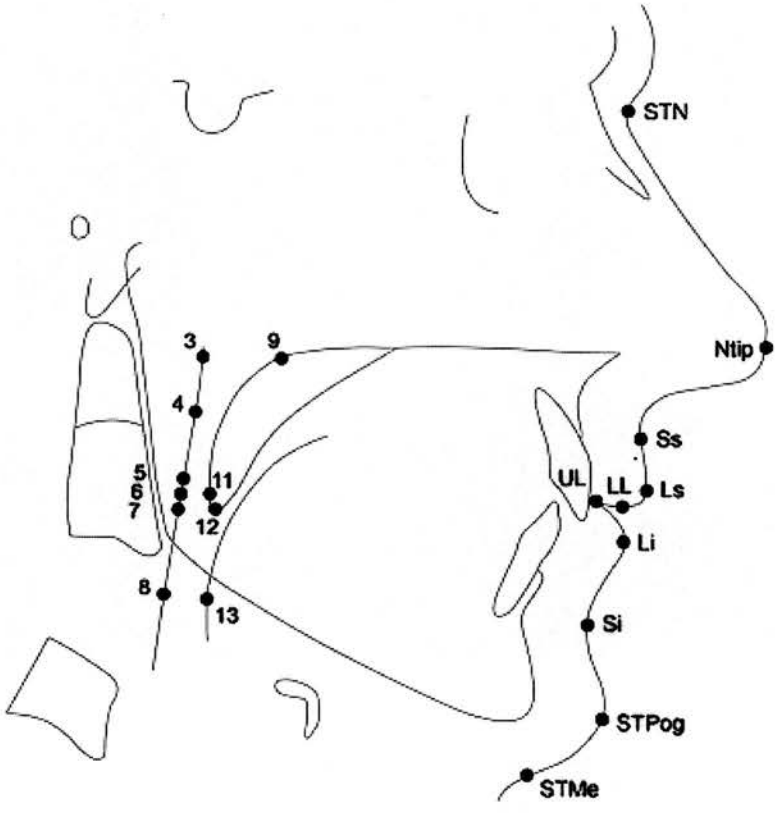


Figure 8: Soft Tissue Points



4.7 Method Part 1: Cephalometric Study

The cephalometric study was a cross-sectional cohort study, examining the relationship between severity of sleep disordered breathing and patients anatomy on a lateral cephalometric radiograph.

Severity of sleep disordered breathing was measured subjectively in terms of daytime sleepiness using the ESS questionnaire and objectively using the AHI.

The 121 patients included in the study were able to complete the Epworth questionnaire. Fifty four patients had attended the Edinburgh University Sleep Centre for overnight polysomnography and had therefore AHI scores.

In order to examine the relationship between anatomy and severity we divided the patients into 2 groups, patients with ESS Scores and patients with AHI Scores

These patient groups were then further subdivided to enable comparison of the range of severity with cephalometric anatomy.

ESS Score Analysis

The Epworth Sleepiness Scale ranges from 0 to 24, patients in this study were divided for analysis dependant on their score.

Epworth Analysis 1 investigated how low or high ESS score related to the cephalometric measurements. Logistic regression was used as the data was categorical rather than linear (Altman 1991). The patient group was divided in two, less than 12 and more than 12 on the Epworth scale. A score of 12 on the scale can be regarded clinically as a threshold where a patient may be thought of as having excessive daytime sleepiness (Johns 1991).

In Epworth Analysis 2 we divided the ESS scores further into more discreet groups to highlight any factors that could be significant as daytime sleepiness increases in severity.

Johns states that the mean ESS for mild OSAHS is 9.5, for moderate OSAHS 11.5 and in severe OSAHS it is 16 (Johns 1991). In order to reveal significant changes in anatomy the sub groups had to be small enough to detect changes in features between mild, moderate and severe OSAHS.

A change of 3 points on the Epworth Scale can be considered clinically significant (Johns 1991). Our groupings followed this, with an interval of three points on the scale contained within each subgroup.

AHI Analysis

Fifty four of the recruited patients had received overnight polysomnography and had an AHI value; patients were divided for data analysis dependant on their score.

In AHI Analysis 1 we examined how low or high AHI score related to the cephalometric measurements using logistic regression.

The patient group was divided in two, less than 20, low AHI and over 20, high AHI. This division in AHI has been used in other studies to divide severity, in terms of mortality (Jiang et al. 1988) and in a cluster analysis of obstructive sleep apnoea sub-types (Tsuchiya1992).

Secondly in AHI Analysis 2 we wished to divide the subjects into more discreet groups to highlight any factors that could be significant as AHI increases in severity.

The clinical importance of any particular cut off point has not been adequately determined for AHI and a range of points have been reported in the literature, such as ≤5, ≥10, ≥15 (Young et al. 1993, Stradling 1995), ≤10, ≥10 (Eveloff et al. 1994, Schmidt-Nowara et al 1995 and Johnston et al 2002), <5, >10 (Lowe et al. 1996, Liu et al. 2000).

Several of the subjects in the study reported by this thesis had AHI values higher than 15, so we required cut off points at intervals above 15 Apnoeas and Hypopnoeas per hour of sleep.

Douglas et al considered that an AHI value of >15 represented clinically significant OSAHS (Douglas et al 1993). Johns stated that the AHI for mild OSAHS was within the range >5-15, for moderate OSAHS the range was >15-30 and for severe OSAHS it was >30 (Johns 1991).

Using these figures we divided the patient group into intervals of 7 Apnoeas and Hypopnoeas per hour of sleep, representative of 2 intervals in the mild category, two in the moderate category and two in the severe AHI category.

These intervals were chosen as they may represent a clinically significant change in AHI and would allow comparison of severity with anatomy over the range of AHI values represented in the study reported by this thesis.

4.8 Method Part 2: Questionnaire Survey

Each subject and sleeping partner completed the ESS at the initial visit and was then invited to complete a follow up postal questionnaire 3 months after provision of the appliance.

The questionnaire repeated the standard ESS and subjects were asked to report on their compliance, experience of side-effects and perceived treatment outcome. These questions are detailed in Appendix 2.

Standard quality of life questionnaires such as the SF36 may not be sensitive to some of benefits of MRS treatment, so a questionnaire was developed specifically for the study in conjunction with a statistician. It was designed to be concise, using closed questions which would not require clarification from an examiner to increase the accuracy of interpretation of the results. Wherever possible questions were utilised that had appeared in previous published studies to enable comparison (Schmidt-Nowara et al. 1995, Johal and Battagel 2001, Shadaba et al. 2000).

An initial pilot study was carried out on 10 subjects who were not included in the study, to test the questionnaire's suitability. Minor alterations in terms of grammar were made to three of the questions to improve clarity.

4.9 Method Part 3: Treatment Success vs. Severity

All patients from the existing cohort who had completed the questionnaire and been included in Part 1 of the study were divided into 2 categories, successfully treated if they were still wearing their appliance and had achieved an improvement in snoring or breathing pauses during sleep. All other patients were classed as unsuccessfully treated. The groups were then compared to examine a link between successful treatment and severity of ESS score, AHI and anatomical features.

4.10 Sample Size

A sample size determination was carried out to determine the number of subjects to be recruited to the study.

We wanted to detect a difference of 3 Epworth Sleepiness Scale points and a change of 7 Apnoeas and Hypopnoeas per hour of sleep (as described in section 4.7 Method of Cephalometric Study).

To have an 80% chance of a statistically significant result occurring with a 95% confidence interval level we would require a sample size of 68 Epworth Sleepiness Score subjects and 48 AHI score subjects.

More patients were recruited to allow for the possibility of a poor response rate to the questionnaire.

4.11 Statistical Evaluation

The data from this study was entered into a spreadsheet and analysed using SAS version 8 (© 2002 SAS Institute Inc).

The data was checked for normality and means, standard deviations and ranges were calculated.

Statistical tests were applied to determine how ESS score and AHI related to the cephalometric measurements in Part 1 and 3 the Cephalometric Studies. Stepwise analysis was performed using forward-conditional logistic regression, as the data was categorical rather than linear (Altman 1991). The variables entered were ESS score and AHI. Odds ratios were calculated for cephalometric measurements found to have significant p values.

In Part 2 the Questionnaire Survey the data was not normally distributed therefore non-parametric tests were used in its analysis. The Wilcoxon signed rank test was used to compare pre and post treatment ESS scores for subjects and sleeping partners.

Response frequencies were calculated for the other questions in terms of the number of respondents and the percent of respondents to each question per sample size.

5. RESULTS

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5.1 Subjects

One hundred and twenty one patients agreed to participate in the study; 67 were non-apnoeic snorers and 54 had received a diagnosis of obstructive sleep apnoea (OSA) which had been confirmed by polysomnography.

The ratio of males to females was 2.3 to 1.

The age of the subjects was from 28 to 85 years old, a range of 57 years which was normally spread (Figure 9).

The Body Mass Indices of the cohort were also normally spread; the mean was 28.7, classed as obese. The range in BMI was from 19 to 44 (Figure 10).

Summary statistics of the characteristics of the study sample are provided in Table 10.

Figure 9: Demonstrating the Normal Distribution of Age

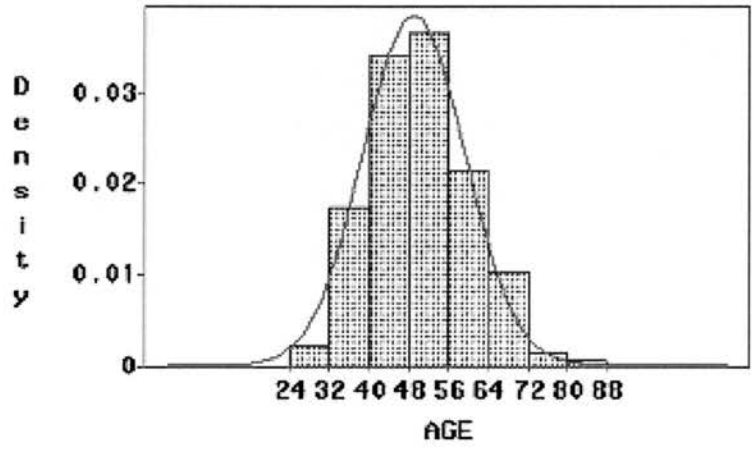


Figure 10: Demonstrating the Normal Distribution of BMI.

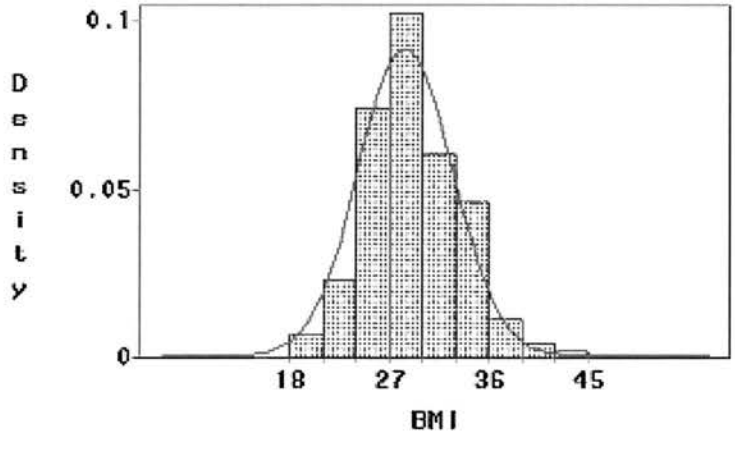


Table 10 Summary Statistics

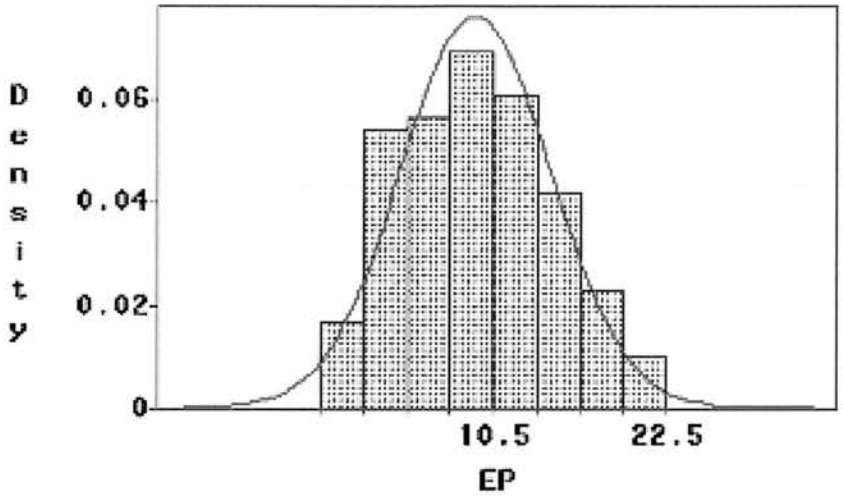
	Female	Male
Mean Age (years)	48 (SD=10.21)	53.7 (SD=11.06)
Mean ESS	9.54 (SD=5.59)	9.46 (SD=5.48)
Mean AHI	14.24 (SD=14.24)	19.03 (SD=10.54)
Mean BMI	28.6 (SD=4.16)	31.41 (SD=4.27)
Ref by GDP (subjects)	2	8
Ref by ENT (subjects)	11	23
Ref by Ed Sleep Centre (subjects)	27	50
CPAP Refuser (subjects)	2	4
Laser Surgery (subjects)	0	2
Surgery (subjects)	0	2
Simple Snorer (subjects)	24	43
Diagnosis by Polysomnography at Ed Sleep Centre	11	27
Diagnosis by Polysomnography at Home	6	10

5.2 Part 1: Cephalometric Study Results

5.2.1 ESS Analysis 1

All 121 patients in the cephalometric study had an ESS score; the mean ESS score for the study group was 5.4. The maximum score was 22 and the minimum 0, patients were divided for data analysis dependant on their score (Figure 11).

Figure 11: Demonstrating the Spread of ESS Score.



ESS Analysis 1

The patient group was divided in two; less than 12 and more than 12 on the ESS. BMI (Body Mass Index), and MMPA (Maxillary Mandibular Plane Angle), were factors which had statistically significant increases with increasing severity of daytime sleepiness when compared those with mild daytime sleepiness (Table 11).

Table 11: ESS Analysis 1

	Odds Ratio	95% Confidence Interval	p value
BMI	1.247	1.088-1.430	0.0016
MMPA	1.115	1.007-1.234	0.0365

Logit Equation

Using logistic regression we can put 2 values into a logit equation and calculate the probability of a patient being in the severe daytime sleepiness group, having an ESS score above 12. The only values required are the subjects BMI and MMPA.

$$\eta = -10.20 + BMI\ (0.2208) + MMPA\ (0.1086)$$

$$\text{probability} = \frac{\exp \eta}{1 + \exp \eta}$$

For example if a subject had BMI of 25 and an MMPA of 25, $\eta = -1.965$, therefore you would have a 12% probability of having an ESS over 12. If a subject had a BMI of 44, and a MMPA of 25, the highest values for the study group, $\eta = 2.2302$ producing a 52.6% chance of having an ESS over 12.

5.2.2 ESS Analysis 2

Secondly the data was analysed by again subdividing into 8 smaller groups with an interval of three points on the ESS contained within each.

When the ESS was compared with the cephalometric measurements it was found that BMI, MMPA, and the distance Pt 7-12 (measured from the point on the posterior pharyngeal wall at the same horizontal level as the tip of the soft palate) showed statistically significant increases as severity of daytime sleepiness increased (Table 12).

Table 12: ESS Analysis 2

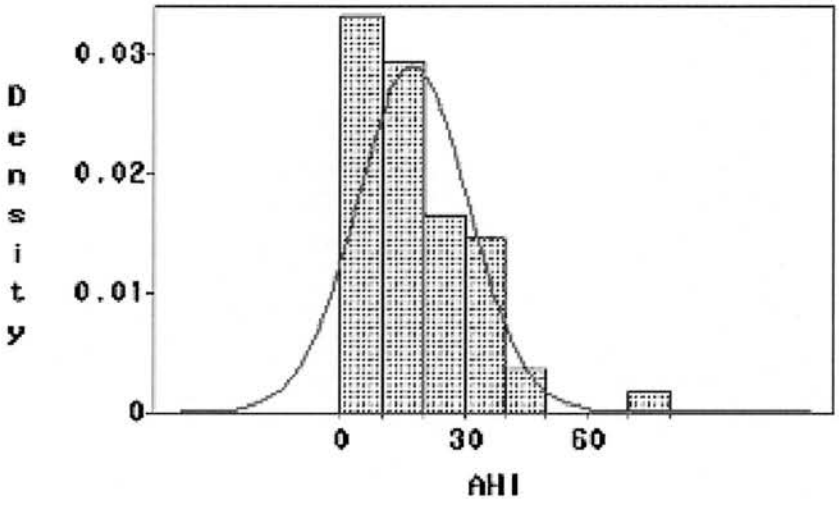
	Odds Ratio	95% Confidence Interval	p value
BMI	1.148	1.034-1.274	0.0096
MMPA	1.097	1.010-1.191	0.0280
Pt 7-12	1.230	1.073-1.411	0.0031

5.2.3 AHI Analysis 1

54 had a diagnosis of OSAHS which had been confirmed by polysomnography and thus had an AHI value, the maximum value being 77 and the minimum value 0, the mean AHI for the study group was 18.2. Patients were divided for data analysis dependant on their score. (Figure 12)

Analysis 1 examined how low or high AHI score related to the cephalometric measurements using logistic regression. The patient group was divided in two, less than 20, low AHI and over 20, high AHI. None of the factors examined by our study was found to show any significant change as severity of AHI increased.

Figure 12: Demonstrating the Spread of AHI Values



5.2.4 AHI Analysis 2

Secondly the subjects with an AHI score were divided into groups with an interval of 7 points of AHI score contained within each. When compared with the cephalometric measurements Overjet (OJ), Lower Lip length (LL length), the linear distance between H1 and point B (H1B) and the linear distance along a perpendicular from H1 to the Maxillary plane (H1NL) were significant factors that showed change with increasing AHI (Table 13).

Table 13: AHI Analysis 2

	Odds ratio	95% Confidence Interval	p value
OJ	1.241	1.046-1.473	0.0135
H1B	1.195	1.082-1.321	0.0005
LL length	1.256	1.093-1.466	0.0016
H1NL	0.904	0.833-0.982	0.0163

H1B

The linear distance between the most anterior superior point on the Hyoid (H1) and the most posterior point on the profile of the mandible, between chin point and alveolar crest (Point B), increases as the severity of AHI increases.

H1NL

The linear distance along a perpendicular from the most anterior superior point on the Hyoid (H1), to the Maxillary plane, decreases as the severity of AHI increases.

The distance H1NL shortens as AHI becomes more severe. The distance H1B lengthens as AHI becomes more severe. The hyoid bone is rotating counter clockwise under the influence of attached musculature.

Logit Equation

The logit equation can also be used with these values to derive the probability of someone being in a higher group for AHI; 4 values (OJ, H1B, H1NL and LL Length) would be required for entry into the formula.

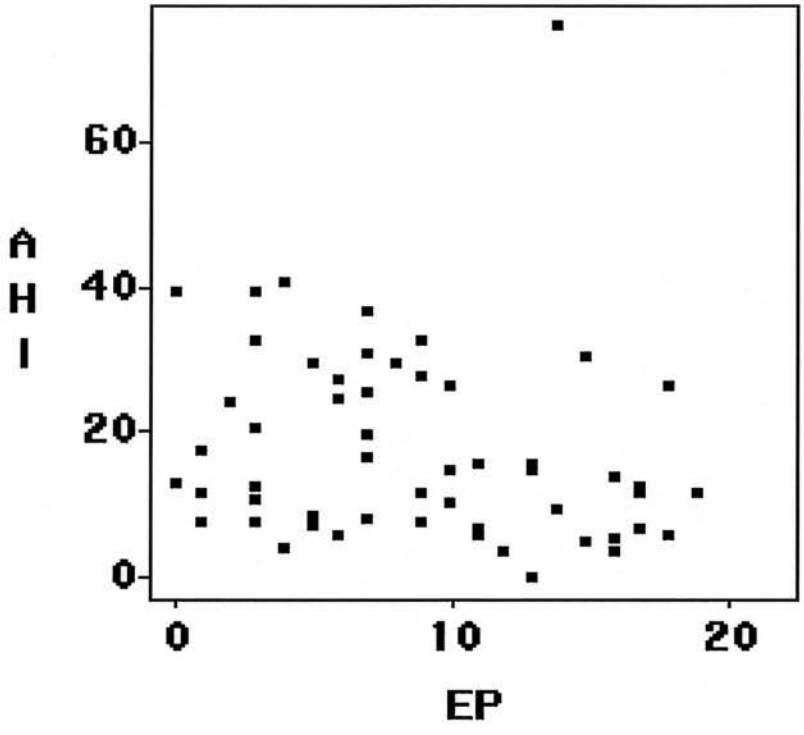
$$\eta = -10.20 + OJ\,(1.241) + H1B\,(1.195) + LL\ length\,(1.256) + H1NL\,(0.904)$$

$$\text{probability} = \frac{\exp \eta}{1 + \exp \eta}$$

5.2.5 Connection between AHI and ESS.

Finally a scatter graph was plotted to explore the connection between each subjects AHI and ESS score. (Figure 13)

Figure 13: Scatter plot Demonstrating Absence of a Link between ESS score and AHI.



5.3 Part 2: Questionnaire Survey Results

Part 2 of the research examined treatment outcome, patient satisfaction and compliance with treatment for sleep-related breathing disorders with a mandibular repositioning splint.

In this section the results are presented chronologically as they appear in the patient satisfaction questionnaire (Appendix 2).

5.3.1 Response Rate

Part 2 the Questionnaire Survey examined treatment outcome, patient satisfaction and compliance with treatment for sleep disordered breathing with a mandibular repositioning splint.

Ninety two of the 121 subjects responded to the questionnaire, a response rate of 76% (Table 14). Subjects who failed to respond had 2 repeat mailings of the questionnaire and then attempts were made to contact the patients by telephone.

Twelve responses were excluded as the subjects did not complete the questionnaire but returned it with a hand written letter commenting on their treatment.

Twelve patients could not be contacted, 1 subject died of a non apnoea related cause, 1 patient was hospitalised, and 3 appliances were lost. Those who responded showed no significant differences to any of the measured parameters when compared to those who did not respond. (Table 14)

Some subjects failed to answer all of the questions or wrote comments in the margin, resulting in a smaller number (n) of responders for some of the questions. There were 39 missing sets of values in the statistical analysis of sleeping partners (n= 53) as 39 of the responders did not have partners available to complete the questionnaire.

The characteristics of the responders and non-responders are compared in Table 11. Chi square and Fishers exact test were applied to the gender data as it was not a continuous variable, 2-sided p value and Kruskal-Wallis values are given for continuous variables i.e., age, Epworth and AHI score.

Table 14: Characteristics of responders and non responders.

	Responders	Non-Responders	Difference between Responders and Non-Responders	
			2-sided p value	Kruskal-Wallis
Mean Age (yrs)	51.4	47.2	0.07	0.07
Mean ESS	9.7	8.7	0.24	0.23
Mean AHI	17.9	14.0	0.91	0.89
			Chi-Square	Fishers
Male Sex (%)	68.0	70.5	0.78	0.83

5.3.2 Comparison of Pre and Post Treatment ESS

The ESS score at the initial visit was compared, using the Wilcoxon signed rank test with the subjects ESS score three months after treatment had commenced.

A statistically highly significant decrease in ESS score had occurred, $p<0.0001$, where the maximum decrease in score was 15 points and the minimum 0. The mean decrease in ESS score was 1.84, not a clinically significant change.

But only 7.8% of the subjects had a change in ESS score which was greater than or equal to 3 points on the ESS, which may be considered a clinically significant change (Johns 1991).

5.3.3 Comparison of Sleeping Partners Pre and Post Treatment ESS

Sleeping partners ESS score at the initial visit was compared, using the Wilcoxon signed rank test with the sleeping partners ESS score three months after treatment had commenced.

A highly significant decrease in sleeping partners ESS score was seen, $p<0.0001$, and the maximum decrease in score was 12 points and the minimum 0.

However, only 1.3% of subjects had a change in ESS score greater than or equal to 3 points.

5.3.4 Comfort

Subjects were asked in terms of comfort how long it took for them to get used to the appliance (Table 15).

Table 15: Comfort

	Respondents	% Sample Size (n=121)
<7 days	20	16.5
1-2 weeks	21	17.4
2 weeks-1 month	13	10.7
Never	25	20.7

5.3.5 Compliance

Fifty four responders (45% of total sample size, 68% of responders) reported that they were wearing their appliance three months after initial treatment, when the questionnaire was conducted. Twenty five (21% of total sample size, 32% of responders) were not wearing their appliance. The appliance was worn for a mean of 5.6 nights per week and the mean number of hours the appliance was worn was 6.2.

5.3.6 Side Effects

Subjects were asked to report on side effects they had encountered during their treatment and how severe they were. Side effects were considered in terms of excess salivation (Table 16), soreness of mouth/teeth/gums (Table 17), jaw discomfort (Table 18), difficulty in falling asleep or frequent awakening (Table 19), difficulty in breathing (Table 20), waking up with appliance detached from teeth or out of mouth (Table 21). A histogram is provided to aid comparison of side effects (Figure 14).

Table 16 Excess Salivation

	Respondents	% Sample Size (n=121)
Minor problem	34	28.1
Significant problem but still using appliance	9	7.4
Significant problem + unable to use appliance	4	3.3
Problem existed before treatment	2	1.7

Table 17 Soreness of Mouth/Teeth/Gums

	Respondents	% Sample Size (n=121)
Minor problem	32	26.4
Significant problem but still using appliance	15	12.4
Significant problem + unable to use appliance	7	5.8
Problem existed before treatment	1	0.8

Table 18 Jaw Discomfort

	Respondents	% Sample Size (n=121)
Minor problem	22	18.2
Significant problem but still using appliance	12	9.9
Significant problem + unable to use appliance	9	7.4
Problem existed before treatment	0	0

Table 19 Difficulty in Falling Asleep or Frequent Awakening

	Respondents	% Sample Size (n=121)
Minor problem	19	15.7
Significant problem but still using appliance	8	6.6
Significant problem + unable to use appliance	8	6.6
Problem existed before treatment	1	0.8

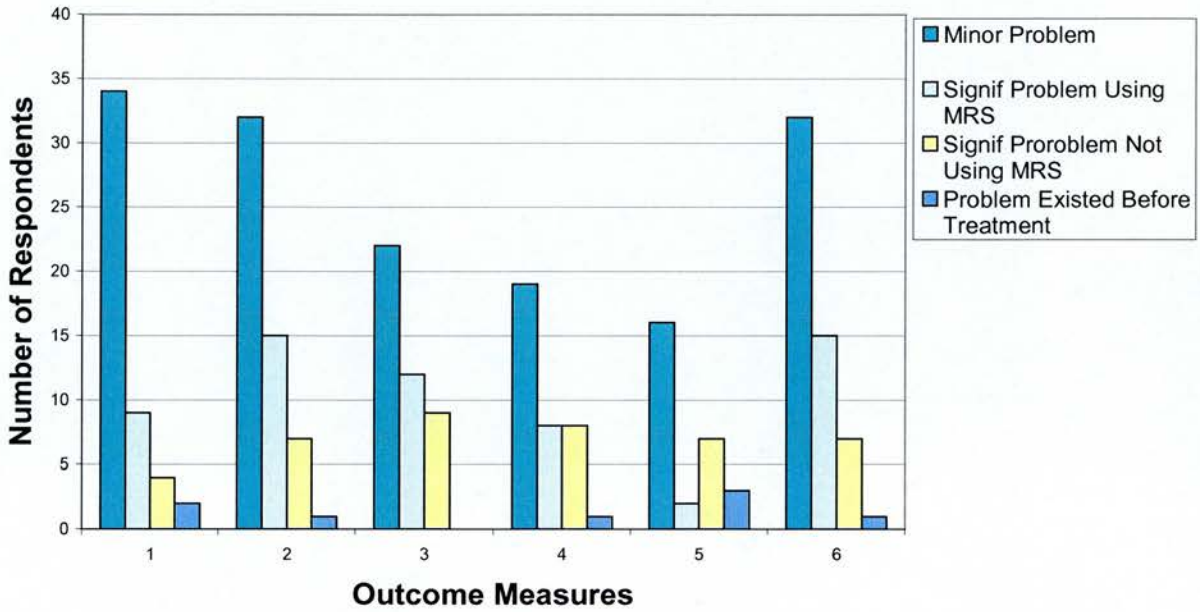
Table 20 Difficulty in Breathing

	Respondents	% Sample Size (n=121)
Minor problem	16	13.2
Significant problem but still using appliance	2	1.7
Significant problem + unable to use appliance	7	5.8
Problem existed before treatment	3	2.5

Table 21 Waking up with Appliance Detached from Teeth or Out of Mouth

	Respondents	% Sample Size (n=121)
Minor problem	19	15.7
Significant problem but still using appliance	8	6.6
Significant problem + unable to use appliance	8	6.6
Problem existed before treatment	0	0

Figure 14 Side Effects



Outcome Measures: 1=Excess Salivation, 2= Soreness of Mouth/Teeth/Gums, 3=Jaw Discomfort, 4=Difficulty Falling Asleep or Frequent Awakening, 5=Difficulty Breathing, 6=Waking Up with Appliance Detached from Teeth or Out of Mouth.

5.3.7 Treatment Outcome

Subjects were asked to report on the effects of their treatment in terms of daytime sleepiness (Table 22), quality of night time sleep (Table 23), snoring (Table 24), concentration (Table 25), moodiness/irritability (Table 26), energy levels (27), breathing pauses during sleep (28), general health (Table 29). A histogram is provided to aid comparison of the effects of treatment (Figure 15).

Table 22 Daytime Sleepiness

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	2	1.7
No change	38	31.4
Improved	20	16.5
Much improved	4	3.3

Table 23 Quality of Night Time Sleep

	Respondents	% Sample Size (n=121)
Much worse	3	2.5
Worse	5	4.1
No change	20	16.5
Improved	31	25.6
Much improved	10	8.3

Table 24 Snoring

	Respondents	% Sample Size (n=121)
Much worse	1	0.8
Worse	0	0
No change	18	14.8
Improved	26	21.5
Much improved	19	15.7

Table 25 Concentration

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	1	0.8
No change	45	37.2
Improved	15	12.4
Much improved	4	3.3

Table 26 Moodiness/Irritability

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	4	3.3
No change	46	38.0
Improved	12	9.9
Much improved	3	2.5

Table 27 Energy Levels

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	3	2.5
No change	45	37.2
Improved	15	12.4
Much improved	4	3.3

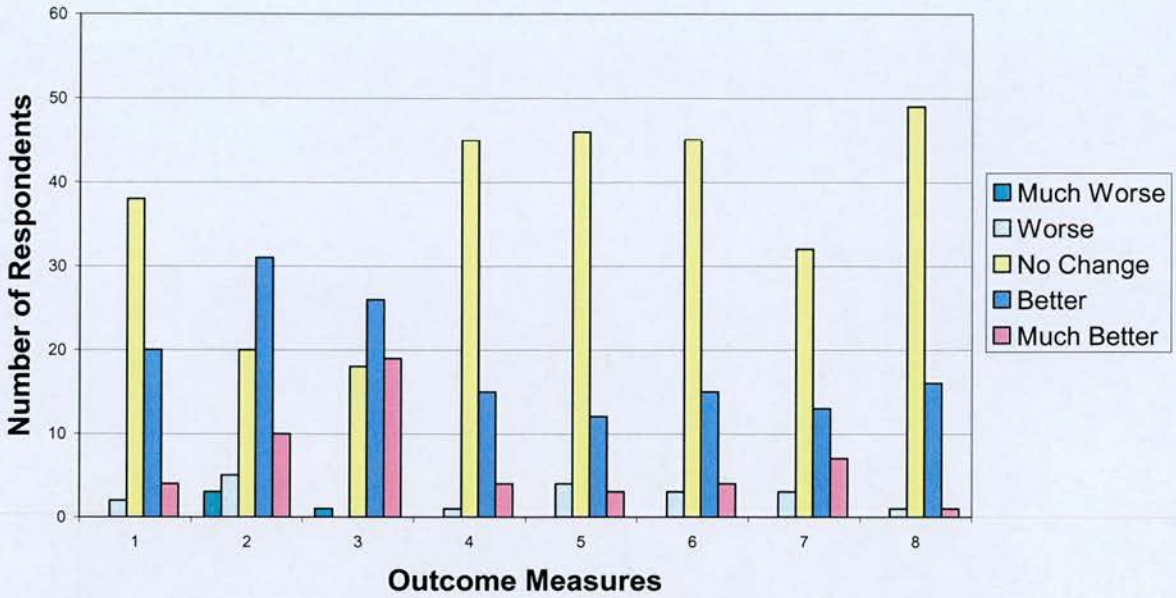
Table 28 Breathing Pauses during Sleep

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	3	2.5
No change	32	26.4
Improved	13	10.7
Much improved	7	5.8

Table 29 General Health

	Respondents	% Sample Size (n=121)
Much worse	0	0
Worse	1	0.8
No change	49	40.5
Improved	16	13.2
Much improved	1	0.8

Figure 15 Treatment Outcome



Outcome Measures: 1=Daytime Sleepiness, 2= Quality of Night Time Sleep, 3=Snoring, 4=Concentration, 5=Moodiness/Irritability, 6=Energy Levels, 7=Breathing Pauses during Sleep, 8=General Health.

5.3.8 Sleeping Partners View of Treatment Outcome

Sleeping partners were asked to report on the effects of their partner's treatment in terms of daytime sleepiness (Table 30), snoring (Table 31), moodiness / irritability (Table 32), breathing pauses during sleep (Table 33) and general health (Table 34). A histogram is provided to aid comparison of partner's views on treatment outcome (Figure 16).

Table 30 Daytime Sleepiness

	Respondents	% Sample Size (n=53)
Much worse	0	0
Worse	3	5.7
No change	30	56.6
Improved	15	28.3
Much improved	5	9.4

Table 31 Snoring

	Respondents	% Sample Size (n=53)
Much worse	3	5.7
Worse	1	1.9
No change	12	22.6
Improved	22	41.5
Much improved	15	28.3

Table 32 Moodiness/Irritability

	Respondents	% Sample Size (n=53)
Much worse	0	0
Worse	4	7.5
No change	31	58.5
Improved	14	26.4
Much improved	2	3.8

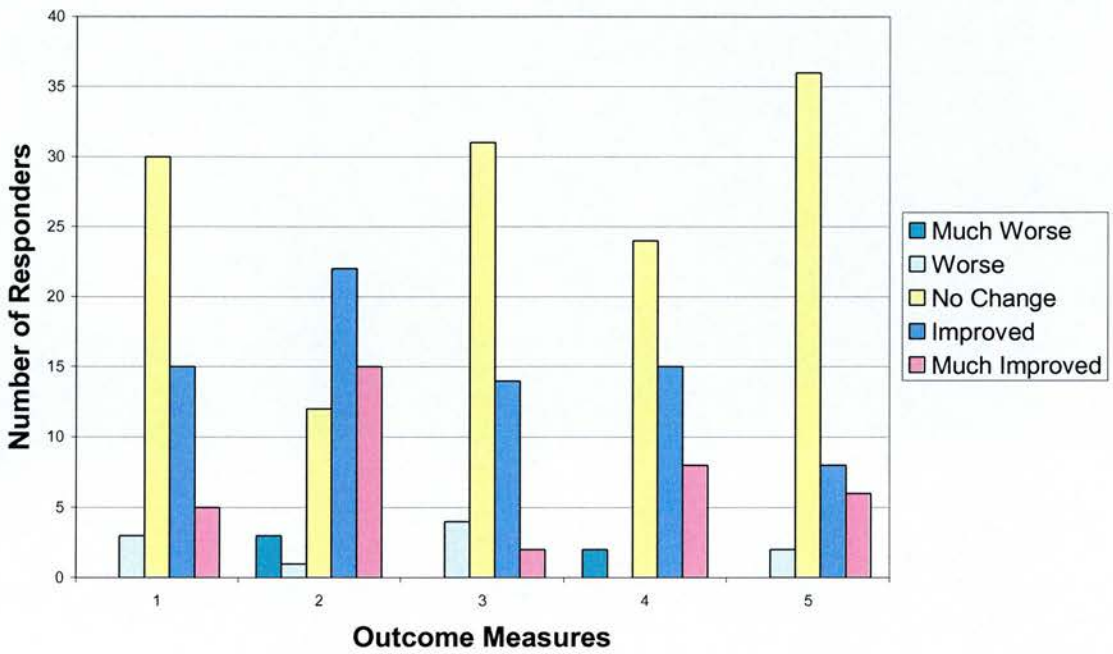
Table 33 Breathing Pauses during Sleep

	Respondents	% Sample Size (n=53)
Much worse	2	3.8
Worse	0	0
No change	24	45.3
Improved	15	28.3
Much improved	8	15.1

Table 34 General Health

	Respondents	% Sample Size (n=53)
Much worse	0	0
Worse	2	3.8
No change	36	67.9
Improved	8	15.1
Much improved	6	11.3

Figure 16 Sleeping Partner's Views on Treatment Outcome



Outcome Measures: 1=Daytime Sleepiness, 2=Snoring, 3=Moodiness/Irritability, 4=Breathing Pauses during Sleep, 5=General Health.

5.3.9 Partners Sleep Change

Sleeping partners were asked to report on the changes to their own night time sleep since their partner started to use the appliance (Table 35).

Table 35 Partners Sleep Change

	Respondents	% Sample Size (n=53)
Much worse	3	5.7
Worse	3	5.7
No change	13	24.5
Improved	21	39.6
Much improved	13	24.5

5.3.10 Funding

Patients were asked whether they thought this type of treatment should continue to be available on the NHS (Table 36).

Table 36 Funding

	Respondents	% Sample Size (n=121)
Yes	69	57.0
No	0	0
Unsure	9	7.4

5.3.11 Other Treatment Recieved

Patients were asked whether they had received any other form of treatment for their sleep problem (Table 37).

Table 37 Other Treatment

	Respondents	% Sample Size (n=121)
Yes	10	8.3
No	68	56.2

If the answer was yes, the subject was asked the type of other treatment (Table 38).

Table 38 Type of Other Treatment

	Respondents	% Sample Size (n=121)
CPAP	6	5.0
Laser Surgery	2	1.7
Surgery	2	1.7
Other	0	0

5.4 RESULTS PART 3: TREATMENT SUCCESS VS. SEVERITY

Part 3 compared treatment success with anatomical features and severity of patients ESS score and AHI.

No anatomical measurement was found to be a statistically significant factor in treatment success or failure.

Severity in terms of AHI and ESS score, BMI and age were not found to be statistically significant factors in success or failure of treatment.

6. DISCUSSION

6.1 Discussion of the Materials and Methods

6.1.1 Recruitment

In the cephalometric study, patients were adult, dentate, Caucasians with a history of snoring or sleep apnoea confirmed by polysomnography and without a history of respiratory disease or having previously undergone surgery to reduce the size of their soft palates.

No subjects were excluded from the questionnaire study, even those who had undergone previous surgery or who were edentulous. It was felt that all patients' experiences of treatment were valid and that to limit the cohort reported on to the dentate would introduce bias.

6.1.2 Cephalometry

In this study we attempted to standardise the radiographic views used as described in the Method (section 4.4). Cephalometric analysis was carried out under optimum conditions and standardised as described in the Method (section 4.5). A single operator, calibrated by carrying out an initial pilot study, carried out all the tracings in order to eliminate the possibility of inter-operator variability. Attempts were made to reduce bias by masking patient details during cephalometric analysis, tracing the radiographs in a random order and completing the measurements in a random order. Randomisation was achieved using numbered cards drawn from sealed envelopes.

6.1.3 Appliance

All MRS were individually manufactured and custom fitted to produce 75% of the maximal comfortable mandibular protrusion and 2-4mm inter-incisal clearance. This amount of protrusion has been used by other authors working in the area of MRS (Clark et al 1996, Gale et al 2000, Johnston et al 2002) and hence was used in the study reported by this thesis in the interests of comparison.

However, it is recognised that the amount of protrusion required for successful treatment varies between individual patients and that perhaps one should aim to achieve the maximal comfortable protrusion (Johal and Battagel 1999, 2001). The standardisation of the advancement in this study may be a factor in the relatively low mean decrease in ESS score of 1.84.

6.1.4 Lateral Cephalometric Radiographs as a Research Tool

Lateral cephalometric radiographs have been used by many investigators in an attempt to identify morphological parameters that may be characteristic in OSAHS (please see Literature Review section 2.10).

Lateral cephalometric analysis of the airway permits precise measurements to be made in the sagittal plane at anatomically well defined locations. However, it does not provide information on the transverse dimensions of the airway.

Computerised Tomography (CT) and magnetic resonance imaging (MRI) scans can provide both transverse and sagittal measurements of airway dimension, but different studies are difficult to compare due to the lack of standardisation of studies in their use of the scans, in terms of thickness, direction and precise location of the sections taken. These scans cannot be justified routinely in patient assessment as they are expensive, require relatively high doses of radiation and the equipment may be difficult to access (Lowe et al 1986).

Another limitation of cephalometric analysis relevant to this study may be the effect that a change in posture has upon cephalometric measurements (Lowe et al 1986, Yildrim et al 1991, Battagel et al 2002). Upright cephalometry is used commonly in the United Kingdom in the assessment of OSAHS patients but in recent years there has been an appreciation that changes occur in the airway and surrounding structures when moving from the upright to supine position. It has been shown that when moving from the upright to supine position that the antero-posterior dimensions of the oropharyngeal airway decrease significantly (Battagel et al 2002). Caution must therefore be exercised when relating results of upright cephalometry as used in this study, to events occurring during sleep in the supine position.

6.1.5 Cephalometric Landmarks and Measurements

The dental, skeletal and oropharyngeal landmarks and the cephalometric measurements were selected to allow comparison of cephalometric morphology with increasing severity of OSAHS in terms of AHI and ESS score. Landmarks and measurements were selected that had been utilised by previous studies in order to aid comparison (Battagel and L'Estrange 1996, Battagel and Johal 2000).

6.1.6 Randomisation

Randomisation was achieved drawing numbered cards from sealed envelopes.

Randomisation was used to eliminate possible sources of bias, i.e. the operator subconsciously measuring larger dimensions for one subject than another.

Blinding of the operator during the cephalometric study was carried out by masking subjects' names.

6.1.7 Random errors

Random error was addressed in this study as described in the Method (section 4.6) by performing duplicate tracings of 25 radiographic films drawn at random from the main series. The tracings were made on separate occasions, under identical conditions, in random order one month apart.

The tracings were then assessed for random errors by plotting on a scatter graph; this demonstrated a high reproducibility of measurement.

Random error was determined as described by Dahlberg in 1940. Errors ranged from 0.12mm for lower lip thickness to 2.69mm for the distance Gonion to Menton (Appendix 3 on CD).

Errors tended to be larger for measurements that were less precise in their definition, or in areas where landmarks were difficult to define, i.e. tip of the soft palate.

The random error was very small; the error variance did not exceed 3% of the total variance for any of the measurements made in the study.

Random errors as described by Houston (1983) can add to the natural variability of the measurements and obscure real differences between groups. They can arise as a result of many factors in this type of study such as;

- Variations in positioning of the subject in the cephalostat, which we attempted to eliminate by using natural head position, a standardised technique as described in the Method (section 4.4).
- Variations in radiographic technique, which we attempted to eliminate by using a standardised technique as described in the Method (section 4.4).
- Quality of the radiographic image, which can affect the clarity of the landmarks used for measuring.
- Difficulty in identifying landmarks or imprecision in their definition may create difficulties in measuring consistently. For example the vertical position of the tip of the soft palate is thought to be less reliable than other landmarks and

can result in errors in the measurement of soft palate length (Miles et al 1995).

Miles et al in 1995 reported that the majority of upper airway landmarks could be reliably identified, irrespective of the quality of the radiograph. However the quality of the radiograph could affect the identification of the horizontal position of the Hyoid and the linear measurement of the posterior airway space, although this was not clinically significant.

6.1.8 Systematic Error

Systematic errors or bias in this type of study can arise for a variety of reasons such as (Houston 1983);

- If radiographs are measured by two operators who have a different concept of the landmarks, this was eliminated in the study reported in this thesis by using one operator.
- Change of practice with experience, resulting in a series of measurements differing systematically from a series taken once the operator has become experienced and refined their technique of measurement. This was reduced by the examiner performing a pilot study.

Bias may be introduced by subconscious weighting of results; therefore the examiner was blinded to the subjects' identity by masking the radiograph.

Systematic error was tested for as described by Houston and was found to be within an acceptable range after Bonferroni correction, which decreases the chances of a false positive result due to performing multiple statistical tests on a data set (Houston 1983, Bland and Altman 1995).

In detecting systematic errors it is important that a sufficient number of cases be replicated; otherwise only large systematic errors will be revealed (Houston 1983). In the study reported by this thesis measurements were repeated on 25 radiographs twice one month apart.

The standard deviation is also an important factor in the detection of systematic error, if the standard deviation is large as a result of large random errors, then systematic error will be obscured from detection. Standard deviations for the cephalometric measurements in this study are small (Ceph Data Summary, Appendix 3 on CD).

6.1.9 Power Calculation and Sample Size

The power calculation revealed that a sample size of 68 ESS score subjects and 48 AHI score subjects for this study to have 80% power and to achieve a 95% significance level, was required assuming a change in Epworth of 3 points and a change in AHI of 7 points.

In Part 1 of the study 121 cephalometric radiographs were examined, a large number of radiographs were examined to allow for the possibility of a poor response rate to the questionnaire.

6.2 Discussion of the Results

6.2.1 Subjects

The study reported by this thesis was carried out on a cohort of adult patients treated by a single Consultant Orthodontist operating at the Victoria Hospital, Fife and Edinburgh Dental Institute. Referrals were made from a variety of sources such as local Ear, Nose and Throat Consultants, General Dental Practitioners and the Edinburgh University Sleep Clinic.

Location of referral was from a large geographical area including the Shetland Isles, Aberdeenshire, Dundee, Fife, Edinburgh and the Borders.

One hundred and twenty one patients consented to participate in the study, every patient treated in the department during data collection agreed to take part (Summary Statistics Table 10).

The ratio of males to females was 2.3 to 1 which mirrors closely the level of OSAHS reported to exist in the population. Young (1993) reported that 4% of middle-aged males were affected and 2% of middle-aged females, a ratio of 2 to 1.

The age of the subjects included was from 28 to 85 years old, a range of 57 years. The spread of ages was normally distributed, with peak incidence during middle age, as may be expected in a cohort of snoring patients (Figure 9).

The Body Mass Indices of the cohort were also normally spread (Figure 10), the mean being 28.7, classed as overweight. This increased mean BMI within the cohort may also be expected as obese patients have been shown to be much more likely of suffering from OSAHS (Schmidt-Nowara et al. 1995).

6.2.2 ESS and AHI Scores

Severity of OSAHS can be measured subjectively in terms of daytime sleepiness using the Epworth questionnaire or objectively using the Apnoea Hypopnoea Index (Johns 1991).

All 121 patients included in the study were able to complete the Epworth questionnaire. Fifty four patients from the cohort had attended the Edinburgh University Sleep Centre and had AHI scores.

The number of patients recruited to the study with an AHI score was lower than for ESS. ESS can be calculated at the chair-side whereas AHI is recorded after polysomnography, which may require an overnight stay at a sleep centre, this may only be carried out in more severe cases where OSAHS is suspected.

The mean ESS of the cohort was 9.4, the maximum being 22 and the minimum 0. The data was normally distributed (Figure 11). This would equate to mild to moderate OSAHS as defined by Johns in 1991. This mean level of ESS was expected as the group of patients best treated with a mandibular repositioning splint are those with mild to moderate OSAHS (Johal and Battagel 2001).

The mean AHI value was 18.2, the maximum value being 77 and the minimum value 0 (Figure 12). The data was skewed towards the lower AHI values, concordant with the referral pattern for treatment with a mandibular repositioning splint, which has been shown to be most useful in cases of mild to moderate OSAHS as is reflected in our cohort.

6.2.3 Link between ESS and AHI

A significant correlation between ESS and AHI has been demonstrated in previous studies (Johns 1991). Data from this study was plotted on a scatter graph to explore the link between subjects ESS score and AHI (Figure 13). No correlation was found between the two sets of values in 54 patients.

It would seem that the best way to appreciate ESS and AHI is to regard ESS score as a subjective assessment of a patients' daytime sleepiness and therefore OSAHS severity and AHI as an objective assessment of OSAHS.

PART 1: Cephalometric Study Results

6.2.4 Epworth Analysis 1

The cohort was divided in two, high and low ESS. It was found that Body Mass Index (BMI) and MMPA (Maxillary Mandibular Planes Angle) showed highly statistically significant increases when compared with increased ESS score (Table 11). Patients who had an ESS score of more than 12 were more likely to have a higher BMI and an increased MMPA.

The study reported by this thesis shows that patients with an increased BMI are more likely to suffer from increased severity of daytime sleepiness as measured by ESS score. Several other studies have also demonstrated that the obese are more likely to suffer from OSAHS; this is the first study to demonstrate that the likelihood of severe daytime sleepiness increases as BMI increases (Ferguson et al 1995, Pracharktam et al 1996, Battagel et al 2000).

It is thought that the increased incidence of sleep-related breathing disorders amongst the obese is due to the fact that they have an increase in fatty deposits in their pharynx and a larger fatty pad in the posterior pharynx. They may also have thicker necks due to increased fatty deposits, thus increasing the external pressure on the airway and making it more liable to collapse (Davies and Stradling 1990). The soft palate and tongue may also contain larger fatty deposits.

This study also shows that patients with increased MMPA are more likely to be sufferer sleep-related breathing disorders. MMPA is the angle produced by the intersection of the maxillary and mandibular planes. Studies have shown that patients with an increased face height and more retrognathic mandibles are more likely to suffer from OSAHS due to restriction of the airway (Tangugsorn et al 1995, Battagel and Johal 2000). An increased MMPA may often be seen in this group of patients.

Using logistic regression as shown in the Results (section 5.2.1) we can put the 2 values found to be significant factors in Epworth Analysis 1 into an equation to work out the probability of a patient being in the severe daytime sleepiness group, having an ESS above 12. The only values required are the subjects BMI and MMPA. This could be a useful clinical tool for prediction of the probability of a patient suffering from severe OSAHS.

6.2.5 Epworth Analysis 2

In Epworth Analysis 2, the data was examined by again subdividing the group according to ESS score, but this time into more discreet groups to highlight any factors that could be significant as daytime sleepiness becomes more severe.

Johns in 1991 stated that the mean ESS score for mild OSAHS is 9.5 and for moderate OSAHS 11.5 and in severe OSAHS it is 16. In order to discover any changes in anatomical features as ESS score and therefore OSAHS becomes increasingly severe, the sub-groups had to be discreet enough to distinguish between mild, moderate and severe OSAHS.

A change of 3 points on the Epworth Scale was considered clinically significant by Johns (1991); therefore our groupings followed this, with an interval of three points on the scale contained within each subgroup.

The data from this study showed that as ESS increases and patients become more daytime sleepy then there are highly statistically significant increases in the BMI, MMPA and the distance Pt 7-12 (Table 12).

The results of the two group analysis 1 are confirmed by this more discriminant analysis 2, BMI and MMPA again show significant increases as ESS score and becomes increasingly severe.

Point 7-12, a linear pharyngeal dimension measured from the point on the posterior pharyngeal wall at the same horizontal level as the tip of the soft palate, was found to increase in length significantly as ESS score increases. This finding is surprising as other studies revealed in the literature search have reported that linear pharyngeal dimensions decrease in OSAHS (Djupesland et al 1987, Lyberg et al 1989, Tangugsorn et al 1995, Battagel and L'Estrange 1996, Pracharktam et al 1996 and Battagel et al 2000).

A possible explanation for this highly significant finding, which also displays a high odds ratio of 1.230, (95% Confidence Interval 1.073-1.411) is that OSAHS sufferers and snorers tend to have larger soft palates (Battagel and L'Estrange 1996). These soft palates may be influenced more by gravity due to their size and therefore when the radiograph is taken in the vertical position they lie vertically giving a clear pharyngeal airway. However once the subject is supine the soft palate is influenced by gravity and may contribute to the obstruction of the airway. It has been shown that pharyngeal dimensions reduce particularly at the level of the soft palate when a patient changes from an upright to supine position (Battagel et al 2002).

6.2.6 AHI Analysis 1

In AHI analysis 1, low and high scores were related to the cephalometric variables with the cohort divided in two, high and low AHI. None of the cephalometric measurements made was found to show statistically significant changes between the two groups.

6.2.7 AHI Analysis 2

In AHI analysis 2 where the groups were subdivided in to units of 7 AHI points allowing the examination of cephalometric changes occurring as AHI increased it was found that the overjet (OJ), the linear distance between H1 and point B (H1B), and the linear distance along a perpendicular from H1 to the Maxillary plane (H1NL), were changing highly significantly with increasing severity as measured objectively by AHI (Table 13).

Overjet

Overjet, the horizontal overlap of the upper and lower incisors, increases as severity of AHI increases, this may be a reflection of skeletal form, such as mandibular size. Retrognathic skeletal patterns have been shown to occur in OSAHS sufferers (Lowe and Fleetham 1995). This is the first study to show that this overlap increases as severity of AHI increases.

Lower Lip Length

Lower lip length increases as severity of AHI increases; this vertical measurement was made from the highest point on the lower lip (UL) to soft tissue Menton (STMe), the lowermost point on the soft tissue of the mandibular symphysis in the midline. This may be as a result of patients who have more severe OSAHS having a greater BMI and therefore fatty deposits in the chin area, but also OSAHS patients have been shown to have long lower face heights and therefore long lower lip lengths (Bacon et al 1989).

Hyoid Bone

Considerable attention has been paid in the literature to the position of the Hyoid bone. The hyoid bone serves as anchorage for the lingual musculature; its position also partly determines the shape, size and position of the tongue. It has been reported that in OSAHS an increased amount of the tongue mass is located at the hypopharyngeal level and that the base of the tongue is in a more upright position (Tangugsorn et al 1995).

A lower position of the Hyoid bone has been a recognised characteristic of OSAHS subjects in numerous cephalometric studies (Jamieson et al 1986, Djupesland et al 1987, DeBerry-Borowieki et al 1988, Partinen et al 1988, Maltais et al 1991, Pracharktam et al 1994, Tangugsorn et al 1995, Battagel and L'Estrange 1996, Johal and Battagel 1999, Battagel 2000 et al, Battagel and Johal 2000). Lowered position of the hyoid bone has also been positively correlated with severity of sleep apnoea (Petri et al 1994).

Differences in antero-posterior position of the hyoid in OSAHS subjects have been reported; Bonham et al (1988) reported that the hyoid bone, measured from the most anterior point, moved upwards and forwards relative to the mandibular plane. The findings of Johal and Battagel (1999) were in agreement, also reporting to a lesser degree an upwards and forwards movement of the hyoid relative to the maxillary plane.

In the study reported by this thesis the distance H1NL shortens as AHI becomes more severe. The distance H1B lengthens as AHI becomes more severe. The hyoid bone is rotating counter clockwise under the influence of attached musculature. Rotation of the Hyoid has not been recorded in previous studies.

This may be because few studies record measurements from more than a single point on the Hyoid. Battagel and L'Estrange (1996) used the most inferior and the most anterior points on the hyoid and found that the horizontal distance from the hyoid to point B decreased in OSAHS patients compared to controls.

It is reported in the literature that an inferiorly positioned Hyoid bone is associated with poor response to splint therapy and that the nearer that the mandible and the hyoid bone approximate the more the AHI improves (Jamieson et al 1986, Bonham et al 1988, Evelof et al 1994). The importance of a low hyoid bone position in the management of OSAHS has been recognised by Riley et al in 1990. In their surgical approach they repositioned the bone anteriorly.

6.2.8 Head Posture

Natural head posture (NHP) is the upright position of the head of a standing or sitting subject, while it is balanced by the post cervical and masticatory suprahyoid, infrahyoid muscle groups, with eyes directed forwards so that the visual axis is parallel to the floor (Solow and Tallgren 1971).

There is a consensus in the literature that individual variations in NHP are related to certain characteristics of the craniofacial structures. The mechanisms responsible are not fully understood (Solow and Tallgren 1971).

One factor which triggers extension of the cranio-cervical posture is obstruction of the airway (Solow et al 1993). This has been confirmed by the demonstration of an increase in cranio-cervical angulation in children with enlarged adenoids, by experimental blockage of the nasal passage, with nasal allergy, with enlarged tonsils and constricted maxillary arches (Solow and Kreiborg 1977, Linder-Aronson 1970, Vig et al 1980, Wenzel et al 1985, Behlfelt 1990, McDonald 1995).

It is reported that an increase in the cranio-cervical angle may be found in OSAHS subjects (Solow et al 1993, Tangugsorn et al 1995). This may be interpreted as an indication of a compensatory mechanism, in which the cranio-cervical relation serves to lift away the base of the tongue and the soft palate from the posterior pharyngeal wall in order to alleviate the obstructive condition (Solow et al 1993, Tangugsorn et al 1995).

In the study reported by this thesis none of the variables recorded to examine head posture showed significant change as ESS score or AHI increased, failing to confirm the findings of Tangugsorn et al (1995) and Solow et al (1993).

PART 2 RESULTS DISCUSSION

6.2.9 Questionnaire Response

Ninety two subjects responded to the questionnaire (Appendix 2), a response rate of 76% (Table 14). This is comparable to other response rates in the literature such as 73.7% achieved by Shadaba et al 2000 and 76% by McGown et al 2001, 69% McArdle et al 2001, but lower than the response rate reported by Schmidt-Nowara et al 1991 of 93%.

Unfortunately not every question was answered by each respondent, a problem reported by other authors such as Schmidt-Nowara et al 1991, Shadaba et al 2000 and Johnston et al 2002.

6.2.10 Comparison of Pre and Post Treatment ESS Score

The first area the questionnaire investigated was the subjects ESS score 3 months after treatment had commenced. This was then compared using the Wilcoxon signed rank test, to the subjects ESS score at the initial visit (Results section 5.3.2).

A statistically highly significant decrease in ESS score had occurred, however the mean decrease was 1.84, $p<0.0001$, which is not clinically significant.

Only 7.8% of the subjects had a change in ESS score which was greater than or equal to 3 points on the ESS, which may be considered a clinically significant change (Johns 1991).

In comparison, Gotsopoulos et al (2002) carried out a randomised, controlled trial evaluating the effect of an MRS on daytime sleepiness by comparing it with an inactive MRS placebo. They found that the MRS resulted in a small but highly significant reduction in the mean ESS score of 9, $p<0.0001$, a larger reduction in ESS score than was found by the study reported by this thesis.

Johnston et al (2002) reported a randomised clinical trial assessing the effectiveness of an MRS in managing OSAHS, and found a mean decrease of 2.29 which was not statistically significant, $p<0.414$.

Johnston et al used a similar design of MRS to that used in the study reported by this thesis; with the mandible protruded by 75% of the maximal comfortable mandibular protrusion and 4mm inter-incisal clearance.

This method of advancement was used in the study reported by this thesis to aid comparison of the results with other studies such as Clark et al 1996, Cameron et al 1998, Gale et al 2000, Engleman et al 2002 and Johnston et al 2002.

Johal and Battagel (1999) advanced the mandible by the maximum comfortable amount of protrusion which they commented was frequently 75% of maximal protrusion.

However, Gotsopoulos et al (2002) used an MRS with an adjustable screw which allowed incremental protrusion of the mandible. The MRS was worn for a period of acclimatisation and then was incrementally adjusted until the maximum comfortable limit was reached.

This difference in mandibular protrusion may aid explanation of the larger decrease in ESS score seen in the study of Gotsopoulos et al (2002).

Subjects in the study reported by this thesis received further advancement of their MRS if required, once the data had been collected.

6.2.11 Comparison of Sleeping Partners Pre and Post Treatment ESS Score

There were 39 missing sets of values in the statistical analysis of sleeping partners (n= 53) as 39 of the responders did not have partners available to complete the questionnaire.

Sleeping partners own ESS score was also recorded at the initial visit for treatment and again via the questionnaire three months after treatment had commenced (Results section 5.3.3). These values were compared statistically using the Wilcoxon signed rank test. A highly significant decrease in sleeping partners ESS score was seen, but the mean change was not clinically significant.

In comparison, McArdle et al (2001) undertook a study to determine the impact on partners of OSAHS patients of the treatment of the patient with CPAP, rather than MRS as reported in the study described by this thesis. They found that the partners had poor sleep quality and self reported health status and that they received subjective sleep quality benefits from the treatment of the patient with CPAP, but did not find any improvement in objective sleep quality.

Johnston et al (2002) found lower scores for the mean severity of snoring, AHI and daytime sleepiness in terms of ESS score when subjects used an MRS compared to a placebo, but there was not a statistically significant difference.

6.2.12 Comfort

Subjects were asked in the questionnaire, in terms of comfort how long it took for them to get used to their appliance (Results section 5.3.4, Table 15). Twenty patients reported that it took less than 7 days to get used to their appliance, a relatively short period of time. A further 34 patients reported that it took less than a month to get used to wearing their appliance and 25 patients, 21% of the whole sample size of 121 subjects reported that they never became used to wearing their appliance.

The subjects who were unable to get used to wearing their appliances were seen again in the department and the appliance adjusted or remade.

In comparison, Schmidt-Nowara et al (1991) reported that 17 of their 68 responders (25%) had stopped trying to use their MRS after an average of 3 months.

Cameron et al (1998) reported on a questionnaire based study using visual analogue scales and involving 16 male subjects. They found that the reported comfort level of the MRS on the visual analogue scale was a mean score of 7.5 out of 10.

6.2.13 Compliance

Schmidt-Nowara et al. in 1995 found that patients must receive initial written instruction regarding the use of their device in order to produce the best compliance rates.

In this study all patients were given a written advice sheet repeating the instructions given to them at their initial visit in order to achieve the best compliance rates.

Compliance with MRS treatment has been reported frequently in the literature and the level of compliance found in this study is comparable with the findings of several authors. Compliance is reported in different ways by different authors, some reporting compliance per total sample size (Schmidt-Nowara et al 1991, Johal and Battagel 1999, Marklund et al 2001, Johnston et al 2002) and others compliance per number of responders, which gives higher percentage figures as non-responders are excluded (Shadaba et al 2000, McGown et al 2001).

In the study reported by this thesis, 54 responders (45% of total sample, 68% of responders) were wearing their appliance three months after initial treatment, when the questionnaire was conducted (Results section 5.3.5) Twenty five (21% of total sample, 32% of responders) were not wearing their appliance. The mean number of

nights per week the appliance was worn was 5.6 and the mean number of hours the appliance was worn was 6.2.

The overall continued usage is quite low at 45% of the total sample; several reasons were given for ceasing to use the appliance, discomfort was cited most commonly.

In comparison, Schmidt-Nowara et al in 1991, found that 51 out of 68 (75%) of patients surveyed were using their MRS an average of 7 months after fitting the appliance.

Johal and Battagel in 1999 reported a compliance rate of 28 out of 37 subjects (76%) after subjects had worn their splints for an average of 13.4 months.

Shadaba et al (2000) reported that after an average of 7.6 months of appliance wear, 78 out of 112 (70% of responders) wore their splints on average 6.2 nights per week, with 35 wearing their splint every night.

McGown et al 2001 found that 69 of their 126 responders (55% of responders) reported that they used their MRS at least once a week, 47 subjects wearing the splint every night for a mean 21.5 months, using the splint for on average 6.6 hrs per night.

Marklund et al 2001 evaluated the long term effects of MRS (5.2 years) in a prospective study of 33 patients and found that 19 out of 33 patients (58%) were still using their MRS and reported that they used their devices for 50-90% of nights.

Gotsopoulos et al (2002) found a high self-reported compliance during a 4 week treatment period, with subjects reporting that they wore their appliance for an average of 6.7 hours per night.

Johnston et al (2002) found that 14 out of 21 (68%) subjects reported that they wore their MRS every or almost every night and 17 out of 21 (79%) subjects reported wearing their appliance for 4 or more hours per night.

6.2.14 Side Effects

Subjects were asked to report any problems or side effects encountered during their treatment (Results section 5.3.6). Many subjects did not respond to some or all of the questions on side effects as they had not experienced them during the study.

Seventy four of the 121 subjects in the study reported by this thesis reported one or more side effects and 4 suffered from all 5 side effect categories (Figure 14).

Other studies of the side effects suffered with MRS treatment also comment that a large majority of patients experience one or more side effects of splint wear (Shadaba et al 2000).

McGown et al (2001) found side effects were reported to occur every night in 28 out of 69 MRS users and 21 out of 37 subjects who reported that they had stopped wearing their appliance.

Gotsopoulos et al (2002) reported that a significantly higher proportion of subjects experienced side effects with an MRS when compared to a control inactive device. Gotsopoulos comments that the majority of side effects reported were mild in nature and lasted for the duration of their treatment.

Excess Salivation

Excess salivation was a common problem reported by 47 out of 121 subjects (Table 16), 34 subjects stated that excess salivation was a minor problem, 4 subjects found that it was a significant problem and as a result they were unable to wear their appliance.

Excess salivation is commonly encountered in the first week of appliance wear until the stimulation of saliva reflexes diminishes, just as occurs with an orthodontic appliance or new set of dentures (Schmidt-Nowara et al 1995, Ferguson et al 1996, 1996). Patients are warned that this reflex salivation may occur.

Johnston et al (2002) reported that the most frequently encountered problem in their study was excess salivation, with14 out of 21 subjects reporting the problem.

McGown et al 2001 reported that excess salivation was less of a problem with 7 out of 69 MRS users and 13 out of 37 subjects who were no longer using their MRS reporting the problem. Fewer subjects in the study by McGown et al reported excess salivation as a problem, perhaps this was because they had already been wearing their MRS for over a year when the questionnaire was carried out and any excess salivation would have diminished.

Soreness of Mouth, Teeth or Gums

Soreness of mouth teeth or gums (Table 17) was reported by 54 subjects to be a minor problem; in 7 it was a significant problem and the patients were unable to wear the appliance. This group of 7 patients were reviewed in the department and their appliances adjusted.

Tooth tenderness was also reported as a significant side effect by Gotsopoulos et al (2002), and 47 out of 68 subjects in Schmidt-Nowara et al' s 1991 study reported discomfort of the teeth, gums or jaw to be a problem.

Jaw Discomfort

Jaw discomfort (Table 18) was reported by 43 subjects; in 22 it was a minor problem, but 9 patients found the problem so significant they were unable to wear the appliance.

Johnston et al (2002) found that 8 out of 21 subjects had temporary temporomandibular joint discomfort on waking, with 2 subject reporting persistent discomfort throughout the day. Schmidt-Nowara et al (1991) also found 1 patient out of 68 that suffered prolonged pain form the temporomandibular joint, but that this resolved once the appliance was discontinued.

Marklund et al 2001 found that no patient in their long term trial reported any increase in craniomandibular symptoms during their study period (5.2 years). Johal and Battagel (1999) also found that none of the subjects in their study reported lasting discomfort in the muscles of the face or jaw joints.

These findings emphasize the importance of careful pre-treatment assessment and the need to inform patients of the possible side-effects of appliance wear.

Difficulty Falling Asleep or Frequent Awakening.

Difficulty in falling asleep or frequent awakening (Table 19) was reported as a problem by 35 subjects, where 8 found that it was so significant they were unable to wear their appliance. McGown et al (2001) also reported sleep disturbance in 12 out of 69 MRS users and in 12 out of 37 subjects who reported that they had stopped using their appliance.

Difficulty Breathing

Difficulty in breathing (Table 20) was cited as the least common problem with 16 subjects finding it to be a minor problem and 7 finding the problem so significant they were unable to use their appliance.

The incorporation of an anterior opening in the design of an MRS has been reported as being particularly helpful for subjects who are mouth breathers (Johal and Battagel 2001).

Waking Up with Appliance Detached

Waking up with the MRS detached was reported as a minor problem by 19 out of 121 subjects and 8 found the problem so significant they were unable to use their appliance (Table 21).

Good retention is very important to ensure that the splint is well retained by the dentition in order to prevent disengagement and loss of the opening of the airway achieved by forward posturing of the mandible (Johal and Battagel 2001).

In the study reported by Johnston et al 2002 it was found that 17 out of 21 subjects reported that their MRS became detached on 2 nights per week or less.

Schmidt-Nowara et al (1991) found that extension of the maxillary wings of their acrylic copolymer appliance produced better attachment and reduced the problem.

Subjects in the present study who had reported problems with retention were seen again in the department and their appliances adjusted or remade.

6.2.15 Treatment Outcome

Subjects were asked to report on the effects of their treatment; not every patient answered every question, some providing written comments rather than the required tick box entries resulting in a disappointing amount of data for analysis (Results section 5.3.7) (Figure15).

Daytime Sleepiness

Daytime sleepiness has been reported to be one of the most significant problems associated with sleep disordered breathing and may be measured objectively by the maintenance of wakefulness test (Engleman et al 2002).

In the study reported by this thesis 24 subjects felt that their daytime sleepiness was improved or much improved and 2 patients felt it was worse (Table 22).

This subjective reported improvement in daytime sleepiness is lower than that reported by Schmidt-Nowara et al (1991) who found that the majority of his subjects (63 out of 68) reported daytime sleepiness before treatment with an MRS, and following treatment this reduced to 35 out of 68 subjects.

Cameron et al (1998) using visual analogue scales, found that subjects reported that their daytime sleepiness had reduced after treatment with an MRS and that they awoke more refreshed.

McGown et al 2001 found that 44 out of 69 MRS users and 12 out of 37 patients, who had ceased to use their MRS, reported an improvement in daytime sleepiness when using their MRS.

Quality of Night Time Sleep

41 subjects felt that the quality of their night time sleep was improved or much improved and 8 felt that it was worse or much worse (Table 23). The subjects who reported that their sleep quality was worse were seen again within the department and their appliances adjusted.

An improvement in sleep quality is in agreement with the findings of Gotsopoulos et al (2002) who reported that significantly more subjects in their study reported improved sleep quality with active MRS treatment than with a control device.

Snoring

Measurement of snoring using sound activated tape recorders has been reported (Stradling 1993), but subjects do not always snore every night and it is recognised that the duration, timing and loudness may vary from night to night (Johnston et al 2002). A questionnaire is used to subjectively assess snoring in the study reported by this thesis.

Forty five subjects felt that their snoring was improved or much improved and 1 patient felt that their snoring was worse, 18 reported that there had been no change (Table 24). Subjects who reported that there had been no change or that their snoring was worse were reviewed.

Despite differences in design of MRS studies reported in the literature agree that the use of an MRS can eliminate or reduce the symptom of snoring.

Schmidt-Nowara et al (1991) reported that out of a sample of 68 subjects, 27 found that their snoring was eliminated when they used their MRS, 37 reported that the intensity was reduced and 1 that there was no change, the other 3 subjects were unable to use their MRS.

Mehta et al (2000) reported the results of a randomised controlled study of an MRS for obstructive sleep apnoea which used a crossover study design using a control MRS which did not advance the mandible compared with an MRS. They found that the majority of patients (70%) reported substantial improvements in snoring, sleep quality (91%) and daytime sleepiness.

Shadaba et al (2000) found that 62 out of 78 MRS users and 11 out of 14 occasional MRS wearers reported that they were no longer snoring or that their snoring was acceptable.

McGown et al 2001 found that 80 out of 94 MRS users and 16 out of 29 patients, who had ceased to use their MRS, reported an improvement in snoring when using their MRS.

Gotsopoulos et al (2002) reported a highly significant reduction in the reported frequency and intensity of snoring with an MRS compared with a control device in their randomised controlled trial.

Concentration

Nineteen subjects felt that their concentration was improved or much improved, 1 subject felt it was worse (Table 25). The majority of respondents (45) felt that there was no difference.

In an objective test of concentration as part of a randomised crossover trial, Engleman et al (2002) compared CPAP and MRS and found no significant differences in cognitive scores between the two treatments, but performance in the tests used was improved when subjects were treated by CPAP or MRS.

Moodiness/ Irritability

Fifteen subjects reported that their mood was improved or much improved following treatment with an MRS, 46 that there was no change (Table 26).

Results of clinical studies suggest that there may be a relationship between sleep related breathing disorders and depressive disorders (Ohayon 2003).

It is thought that due to disrupted sleep architecture and intermittent hypoxemia, OSAHS leads to impaired daytime functioning in various neuropsychological and affective domains. Ohayon (2003) suggests that treatment of OSAHS may reverse the cognitive and affective dysfunction.

Energy Levels

Nineteen subjects felt that their energy levels were improved or much improved and 3 felt that they were worse; the majority of responders (45) felt that there was no change (Table 27). The 3 subjects who felt that their energy levels were worse also complained that they had difficulty in falling asleep whilst wearing their MRS.

Breathing pauses During Sleep

Twenty subjects felt that their breathing pauses during sleep were improved or much improved and 3 felt that they were worse, 32 felt that there was no difference (Table 28). In retrospect it may be that sleeping partners are better able to answer this question than the subject, as the subject is asleep. Other studies reported in the literature report on observed or witnessed apnoea rather than the subjects own perception of their breathing pauses during sleep (Schmidt-Nowara et al 1991, McGown et al 2001).

General Health

Seventeen subjects felt that their general health was improved or much improved with 49 feeling that there was no change (Table 29).

Standard quality of life questionnaires such as the SF36 used by Engleman et al (2002) may not be sensitive to some of benefits of MRS treatment but could be used as a validated assessment of well being before and after MRS treatment.

6.2.16 Partners View of Treatment Outcome

The symptoms of sleep disordered breathing may be very disruptive for those living with the patient. Sleeping partners were asked to report on their partner's treatment (Figure 16).

Daytime Sleepiness

Twenty out of 53 (37.7%) sleeping partners felt that the subject's daytime sleepiness was improved or much improved, 30 that there was no change and 3 that it was worse (Table 30).

Cameron et al (1998) found that sleeping partners reported that the subject was more refreshed upon wakening since their treatment with an MRS.

Snoring

Sleeping partners may be able provide a more accurate reflection of the improvement in snoring than the subject.

Thirty seven out of 53 (69.8%) sleeping partners in the study reported by this thesis felt that the subjects' snoring was improved or much improved, 12 that there was no change and 4 that it was worse or much worse (Table 31).

Cameron et al (1998) also found that the majority of sleeping partners felt that the subject's snoring was improved. The mean score for partners' assessment of the subjects' level of snoring was 8.8 on a visual analogue scale and that this reduced to 4.2 after the MRS had been worn, a statistically significant decrease.

Marklund et al (2001) asked sleeping partners to estimate the effect of MRS on snoring as satisfactory or unsatisfactory. Fourteen of 19 long term (5.2yrs) MRS users reported that the device was having a satisfactory effect on snoring, 5 that the effect had become unsatisfactory.

Moodiness and Irritability

Sixteen out of 53 (30%) partners felt that the subject's mood or irritability was improved or much improved since their treatment with an MRS, 31 that there was no change and 4 partners felt it was worse (Table 32).

As discussed previously (Discussion section 6.2.15) a link has been reported between sleep related breathing disorders and depression, a sleeping partner may again be able to provide an accurate reflection of any improvement in such symptoms. Emotional and marital impairment in subjects with sleep disordered breathing has also been reported (Guilleminault et al .1985)

Breathing Pauses during Sleep

Sleeping partners may be able provide a more accurate reflection of the improvement in breathing pauses during sleep than the subject.

Twenty three out of 53 (43.3%) sleeping partners felt that the subject's breathing pauses during sleep had improved or much improved. This comment was marked in the margin by patients on several of the questionnaires. Twenty four partners felt that there was no change and 2 that the pauses were much worse (Table 33).

Some patients treated with MRS may experience a decrease in upper airway size due to downward rotation of the mandible (Ferguson et al 1997). It is important that patients treated with MRS are diagnosed by physicians using the appropriate tests and that "anti-snoring "devices are not offered without proper diagnosis and evaluation (Cameron 1998). Follow up should also take place to ensure that the MRS is effective in controlling not only snoring but the other effects of sleep disordered breathing.

In comparison with the results of the study reported by this thesis, Schmidt-Nowara et al (1991) reported that out of a sample of 68 subjects 63 were suffering from apnoeas that were observed by their sleeping partner, after treatment with an MRS 30 subjects still reported the problem.

McGown et al 2001 found that there was an improvement in witnessed apnoea for all responders to their questionnaire (126 responders out of 166 surveyed).

General Health

Fourteen (26.4%) sleeping partners felt that the subjects general health was improved or much improved, 36 that there was no change and 2 that it was worse (Table 34).

Lack of subjective improvement noticed by the subject or their sleeping partner in daytime sleepiness, snoring and the symptoms of sleep disordered breathing has been associated with subjects ceasing to use their MRS (McGown et al 2001).

6.2.17 Partners Sleep Change

Sleeping partners were asked to report on the change to their night time sleep since their partner started to use their appliance 34 out of 53 (64.1%) of partners felt that their sleep was improved or much improved (Table 35). Six partners (11.4%) felt that their sleep was worse or much worse.

Cameron et al (1998) and McGown et al (2001) also found in their questionnaire based studies an improvement in the reported quality of partners' sleep.

Anecdotally, many sleeping partners have personally thanked the department for the treatment their snoring partner has received.

6.2.18 Funding

Patients were asked whether they believed that this type of treatment should continue to be available on the NHS; 69 subjects believed that it should (Table 36). In most European countries and in the United States of America this type of simple treatment for OSAHS is not state funded and can be expensive.

6.2.19 Other Treatment Received

Only 10 of our 121 subjects had received other treatment for their sleep problem, with 2 patients having received laser surgery and 2 conventional surgery (Tables 37 and 38). These subjects were not included in the cephalometric part of the study, but were still treated and their views are included in the questionnaire analysis. Six subjects had received CPAP and found it unsuccessful, 4 of these patients were successfully treated with a mandibular repositioning splint.

Part 3: Results Discussion

No anatomical measurement was found to be a statistically significant factor by this study when compared to treatment success or failure. Severity in terms of AHI and ESS, BMI and age were not found to be statistically significant factors when compared to success or failure of treatment.

This means that we are unable to predict the likelihood of a patient succeeding with MRS treatment from any of the measurements made by this study.

Comparing these findings with the literature we find that Lowe et al (1995) agreed that we cannot predict with a significant degree of accuracy the potential success of a dental appliance based upon anatomical considerations.

Mehta et al. (2001) used multiple regression analysis to identify four independent predictors of outcome, neck circumference, baseline AHI, retro-palatal airway space and the angle between the anterior cranial base and the mandibular plane. The study reported by this thesis did not reveal any evidence to confirm or refute the findings of Mehta's study.

Liu et al (2000) found that subjects with a high Maxillary-Mandibular Planes Angle and a vertical facial pattern were more likely to be treated unsuccessfully than those with lower angles. They also postulate that subjects with larger initial oropharynx size may have less potential for anatomical modification with an MRS.

Mayer and Meier-Ewert (1995) carried out a cephalometric analysis of two groups, 30 sleep apnoea patients and 30 age and sex matched control patients, aiming to establish predictors for successful treatment of OSAHS with an MRS.

They reported that the narrower the SNB angle, the wider the SNA angle, and the shorter the uvula, the more effective the device.

6.3 Limitations of the Study

Part 1: Cephalometric Based Study

In common with all cephalometric investigations this study suffers from limitations in examining a three dimensional object using a two dimensional technique (Literature Review section 2.10). The transverse dimension of the structures cannot be seen and thus the picture may be incomplete.

Limitations in radiographic technique such as magnification factors were accounted for by using the same radiographer and radiographic equipment for each film; precise magnification factors were not calculated for every radiograph, it is possible that this could increase the variance, the variance calculated in the pilot study was very small.

The aetiology of sleep related breathing disorders is complex; this is reflected in the many different management options. The different variables highlighted by this study are a perhaps a small part of the aetiology for each patient and variations in pathology elsewhere in the body must be recognised. Evidence from this study does not prove the existence of a causal relationship between craniofacial anatomy and sleep related breathing disorders.

Forty eight cephalometric variables were examined (Materials and Methods: Table 6-9), there is a possibility of discovering false positive statistical findings by chance when looking at a large array of variables and this must be borne in mind when considering the results of large cephalometric studies. Supporting data from the literature is provided in the discussion of each significant factor found in the study (Discussion sections 6.2.4, 6.2.5 and 6.2.7).

This study did not use a control group but compared sufferers of sleep related breathing disorders as a continuum increasing of severity (Materials and Methods section 4.7). Finding an age and sex matched control group who require lateral cephalometric radiographic examination with the equipment used in this study would be prohibitively difficult. However, there is an increasing demand for orthodontic treatment amongst the adult population. In future studies it may be feasible, with ethical approval, to seek a control sample to aid in verification of the results of this study from the increasing number of lateral cephalograms taken for orthodontic purposes in the adult population.

The range of severity looked at by this study was limited to those referred for treatment with MRS, therefore patients tended to be mild to moderate sufferers of sleep related breathing disorders. If another study were carried out on a broader

range of severity more significant factors may be found. This extension of the study may be limited by ethical considerations relating to best practice in treatment of severe OSAHS (SIGN 73 (2003)).

The Scottish Intercollegiate Guidelines Network (SIGN) guideline 73 on the management of OSAHS suggests that intra-oral devices are the most appropriate therapy for snorers and for patients with mild OSAHS with normal daytime alertness. They also suggest that intra-oral devices are a suitable alternative for patients who are unable to tolerate CPAP. The guideline recommends that CPAP is the first choice therapy for patients with moderate or severe OSAHS that is sufficiently symptomatic to require intervention.

It would be unethical therefore to recruit a cohort of patients with severe OSAHS for a study on treatment with MRS. It may be possible however to recruit those who fail to succeed with CPAP.

Part 2: Questionnaire Based Study

The response rate to the questionnaire was disappointing, but was comparable to the work of other authors (Results section 5.3.1 and Discussion section 6.2.9). The effect of subjects also failing to answer all of the questions in the desired way, but writing comments in the margins also reduced the data for interpretation and made robust conclusions difficult. A possible solution to this in future studies would be to have an electronic questionnaire which could be emailed to patients; this could have space for typed comments at the end but require every question to be answered before progressing to the next.

The response rate to the postal questionnaire could have been increased by collecting patient telephone numbers, available telephone numbers were found for non-responders through the hospital computer system, which proved arduous and in many cases unsuccessful as the patient notes often did not contain patient's telephone numbers, or the numbers were not kept up to date.

The questionnaire assessed compliance rates and satisfaction after a relatively short period of time. It would be useful to undertake another study with the same cohort in a year and then again at a 5 year interval, to increase the evidence base on long-term compliance rates, many other surveys of this nature currently available in the literature are also short term (Schmidt-Nowara et al 1995, Cameron et al 1998, Johal and Battagel 1999, Mehta et al 2001).

The questionnaire study was limited by being purely questionnaire based without objective evidence of efficacy. Assessing the effectiveness of a treatment for sleep

disordered breathing by questionnaire is subjective (Johns 1991, Schmidt-Nowara et al 1991, Clark et al 1993, Cameron et al 1998 and McGown et al 2001) and may be replaced by objective measurements such as clinical measurement of snoring levels, Maintenance of Wakefulness Test, Multiple Sleep Latency Test or the measurement of AHI or Oxygen Desaturation Index (ODI) at baseline and after treatment in single night sleep studies.

As shown by this study (Discussion section 6.2.3) the correlation between objective and subjective measures may be weak, postal surveys also rely on the subject and partner's perceptions which may not agree with objective measures of sleep disordered breathing (Shadaba et al 2000) Thus subjective and objective outcome measures should be considered separately.

There may also have been an element of subjects responding to the questionnaire in desirable way, so called response bias. If the study were to be repeated this could be eliminated by comparing patients reported subjective outcomes with objective measurements taken before and after treatment with an MRS.

Part 3 Treatment Success vs. Severity

In the study reported by this thesis subjects were classified as successfully treated if they were still wearing their MRS at the time of the questionnaire survey and had reported an improvement in snoring or breathing pauses during sleep. All other patients were classed as unsuccessfully treated. The groups were then compared to examine a link between successful treatment and severity of ESS score, AHI and anatomical features.

McGown et al (2001) classified their groups as users and non users of MRS, which on reflection may have been more pragmatic as we did not have an objective measure of success in the study reported by this thesis.

Johnston et al (2002) comments that there is currently no universally agreed definition of what constitutes treatment success with MRS. In their study in order to allow comparison with previously published reports of MRS treatment, success was defined according to 2 definitions based on reduction of AHI to 10 or less per hour (Schmidt-Nowara et al 1995) and the hourly rate of arterial oxygen desaturations (ODI) to 10 or less per hour (Lojander et al 1996).

Subjective questionnaires were also used as in the study reported by this thesis and compared with baseline scores for each subject to evaluate whether the appliance provided an improvement in reported snoring and the frequency of waking unrefreshed.

7. CONCLUSION

7.1 Part 1: Cephalometric Study

1. Increasing severity ESS score is related to increases in BMI, MMPA, and the pharyngeal dimension pt 7-12 (measured from the point on the posterior pharyngeal wall at the same horizontal level as the tip of the soft palate)
2. Increasing severity of AHI is related to increases in overjet, H1B and lower lip length and to decreases in H1NL.
3. The hyoid bone rotates counter clockwise as AHI becomes more severe.
4. Subjects with increasing BMI's were shown to have increasing severity of AHI and ESS score.
5. The logit equation could provide a useful clinical tool in assessment of a patient's likelihood to suffer from a severe sleep related breathing disorder.
6. No correlation was found between AHI and ESS score.

7.2 Part 2: Questionnaire Survey

1. A statistically highly significant decrease in both subjects and sleeping partners ESS score had occurred with MRS use, however the mean decrease was not clinically significant.
2. Twenty five out of 121 subjects did not get used to wearing their MRS within the 3 month study period.
3. Fifty four out of 121 subjects were wearing their MRS when the survey was conducted.
4. Mild, reversible side effects of splint wear were commonly reported.
5. A partner's perception of improvements symptoms following treatment with MRS can differ to that of the sufferer.
6. Sixty four percent of sleeping partners' reported that their night time sleep is improved if their partners are treated with a mandibular repositioning splint.

7.3 Part 3: Treatment Success vs. Severity

No predictors for success or failure of treatment were found.

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10. APPENDICES

10.1 Appendix 1 Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the following 8 situations in contrast to just feeling tired?

This refers to your usual way of life in recent times. Even if you have not done some of these things please try and work out how they would have affected you.

Use 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 a few minutes in traffic	_____
TOTAL (max 24)	

10.2 Appendix 2 Patient Satisfaction Questionnaire

Thank you very much for agreeing to take part in my study, this questionnaire follows the one you completed at your last appointment and should only take five minutes of your time. Firstly you will be asked to complete a sleepiness scale, similar to the one you filled in at the start of your treatment, followed by a few extra questions which will ask your views about the treatment you are receiving.
I would be very grateful if you could return this questionnaire to me in the envelope provided. Thank you very much for your help.

Claire Bates.
Orthodontic Department, Victoria Hospital, Kirkcaldy.

EPWORTH SLEEPINESS SCALE

How likely are you to doze off or fall asleep in the following 8 situations in contrast to just feeling tired? This refers to your usual way of life in recent times. Even if you have not done some of these things please try and work out how they would have affected you. Use 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 a few minutes in traffic	_____
TOTAL (max 24)	

1. In terms of comfort, how long did it take you to get used to your appliance? Please tick the appropriate box

- ☐ Less than 7 days
- ☐ Between 1 and 2 weeks
- ☐ Between 2 weeks and 1month
- ☐ Never

Are you still using your appliance? Yes ☐ No ☐

2. If yes, please enter in the box the number of nights per week you currently use your appliance? ☐

3. On these nights, please enter the average number of hours that your appliance is worn. ☐

4. If you have stopped wearing or decreased the amount you wear the appliance, please could you indicate when and why you did so?

5. Occasionally people may experience problems or side effects with the treatment.

Please tick a box to indicate if you have encountered any of these problems and how severe the problem was.

	Minor problem	Significant problem-still using appliance	Significant problem-not using appliance	Problem I had before treatment
Excess Salivation				
Soreness of Mouth/Teeth/Gums				
Jaw Discomfort				
Difficulty falling asleep or frequent awakening				
Difficulty breathing				
Waking up with appliance detached from teeth/ out of mouth				

6. Please tick a box to indicate whether treatment with your appliance has made any difference to the following.

	Much worse	Worse	No change	Better	Much better
Daytime sleepiness					
Quality of night time sleep					
Snoring					
Moodiness / irritability					
Concentration					
Energy levels					
Breathing pauses during sleep					
General health					

7. Do you think this treatment should continue to be available on the NHS?

Yes ☐ No ☐ Unsure ☐

8. Have you had any other form of treatment for your sleep problem?

Yes ☐ No ☐

9. If yes, please specify the type:

C.P.A.P ☐ Laser Surgery ☐ Surgery ☐ Other ☐

If other please state treatment received_____

Thank you very much for completing my questionnaire. If you have a spouse or partner, I would be grateful if you could ask him/her to complete the last section independently, without consulting you.

PARTNER QUESTIONNAIRE

Thank you very much for agreeing to take part in my study, this questionnaire should only take two minutes of your time.

Firstly you will be asked to complete a sleepiness scale, similar to the one you may have filled in at the start of your partners' treatment, followed by a few extra questions which will ask your views about the treatment they are receiving. The following questions refer to your partner-who is using the snoring appliance.

EPWORTH SLEEPINESS SCALE

How likely was your partner to doze off or fall asleep in the following 8 situations in contrast to just feeling tired, before starting treatment with their appliance? And how likely are they to do so since starting their treatment.

These questions refer to his/her usual way of life both before and since starting treatment. Even if he/she has not done some of these things please try and work out how may have affected him/her now and in the past.

Please use 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	
	After treatment	Before treatment
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 a few minutes in traffic		
TOTAL (max 24)		

Please tick a box to indicate if there have been any changes to the following aspects of your partner's health since the start of their treatment.

	Much worse	Worse	No change	Better	Much better
Daytime sleepiness					
Snoring					
Moodiness/irritability					
Breathing pauses during sleep					
General Health					

The final question refers to you.

Please tick a box to indicate if there have been any changes in your night time sleep since your partner started to use their appliance.

	Much worse	Worse	No change	Better	Much better
Quality of your night time sleep					

Thank you very much for completing my questionnaire. I would be very grateful if you could return this questionnaire to me in the envelope provided.

10.3 **Appendix 3**

Please see CD