European Journal of Orthodontics 24 (2002) 191–198

A comparative study of two mandibular advancement appliances for the treatment of obstructive sleep apnoea

Edmund Rose*, Richard Staats**, Christian Virchow** and Irmtrud E. Jonas*
*Department of Orthodontics, School of Dental Medicine, and **Department of Pneumology, Robert-Koch Clinic, Medical School, Albert-Ludwigs-University of Freiburg i. Br., Germany

SUMMARY Mandibular advancement appliances (MAAs) are accepted as a treatment option for snoring and mild obstructive sleep disorders. In the present clinical study two differently designed devices were examined for their effectiveness in treating obstructive sleep apnoea (OSA). The study was based on an assessment of 26 patients with a polysomnographic diagnosis of mild OSA [22 men, four women; mean body mass index 27.3 kg/m^2 (SD 3.1); mean age 56.8 years (SD 5.2); mean respiratory disturbance index (RDI): 16.0 events/hour (SD 4.4)]. After insertion of the first MAA and a 6–8-week habituation period, a cardio-respiratory home-sleep study was carried out. Following a 2–3-week period with no treatment, the second appliance was inserted. The sequence of the devices was randomized. Once the patients had become accustomed to the second appliance, another somnographic registration was carried out. Daytime sleepiness, snoring, and sleep quality were assessed subjectively on a visual analogue scale.

The results showed that a statistically significant improvement in the respiratory parameters was achieved with both appliances ($P < 0.01$). However, the activator [RDI: 5.5 events/hour, SD 3.3; apnoea index (AI): 3.4 events/hour, SD 2.1] was significantly more effective ($P < 0.01$) than the Silencor® (RDI, 7.3 events/hour, SD 5.3; AI: 5.8 events/hour, SD 3.2). No difference was recorded in the subjective assessment of the therapeutic effects. Both appliances reduced daytime sleepiness and snoring and improved sleep quality, and both influenced the treatment outcome.

Introduction

Repetitive partial or complete obstruction of the upper airway in obstructive sleep apnoea (OSA) is caused by narrowing of the pharyngeal space and a sleep-induced loss of muscle tone. Possible therapeutic options include weight reduction, avoidance of alcohol, and surgical procedures such as uvulo-palato-pharyngoplasty (UPPP), maxillomandibular advancement, and tracheostomy. Nasal continuous positive airway pressure therapy (nCPAP) has become established as a standard means of treating OSA. Mandibular advancement appliances (MAAs) are considered as an alternative, non-invasive treatment option in patients with a mild to moderate degree of OSA. MAAs enlarge and stabilize the oro- and hypo-pharyngeal airway space by advancing the mandible, and stretching the attached soft tissue, and in particular the tongue (American Sleep Disorders Association, 1995; Lavigne *et al.*, 1999). Treatment with MAAs is likely to increase in the near future, following the discovery of a correlation between even mild sleep-disordered breathing and incidence of hypertension (Peppard *et al.*, 2000).

Originally, MAAs were derived from an orthodontic functional appliance, the Esmarch appliance as proposed by Meyer-Ewert and Brosik (1987), which has been variously modified with the aim of increased effectiveness and patient compliance (Eckhart, 1998; Lowe, 2000). A wide range of oral appliances are now available and more than 34 oral appliances have been approved by the American Food and Drug Administration

for intra-oral use (US Food and Drug Administration, 1999). However, only a few of these have been investigated clinically in controlled studies to confirm their somnographic effectiveness.

In the Department of Orthodontics, University of Freiburg i. Br., Germany, two different MAAs are routinely used in the treatment of mild OSA and snoring. Both appliances have been reported to reduce snoring and/or to improve the incidence of OSA (Clark *et al*., 1993; Rose *et al*., 2000).

One appliance is a tooth-borne device requiring firm retention on the teeth; the other is a modified activator, which is tooth- and tissue-borne passively and has a loose fit. There are various reasons for using one specific type of appliance in a given patient. However, there is not sufficient scientific evidence for clinicians to determine which appliance is most likely to be effective, because data on effectiveness are inconsistent.

When comparing differently designed oral appliances in various patient groups, the results may reflect differences between the groups, e.g. due to intra-oral and pharyngeal anatomy, rather than between appliances. In a prospective computerized tomographic study, Gale *et al*. (2000) showed that there is a wide and unpredictable intra-individual variation in the response to mandibular advancement. The aim of the present investigation was to compare two differently designed MAAs, recording their subjective and objective effectiveness in patients with mild OSA in a crossover comparative study.

Subjects and methods

Study population and protocol

Twenty-six otherwise healthy subjects (22 males, four females) with a diagnosis of mild OSA were referred to the Department of Orthodontics, University of Freiburg, for treatment with an oral appliance. All subjects were enrolled in the study on the basis of full polysomnographic assessment at the sleep laboratory of the Department of Pneumology, University of Freiburg. Having refused nCPAP therapy, they were offered oral appliance treatment.

The criteria for treatment with a MAA were sufficient dental retention for the appliance (>10 periodontically healthy teeth per arch) and the absence of temporomandibular dysfunction.

A thorough dental examination was carried out before and after each somnographic registration. Before the appliance was inserted, dental rehabilitation was carried out on three subjects. This involved fixing a partial denture in the lower arch in one subject and periodontal treatment with scaling and root planing of the lower incisors in two others. None of the subjects had previously undergone other treatment such as UPPP or a course of nCPAP. The patients had a mean age of 56.8 years (SD 5.2) and the mean body mass index (BMI) was slightly increased (27.5 kg/m^2, SD 3.1). The mean respiratory disturbance index (RDI) was 16.0 events/hours (SD 4.4) and the apnoea index (AI) 10.5 events/hours (SD 3.7). The mean oxygen saturation (O_2 basal) was 96.4 per cent (SD 1.2) and the minimum oxygen saturation (O_2 min.) 89.1 per cent (SD 3.2).

The appliance sequence was randomized. Following a one-week habituation period, the subjects wore the device nightly for 6–8 weeks. Seven-channel sleep studies with the appliance in place were then carried out at home without supervision. A portable Merlin® somnograph (Heinen + Löwenstein, Bad Ems, Germany) was used to record chest and abdominal movements, oxygen saturation, oro-nasal airflow, heart rate, body position, and parapharyngeal noise. OSA was defined as a cessation of oro-nasal airflow for at least 10 seconds and a reduction in basal oxygen saturation of at least 4 per cent below the individual's baseline level. Hypopnoea was defined as a reduction in airflow to 50 per cent below average amplitude for at least 10 seconds. The treatment effectiveness of the oral appliances was assessed predominantly by analysing respiratory parameters. The most common and important parameters used for this purpose were the RDI, the AI, baseline oxygen saturation, minimum oxygen saturation, and oxygen desaturation. The RDI is defined as the number of apnoeic and hypopnoeic events during sleep divided by the hours of sleep, whilst the AI is the total apnoeic time divided by total sleep time.

After a second dental examination the other device was manufactured in the laboratory. The second MAA was inserted after a washout period of 2–3 weeks. Again, patients underwent a one-week habituation period and after 6–8 weeks of use a nocturnal sleep study was carried out with the MAA in order to monitor its effectiveness.

At the start of the investigation and before each home-sleep study, the subjects completed a visual analogue scale questionnaire relating to daytime sleepiness and sleep quality, with '0' representing 'not present' and '10' the maximum. Snoring was judged by the bed partners. The patients were asked directly about side-effects of the apparatus, e.g. increased salivation, tenderness of the masseter muscle, painful teeth or gingiva, and tenderness of the temporomandibular joint (TMJ). In addition to collecting objective somnographic data, the subjects were asked to give an overall assessment of both appliances at the end of the survey.

Mandibular advancement appliances (MAAs)

The two mandibular advancement devices were manufactured in the dental laboratory of the Department of Orthodontics. The type A device was the Silencor® (Erkodent GmbH, Pfalzgrafenweiler, Germany), made of a transparent, soft polyethylene material and prepared according to the manufacturer's instructions. Two bilateral connectors fixed in the region of the upper canine to the lower first molar provide a mechanism for moving the mandible approximately 4–8 mm forward during jaw opening (Figure 1). They are interchangeable with connectors of different lengths, allowing protrusive adjustment. The vertical dimension is increased by approximately 5 mm by the occlusal coverage splint material. The maximum possible protrusion in a given subject was determined from a wax impression. Those connectors providing an advancement of 75 per cent of the maximum were chosen.

The type B device was a Karwetzky U-clasp activator (Karwetzky, 1970; Figures 2 and 3), a horizontally split functional appliance. Two U-shaped springs are fixed lingually to the first molar on both sides, allowing the mandibular protrusion to be adjusted. The protrusion and the vertical opening were determined from an individual construction bite. The vertical opening

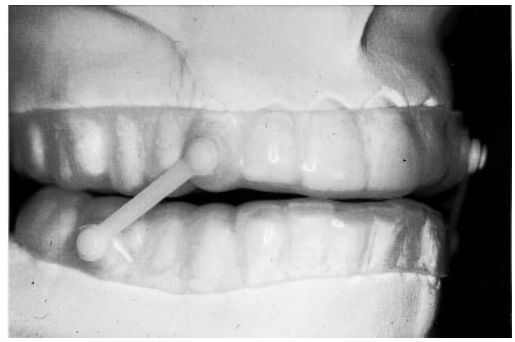

Figure 1 Mandibular advancement appliance A: Silencor®. Protrusion is created by the bilateral connectors supplied in different sizes by the manufacturer.

Figure 2 Mandibular advancement appliance B: Karwetzky U-clasp activator (lateral view).

Figure 3 Karwetzky activator: lateral view from the rear showing the U-shaped spring, which allows the protrusion to be adjusted.

of approximately 10–12 mm and protrusion of 75 per cent of the maximum possible protrusion were controlled intra-orally and on the dental models. The activator was made of hard orthodontic acrylic (Orthocryl®, Dentaurum, Pforzheim, Germany).

Both appliances fulfilled the criteria of adjustability of mandibular protrusion, and limited lateral and vertical mandibular movement during sleep. In contrast to the Silencor®, which requires sufficient dental retention, the activator is a passive tooth- and tissue-borne functional appliance with a loose fit.

Compliance

Compliance was assessed from the information provided by the patients and their bed partners. Sufficient compliance was assumed when subjects assured us that the device had been worn every night for at least six hours throughout the study period. If a patient could not tolerate the appliance or failed to use it for at least three successive weeks before somnographic assessment, a lack of compliance was assumed and that subject was excluded from the study.

Statistical analysis

Statistical analyses were carried out using SAS 6.12 software (Statistic Analysis System Institute, Cary, NC, USA). The two groups were comparable at baseline (Table 1). Mean and standard deviations were calculated for each treatment group. The Wilcoxon signed rank and Friedmann tests were applied. A *P*-value of less than 0.05 was used to assign statistical significance for all tests.

Results

The Silencor® appliances were inserted in 21 subjects. In eight patients they had to be repaired repeatedly during the first month and in two they had to be replaced after 20 days due to lack of retention. One patient was unable to tolerate the appliance despite repeated instruction and repairs, and a further two patients withdrew from the study for no given reason. Somnographic assessment was thus carried out after 6–7 weeks in 18/21 (85.7 per cent) subjects.

Twenty-three subjects were fitted with the Karwetzky activator. Within the habituation

Table 1 Results before treatment and 6–8 weeks after treatment with a Karwetzky activator and a Silencor®, respectively.

	Before treatment Mean (SD)	After treatment Mean (SD)
Type A: Silencor® (*n* = 18)		
AI (/hour)	10.5 (3.7)	5.8 (3.2)
RDI (/hour)	16.0 (4.4)	7.4 (5.3)
O_2 basal (%)	96.4 (1.2)	93.9 (3.6)
O_2 min. (%)	89.1 (3.2)	90.1 (4.8)
DS (VAS: 1–10)	7.2 (1.7)	5.4 (1.0)
S (VAS: 1–10)	9.1 (0.8)	3.2 (1.4)
SQ (VAS: 1–10)	6.4 (1.8)	4.1 (1.4)
Type B: Karwetzky activator (*n* = 20)		
AI (/hour)	10.3 (2.4)	3.4 (2.1)
RDI (/hour)	16.2 (4.6)	5.5 (3.3)
O_2 basal (%)	96.5 (1.2)	95.2 (1.6)
O_2 min. (%)	88.7 (1.2)	92.2 (2.1)
DS (VAS: 1–10)	7.0 (1.5)	4.1 (0.7)
S (VAS: 1–10)	8.8 (1.0)	3.4 (2.7)
SQ (VAS: 1–10)	6.2 (1.2)	4.5 (2.1)

Abbreviations: AI = apnoea index; RDI = respiratory disturbance index; O_2 basal = mean oxygen saturation; O_2 min. = minimum oxygen saturation; DS = daytime sleepiness; S = snoring; SQ = sleep quality; VAS = visual analogue scale.

period, three withdrew from the study, one due to pain in the TMJ, one because of tenderness in the region of the masseter muscle, and a third on account of a gag reflex, which could not be eliminated by modifying the appliance. After 6–7 weeks, 20/23 patients (86.6 per cent) underwent somnographic assessment while wearing the activator.

Six of the patients who had worn the first appliance were unable to adjust to the second device and became non-compliant. This applied to four subjects who had started with the activator and two who had initially been treated with the Silencor®.

Of the 26 subjects originally enrolled in the study, 16 (61.7 per cent) used both appliances and were available for examination.

In the nocturnal assessments of the Karwetzky activator, the mean RDI and the AI were significantly reduced ($P < 0.01$). Baseline oxygen saturation remained unchanged, but minimum oxygen saturation increased significantly. RDI and AI were also significantly reduced with the Silencor®. The baseline oxygen saturation was again unchanged, but minimum saturation increased significantly (Table 1).

Statistical comparison of the appliances showed that the activator was significantly more effective with respect to RDI and AI, but not to minimum oxygen saturation. Baseline oxygen saturation remained unchanged in both groups.

Subjective assessment suggested that both appliances reduced daytime sleepiness and snoring significantly while enhancing sleep quality. No differences were found in this respect between the two appliances (Table 1).

The initial side effects of the Silencor® were only minor. The subjects reported higher salivation, and complained of pain in the gingiva and teeth, both of which disappeared prior to the somnographic test. Side-effects were more frequent with the activator; in addition to increased salivation, seven patients complained of pain in the TMJ and of tenderness in the masseter muscle. Two patients withdrew from the study because of these symptoms. In five cases the individually predetermined amount of mandibular protrusion had to be reduced by 2 mm; in one patient the appliance was modified distolingually to counter the effects of a gag reflex. The post-sonography dental examination revealed no clinical side-effects.

In the final overall assessment by the 16 patients who had worn both appliances, 11 preferred the activator because of its higher stability and reduced need for repair, whilst five subjects favoured the Silencor® on account of its smaller size and comfortable, soft material.

Discussion

The present investigation provides a direct comparison between two different types of MAA used in the treatment of mild OSA. The appliances differ in the vertical opening of the bite, the type of retention, and the material used. Both types of MAA reduced obstructive apnoea and hypopnoea significantly, but to a statistically different extent. In both groups, baseline oxygen saturation remained unchanged, but minimum oxygen saturation was increased. Both appliances were found to reduce daytime sleepiness and snoring, and to improve subjectively assessed sleep quality.

The therapeutic effect of a MAA in the treatment of obstructive sleep disorders is controversial and the success rate, being subject to different definitions, varies substantially in clinical studies (Bonham *et al*., 1988; Clark *et al*., 1993; Schmidt-Nowara *et al*., 1995; Tegelberg *et al*., 1999). This might be due to differences in study protocols, appliance design, and subject selection.

With treatment success based on RDI reduction alone, improvements of 66 per cent (Karwetzky activator) and 53 per cent (Silencor®) were measured; these success rates are thus similar to those of other, comparable designed appliances (Schmidt-Nowara *et al*., 1995; Clark *et al*., 1996; Liu *et al*., 2000).

Concerning the respiratory parameters, the results demonstrate that the activator was statistically more effective than the Silencor®, although both appliances were given the same subjective rating. This difference in treatment success might be due in part to the design characteristics of the appliances, since the materials and the rate of retention differed. However, as no specific assessment of the

different materials was undertaken, no conclusions can be drawn from this investigation. Another more likely explanation for the differences is the amount of vertical and sagittal opening of the mandible. While both appliances were constructed with 75 per cent of maximum protrusion, the Karwetzky activator was opened 10–12 mm vertically and the Silencor® only 5 mm. This is just sufficient to provide an airway between the upper and lower dentition. In the Karwetzky activator, the area between the upper and lower incisors was kept free of any material to provide space for advancement of the tongue and to prevent it from blocking the airway. The present study confirms the results of Hans *et al*. (1997) and Lamont *et al*. (1998), who compared differently designed oral appliances, and reported that a device that forces the mandible forward and increases the vertical dimension is more effective in reducing OSA than one that only advances the mandible. This might be due to increased stretching of the velopharnygeal wall. An improved response to treatment might have been obtained with both appliances if the degree of mandibular advancement had been adjusted.

One of the main reasons for making subjective assessments of the devices is that appliances cannot be effective unless they are worn. One precondition for acceptance by the patient is the comfort of the appliance (Hans *et al*., 1997; Lamont *et al*., 1998). The majority of patients initially favoured the Silencor®. However, its frequent defects necessitated more dental sessions. Six patients described loss of retention during the night; the mandible can slide out of the appliance, which may wake the patient or more dramatically move the mandible into an even more posterior position. The clinical recall revealed loose retention, especially at the lower molars, when the patients were asked to open their mouths. An additional retentive element such as an Adams' clasp on the molars cannot be added due to the material properties. One disadvantage of the activator was the increased incidence of TMJ pain, which might have been due to the increased vertical opening, the decreased lateral freedom and the hard acrylic material used. This study underlines the fact that MAAs need to be assessed for stability and daily handling, because the treatment should be for life. However, good compliance was reported by the patients and their bed partners.

Compliance in this study was assessed on the basis of information given by the patients. This is not ideal and might lead to a methodological error in the study. From clinical experience with functional appliances, it is well known that patients have to get used to an appliance before using it nightly (Sander, 1983). Therefore, a habituation period of one week was introduced. Lowe *et al*. (2000) described a monitor for direct intra-oral recording of the time the appliance is used during sleep. Comparable registration was not performed in the present study because no such monitor was available at baseline. The intra-oral recording of compliance is still complex and cannot be considered a standard method applicable to all types of appliance (Lowe *et al*., 2000). In future investigations, registration of compliance time may lead to more objective data.

Snoring is often the chief complaint expressed by the bed partner. One major shortcoming of the present study is the lack of objective snore data collected by the microphone for subsequent assessment. One disadvantage of this home-sleep study was that the microphone was not placed in a standardized position during sleep, so that data were not comparable. Although paratracheal noise events are recorded by the somnograph, there is no software available to quantify snoring data reproducibly. Assessment by the subject and/or the bed partner were included, although this information may not always be available or consistent. For example, two subjects changed their partners during the study period and one subject preferred to sleep alone.

To reduce the chance of a 'carry-over' effect from the previous appliance, the sequence of the devices was randomized, and there was a 2–3-week 'washout' period without treatment with either appliance. Each appliance was introduced for the same length of time prior to somnographic assessment. However, the possibility of soft tissue reactions caused by the first appliance cannot be ruled out.

Desaturation was occasionally registered when patients slept in a supine position. With the Silencor®, the protrusion in supine sleep position depends on the patient's dental status, which in turn is responsible for sufficient appliance retention, whilst the mandibular position with the activator is determined by stretching of the soft tissues. This varies, however, in the different sleep stages. Another shortcoming of this study was that changes in body position were not analysed regarding apnoeic and hypopnoeic events. Body position is known to influence the severity of OSA in that the RDI usually worsens in supine position (Cartwright *et al.*, 1991). To control this parameter in one single nocturnal registration, the subject would have to be forced into one distinct sleep position, which might well influence the sleep pattern. Future research in a sleep laboratory with complete polysomnographic measurements might provide a more precise analysis with differentiation between sleep position, sleep stages, frequency of arousals, and apnoeic events still occurring during treatment.

Conclusions

This study confirms that both appliances investigated are effective in treating patients with mild OSA and can be used as an alternative treatment option. Concerning the RDI and AI, the non-retentive activator proved to be statistically more effective than the retentive Silencor® appliance. The treatment outcome was influenced by differences in appliance design. Long-term studies designed to investigate compliance, side-effects, service life, and cost-effectiveness are an essential prerequisite for thorough assessment.

Address for correspondence

Dr Edmund Rose
Department of Orthodontics
Dental Medical School
University of Freiburg
Hugstetter Strasse 55
D-79106 Freiburg i. Br.
Germany

Acknowledgement

The authors wish to express their gratitude to Professor Dr Jürgen Schulte-Mönting, Centre for Biometrics and Medical Informatics, University of Freiburg, for providing the statistical analyses.

References

American Sleep Disorders Association. Standards of Practice Committee 1995. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep 18: 511–513

Bonham P E, Currier F, Orr W C, Othman J, Nanda R 1988 The effect of a modified functional appliance on obstructive sleep apnea. American Journal of Orthodontics and Dentofacial Orthopedics 94: 384–387

Cartwright R, Ristanovic R, Diaz F, Calderelli D, Alder G 1991 A comparative study of treatment for positional sleep apnea. Sleep 14: 546–552

Clark G T, Arnad D, Chung E, Tong D 1993 Effect of anterior mandibular positioning on obstructive sleep apnea. American Review of Respiratory Disease 147: 624–629

Clark G T, Blumfeld I, Yoffe N, Peled E, Lavie P 1996 A crossover study comparing positioning devices on patients with obstructive sleep apnea. Chest 109: 1477–1483

Eckhart J 1998 Comparison of oral devices for snoring. Journal of the California Dental Association 26: 611–623

Gale D, Sawyer R, Woodcock A, Stone P, Thompson R, O'Brien K 2000 Do oral appliances enlarge the airway in patients with obstructive sleep apnoea? A prospective computerized tomographic study. European Journal of Orthodontics 22: 159–168

Hans M G, Nelson S, Luks V, Lorkovich P, Baek S J 1997 Comparison of two dental devices for treatment of obstructive sleep apnea syndrome (OSAS). American Journal of Orthodontics and Dentofacial Orthopedics 111: 562–570

Karwetzky R 1970 The Karwetzky U-clasp activator. Quintessence International 8: 51–55

Lamont J, Baldwin R D, Hay K D, Veale A G 1998 Effect of two types of mandibular advancement splints on snoring and obstructive sleep apnoea. European Journal of Orthodontics 10: 292–287

Lavigne G, Goulet J P, Zuconni M, Morisson F, Lobbezoo F 1999 Sleep disorders and the dental patient—an overview. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics 88: 257–272

Liu Y, Zeng X, Fu M, Huang X, Lowe A A 2000 Effects of a mandibular repositioner on obstructive sleep apnea. American Journal of Orthodontics and Dentofacial Orthopedics 118: 248–256

Lowe A A 2000 Dental appliances for the treatment of snoring and obstructive sleep apnea. In: Kryger M, Roth T, Dement W (eds) Principles and practice of

sleep medicine, 3rd edn. W B Saunders, Philadelphia, pp. 929–939

Lowe A A, Sjöholm T T, Ryan C F, Fleetham J A, Ferguson K A, Remmers J E 2000 Treatment, airway and compliance effects of a titrable oral appliance. Sleep 23: 172–178

Meyer-Ewert K, Brosik B 1987 Treatment of sleep apnea by prosthetic mandibular advancement. In: Peter H, Podszius T, von Wickert P (eds) Sleep related disorders and internal medicine. Springer-Verlag, Berlin, pp. 341–345

Peppard P, Young T, Palta M P, Skatrud J 2000 Prospective study of the association between sleep-disordered breathing and hypertension. New England Journal of Medicine 19: 1378–1384

Rose E, Mering L, Frucht S, Jonas I 2000 Oral appliances in patients with obstructive sleep apnoea—polysomnographic outcome. European Journal of Orthodontics 22: 456 (Abstract)

Sander F G 1983 The effects of functional appliances and Class II elastics on masticatory patterns. In: McNamara J A, Ribbens K A, Howe R P (eds) Clinical alterations of the growing face, Monograph No. 14, Craniofacial Growth Series. Center of Human Growth and Development, University of Michigan, Ann Arbor, pp. 155–178

Schmidt-Nowara W, Lowe A, Wiegand L, Cartwright R, Perez-Guerra F, Menn S 1995 Oral appliance for the treatment of snoring and obstructive sleep apnea: a review. Sleep 18: 501–510

Tegelberg A, Wilhelmsson B, Walker-Engström M L, Rinqvist M, Andersson L, Krekmanov L, Ringqvest I 1999 Effect and adverse events of a dental appliance for treatment of obstructive sleep apnoea. Swedish Dental Journal 23: 117–126

US Food and Drug Administration 1999 Oral devices cleared for treatment of snoring and/or obstructive sleep apneas of 1/7/99. Food and Drug Administration, Washington DC, USA