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Clinical audit of subjects with snoring & sleep apnoea/hypopnoea syndrome fitted with mandibular repositioning splint

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Summary Snoring and obstructive sleep apnoea/hypopnoea syndrome (OSAHS) are often treated with mandibular repositioning splints (MRS), but the efficacy and satisfaction of them has not been comprehensively addressed. A survey on the use of and satisfaction with MRS was posted to 177 patients referred by a hospital orthodontic department for custom-fitting of a MRS. Data were analysed using non-parametric techniques. The response rate was 81% ($n = 144$). Responders (30F, 114M) had mean (SD) age of 51 (11) years, apnoea+hypopnoea index (AHI) of 24 (21) per hr and Epworth Score of 10 (5) at diagnosis, and had been supplied with their MRS a median 7 (IQR 5–11) months previously. Fifty of the 144 patients (35%) had been offered continuous positive airway pressure (CPAP) treatment but had declined or abandoned this. Self-reported MRS use was 5 (2) h/night, with 74 of the 144 patients (51%) continuing to use MRS at least occasionally at a median 7 months after fitting. Survival analysis showed 12% still using MRS at 12 months. Epworth score fell slightly with MRS therapy [−2.4 (3.5); $P = 0.005$] and 7 daytime and 2 nocturnal symptoms improved in MRS users (all $P < 0.05$). Marital satisfaction did not change with MRS. Problems preventing MRS use in 70 non-users included: non-retention ($n = 12$), sore mouth ($n = 13$) or jaw ($n = 7$), difficulties falling asleep ($n = 10$) or breathing ($n = 7$), excessive salivation ($n = 4$), dental damage ($n = 4$) and other problems ($n = 3$). Continued use of MRS therapy was associated with a higher number of teeth, low marital satisfaction perceived by partners and greater improvement in symptoms reported by patients and partners. Continuance with MRS may be low and linked to tolerance problems.

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Introduction

Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a condition characterised by repeated episodes of upper airway closure during sleep, resulting in nocturnal hypoxaemia and sleep fragmentation.[1] Untreated OSAHS is associated with an increased incidence of daytime sleepiness, motor vehicle accidents, impaired social relationships and quality of life.[1–6] The treatment of OSAHS is primarily focused on alleviating these symptoms.[4–6] Continuous positive airway pressure (CPAP) is the most common and highly effective treatment for snoring and OSAHS. However compliance with nasal CPAP is variable due to its inconvenient nature.[7,8] Thus oral appliances (OAs) are considered as a promising alternative, due to some advantages over CPAP such as being less obtrusive, non-invasive, silent and easy to use.[5,9]

Most OAs, including mandibular repositioning splints (MRSs), are designed to hold the mandible and/or tongue in a protruded posture during sleep, thereby preventing upper airway occlusion.[4,5,9] Studies using different techniques—such as cephalometry,[10–13] magnetic resonance imaging (MRI),[14] video-endoscopy [15] and computed tomography [16] have demonstrated that OAs advance the mandible and alter the volume of the upper airway.

Snoring is one of the most common and disturbing symptoms for partners of patients due to the fact that it decreases their sleep quality and may affect their relationship. Thus, the insights of partners can be valuable in determining whether patients continue to use of the device and overcome its side effects. Side -effects associated with the use of OAs have been reported such as discomfort in the temporo-mandibular joint (TMJ) or dental pain, bite change, excessive salivation or dryness of the mouth and there is the potential for adverse effects on breathing.[5,6,11,13,17–28] But recent developments with OAs, specifically the adjustability of mandibular advancement and the ability to titrate, may significantly increase their efficacy for optimal treatment [9,26,29] and increase the quality of life for both patients with non-apnoeic snoring, mild to moderate OSAHS or severe OSAHS patients who could not tolerate CPAP and their partners.

It is important to define OAs' long-term efficacy, compliance and side effects. Early studies of OAs either relied on a short time usage with a small sample size, provided a small amount of data with long-term usage or obtaining data in the awake state and were based on effectiveness of symptoms on side effects and maintenance requirements.[4–6] Furthermore, no study exists which uses bed partners' sleep in determining the effectiveness of the device. Nor is there any research which employs marital satisfaction to this end. Therefore, more long-term studies are needed to define the therapeutic role of OAs in different sleep disorders related to upper airway obstruction. Thus, this questionnaire-based retrospective study aims to evaluate patient compliance, perceived efficacy, satisfaction and side effects of MRS devices in the treatment of patients who suffer from non-apnoeic snoring to severe OSAHS.

Subjects and methods

A survey was posted to 177 consecutive patients referred from the Department of Sleep Medicine to the Post-Graduate Dental Institute, Edinburgh University for custom-fitting of intra-oral MRS devices. A second survey was mailed to non-responders two months later. Telephone contact was subsequently attempted if no written response was received from the second mailing. Written or telephone response was achieved in 144 from 177 patients.

All subjects had a diagnostic sleep study to determine their level of sleep-disordered breathing before referral to the Dental Institute for MRS treatment. No one with central sleep apnoea was included in the study. OSAHS was defined as apnoea+hypopnoea index (AHI) $\geqslant 5$ with excessive daytime sleepiness (Epworth sleepiness scale (ESS) >10). Patients were only accepted for MRS treatment if periodontal status was considered adequate. Excluded were those with pre-existing TMJ problems, periodontal disease, maxillo-facial abnormalities and insufficient teeth in each arch to enable the device to engage. Those offered MRS treatment included a wide spectrum of patients with 12 non-apnoeic [AHI=3 (1) per hr] and 58 apnoeic snorers without sleepiness [Mean AHI= 23(15)], 25 mild [AHI=9 (3)], 26 moderate [AHI=21 (4)], and 23 severe OSAHS [AHI=55 (28)]. Fifty patients in the mild, moderate and severe OSAHS patients' groups [AHI=35 (27)] had not tolerated or had failed to comply with CPAP. Although the number of teeth present and the occlusal relationships of the patients varied, all patients had at least four of their own teeth remaining in each arch, when the MRS was fitted.

Mandibular repositioning splint

MRS devices were individually manufactured and fitted by the same orthodontist (JMcD) to produce approximately 80% of maximal comfortable

mandibular protrusion, with 2–4 mm of inter-dental clearance.The device was not titratable. The device was manufactured from 1-MEDL dual laminate material, moulded to fit the interior contours of the hard palate and frontal dentition during mandibular protrusion. This single position device affixed to dentition from the interior with metal Adams clasps, holding the mandible in a protruded but closed-mouth manner. It did not provide full occlusal coverage (Fig. 1).

Standard education about the device use, maintenance and possible side-effects were supplied. All patients were followed up until the device was as effective as workable. Re-moulding or adjustment of the MRS was offered in all instances of persisting or uncomfortable side-effects or lack of symptomatic benefit. Patients had been fitted with their MRS 1–31 months before receiving the survey.

Survey

The survey was based on a previous questionnaire used inquiring about use of CPAP, sleepiness, changes in function and symptoms with CPAP therapy and CPAP-related problems.[7] The survey used in present study requested subjects and their partners to record perceived changes in daytime and nocturnal symptoms, sleepiness, marital harmony, MRS usage and side-effects from the MRS.

Symptoms and functions

Patients were asked to rate alterations in daytime and nocturnal symptoms and functions on a five-point scale corresponding to 'much worse (1)', 'worse (2), 'no change (3)', 'better (4)', 'much better (5)'. Symptoms and functions were snoring, breathing pauses, daytime sleepiness, concentration, memory, night time sleep quality, work efficiency, tiredness, general health, mood, ability to drive long distance safely. Partners also rated patients' snoring, breathing pauses and daytime sleepiness separately as well as their (partner) sleep quality.

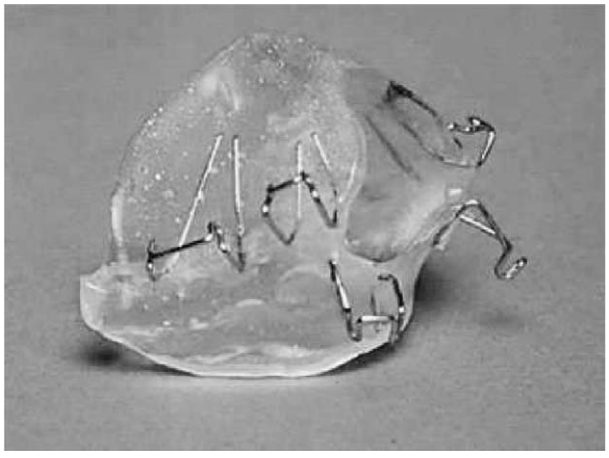

Figure 1 Mandibular repositoning splints.

Epworth sleepiness scale

The ESS provides a subjective estimate of patients' daytime sleepiness in eight every-day situations (each question scores 0–3, total=0–24). It has been shown to have good test-retest reliability ($r = 0.82$) and internal consistency (Cronbach alpha=0.88).[30] Higher ESS scores indicate greater daytime sleepiness. The pre-treatment ESS scores were obtained from a review of Department of Sleep Medicine's clinical records when the ESS was completed by patients and partners at the diagnostic stage. The follow-up ESS was contained in the survey. The administration of follow-up ESS permitted both the patient and their partners to rate their response during their usage of MRS.

Side effects

The patients were given a list of side effects comprising difficulty falling asleep, soreness of mouth, soreness of jaw, excessive salivation, difficulty in breathing, retention problems and tooth damage. Additionally, the list of side effects also included an item for 'other problems' to allow for an open-ended report of problems not on the list. If they had any of these problems then they were requested to rate them on a five-point scale: not a problem (0), minor problem (1), but able to continue using MRS (2), unable to continue using MRS (3).

ENRICH marital satisfaction questionnaire (EMS) and marital-related behaviours

The ENRICH marital satisfaction (EMS) questionnaire is a 15-item Likert scale that includes 10 items assessing marital quality, whose score is scaled according to an embedded 5 item idealistic distortion score.[31] It has an alpha coefficient of 0.81 and a 4-week test–retest reliability of 0.86.[31] Its construct validity has been satisfactory in previous research.[31] The EMS was presented in a format that allowed the patient and their partners to retrospectively rate their response for the period before starting MRS and during their usage of MRS.

In addition to the EMS, patients and partners were asked to rate the frequency of three other

marital-related behaviours in last week: bed-sharing, the number of cuddles/hugs shared, and the number of disagreements or arguments.[3] The median EMS score of 46 in this study was chosen as a cutoff to differentiate between less and more martially satisfied patients.

Self-reported MRS use

Patients were asked how many nights per week and how many hours per night MRS was applied. The survey was enhanced with diagnostic data obtained from a review of Department of Sleep Medicine's clinical records of age, gender and AHI, and with standard sleep questionnaires completed by patient and spouse, which included the ESS.

Statistical analysis

Statistical analysis was performed using SPSS for Windows, version 10 (SPSS inc., Chicago, IL, USA). When the variables measured were either categorical or not normally distributed, non-parametric statistics (Mann–Whitney, Wilcoxon, Spearman rank correlation and χ^2 tests) were used. T-test was applied if variables were normally distributed. A *P*-value less than 0.05 interpreted as statistically significant. Descriptive data in tables are expressed as means and SDS to clarify the direction of changes in scores with treatment, as some median values were zero. Survival analyses (Kaplan–Meier) were used [32] to examine MRS use over the follow-up period, and Mantel–Haenszel tests [33] to analyse variables influencing continued MRS use. Continuous variables were categorized by commonly used clinical cutoffs or by median values.

Results

Response rate and self-reported MRS usage

One-hundred and forty-four from 177 patients (81%) responded to the survey. Of the 144, 50 (35%) had been offered CPAP treatment but had declined or abandoned this (Table 1). Of 144 patients in whom contact was made, 76 answered the written survey and 68 by telephone. When compared with patients who returned the questionnaires, those answering by telephone were younger (49 (SD 11) versus 54 (10) years; $P<0.01$). No other clinical or demographic variable was different between the contact groups.

Responders (30 female, 114 male) averaged 51 (11) years with a mean AHI of 24 (21) events/h during sleep study and ESS score of 10 (5) at diagnosis (Table 1). At follow-up, responders had been supplied with an MRS device a median 7 (IQR 5–11) months previously.

Self-reported compliance

Self-reported MRS use was 5 (2) h/night, with 74 of the 144 patients (51%) continuing to use MRS at least occasionally at a median 7 months after fitting. A Kaplan–Meier plot of the percentage of patients including both users and non-users showed that 12% were still using MRS at the end of 12 months. (Fig. 2). Thirty-seven of these 74 current users (50%) reported wearing their MRS device every night. Within the 144 patients, 70 (49%) patients reported they were not now using their MRS devices at all (Table 1). Ninety six percent of the 70 patients abandoning MRS therapy reported no benefit, or indeed reported a

Table 1 Subjects' characteristics and initial data.

Variable	All Patients	Users	Non-users	CPAP failure/ refuser
N	177	74	70	50
Contacted	144 (81%)	74 (100%)	70 (100%)	50 (100%)
Female/male	30/114	16/58	14/56	11/39
Mean (±SD) Age (yr)	51 ± 11	51 ± 10	51 ± 10	54±11
Employed full time	102 (76%)	55 (76%)	47 (75%)	37 (80%)
Marital situation	113 (81%)	59 (80%)	54 (81%)	39 (81%)
Mean (±SD) AHI, events/h	24 ± 21	22 ± 16	25 ± 26	35±27
Mean (±SD) ESS	10 ± 5	10 ± 5	10 ± 6	12±6
History of snoring	140 (99%)	72 (99%)	68 (99%)	50 (100%)
Snoring in all position	104 (78%)	49 (74%)	55 (82%)	37 (84%)
Snoring in back and side	23 (17%)	12 (18%)	11 (16%)	6 (14%)
History of unrefreshing sleep	66 (47%)	33 (46%)	33 (48%)	23 (48%)

SD-Standard deviation, AHI-Apnoea hypopnoea index, ESS-Epworth sleepiness scale.

worsening of the problem. There were no significant differences in age, AHI, ESS scores at diagnosis and frequency of snoring between MRS users and non-users (all $P > 0.05$). The mean AHI and ESS scores (baseline data) and subjects' characteristics for users and non-users are given in Table 1.

Sleepiness with MRS

ESS scores for patients, rated both by patients and partners, improved marginally but significantly after MRS therapy in users (Table 2). Changes in ESS score showed significantly better improvements in users than in non-users of MRS ($P < 0.05$) (Table 2).

Changes in symptoms and function during MRS treatment period

Snoring, breathing pauses, daytime sleepiness, concentration, night time sleep quality, work efficiency, tiredness, general health and mood as rated by patients showed significantly greater improvements in users than in non-users of MRS (Table 3). Also snoring, breathing pause and daytime sleepiness as rated for patients by partners improved in continuing users of MRS more than in non-users (Table 3). The same was true of partners' sleep quality (Table 3). There were no significant improvements in memory or ability to drive long distance safely with MRS use.

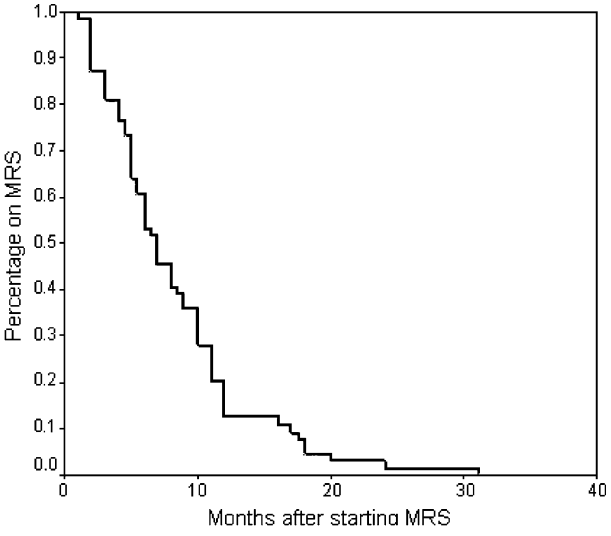

Figure 2 Percentage of patients using MRS versus time.

Changes in marital satisfaction with MRS treatment

Amongst users, patients and their partners reported an increase in sharing the same room after MRS usage. However, patients and their partners did not report any other improvements in marital satisfaction with MRS (Table 4). MRS usage correlated weakly with changes in sharing the same room and cuddling in all patients (users and non-users), and also with partners' reports of changes in sharing the same bedroom ($r = 0.3-0.5$; $P < 0.01 - P < 0.05$).

Side effects with MRS treatment

Reported side effects of MRS treatment were more common for non-users than for current users (all $P < 0.001$), although both current users and non-users reported frequent side effects. There were no serious complications reported. Problems were rated as at least sometimes preventing MRS use in non-users and users. Problems preventing MRS use in 70 non-users included: non-retention ($n = 12$), sore mouth ($n = 13$) or jaw ($n = 7$), difficulties falling asleep ($n = 10$) or breathing ($n = 7$), excessive salivation ($n = 4$), dental damage ($n = 4$) and other problems such as difficulty swallowing

Table 2 Changes in Sleepiness with MRS (Mean ± SD).

	Pre-MRS	Post-MRS	*P*
Users ($n = 74$)			
ESS (patient)	10±6	7±5	<0.001
ESS (partner)	10±5	8±5	0.001
Non-users ($n = 70$)			
ESS (patient)	9±6	8±6	>0.3
ESS (partner)	9±6	9±7	>0.3
	Users	Non-users	
Diff in ESS (patient)	−2.4±3.5	−1±4	0.005
Diff in ESS (partner)	−2.3±4.5	−0.05±0.2	0.002

SD-Standard deviation, ESS-Epworth sleepiness score, Diff in-differences in.

Table 3 Changes in Symptoms during MRS treatment (Mean ± SD).

Measures	Users $n = 74$	% RI	Non-users $n = 70$	% RI	P
Patient rating					
Snoring	4.3±0.7	86	3.3±0.9	23	<0.001
Breathing pause	4.0±0.9	62	3.2±0.6	16	<0.001
EDS	4.0±0.9	50	3.1±0.7	9	<0.001
Mood	4.0±0.8	47	3.1±0.5	9	<0.001
Concentration	3.3±0.7	29	3.0±0.2	2	0.04
Night-time sleep quality	4.0±0.8	71	3.0±0.4	7	<0.001
Work efficiency	3.5±0.7	39	3.2±0.2	5	0.001
Tiredness	3.7±0.9	59	3.0±0.4	5	<0.001
General health	3.6±0.9	44	3.0±0.4	2	<0.001
Memory	3.1±0.7	20	3.0±0.3	0	>0.06
Ability to drive long distances	3.4±0.8	25	3.1±0.2	5	>0.07
Partner rating					
Snoring	4.3±0.7	86	3.6±0.8	47	0.003
Breathing pause	4.0±0.9	59	3.5±0.8	26	<0.04
EDS	3.8±0.8	51	3.2±0.4	16	0.008
Partner sleep quality	4.1±0.7	80	3.7±0.8	47	0.04

SD-Standard deviation, RI-Reporting improvement, EDS-Excessive daytime sleepiness

Table 4 Changes in marital satisfaction with MRS treatment (Mean ± SD).

Patient rating	Users $n = 74$			Non-users $n = 70$		
		% RI	P		% RI	P
Sleeping in the same room	1±2	30	<0.03	0.1±0.4	5	>0.3
Having a cuddle	1±2	19	>0.1	−0.2±1	0	>0.3
Enrich marital satisfaction	0.2±4	21	>0.9	0.1±0.01	0	>1
Partner rating	Users			Non-users		
Sleeping in the same room	1±2	30	0.02	0.1±0.5	6	>0.3
Having a cuddle	0.4±2	24	>0.1	–0.4±1.3	0	>0.3
Enrich marital satisfaction	2±7	11	>0.3	0.1±0.01	0	>1

SD: Standard deviation, RI: Reporting improvement.

and dry mouth ($n = 3$). Ten patients noted problems but did not specify these. The problems for users were non-retention ($n = 1$), sore mouth ($n = 1$) or jaw ($n = 1$), difficulties falling asleep ($n = 10$), excessive salivation ($n = 2$) and other problems ($n = 1$). None of the continuing MRS users had problems with dental damage or difficulties in breathing.

Factors influencing MRS usage

We sought associated factors related to compliance with MRS therapy from baseline data and from variables obtained after beginning MRS therapy ($\geqslant$1 mo). The factors were patient-related (age, sex, occupation, marital situation and satisfaction, and number of teeth), disease-related (symptoms at diagnosis; snoring, refreshment after sleep, daytime somnolence, driving problems, baseline ESS score, AHI), and treatment-related (MRS/CPAP treatment, changes in symptoms with MRS and side effects with MRS) variables.

Neither age, gender, occupation, marital situation, diagnostic AHI, baseline symptoms, nor diagnostic ESS were associated with continuing MRS usage ($P > 0.09$). This analysis indicated that continued use of MRS therapy was associated with a greater number of teeth, with low marital satisfaction ratings by partners before starting MRS, and

Table 5 Mantel–Haenszel tests: variables influencing MRS use.

Factors	OR (95% CI)	*P*-value
1.Influencing continued MRS Use		
Number of teeth <12 versus $\geqslant 12$	0.16 (0.05–0.53)	0.004
Less snoring	0.05 (0.02–0.13)	0.0001
Less breathing pauses	0.20 (0.04–0.32)	0.0001
Improved sleep quality	0.03 (0.008–0.12)	0.0001
Improved tiredness	0.04 (0.008–0.17)	0.0001
Partner's reports		
Less snoring	0.15 (0.04–0.55)	0.008
Less breathing pauses	0.24 (0.07–0.85)	<0.05
Improvement in sleepiness	0.18 (0.04–0.72)	<0.03
Improvement in partner sleep quality	0.23 (0.07–0.77)	<0.04
Poor marital satisfaction before using MRS	5.63 (1.34–23.63)	<0.04
2.Influencing stopping MRS use		
Difficulty falling sleep/frequent awakening	15 (1.83–122.95)	0.005
Soreness of mouth, teeth/gums	19.1 (2.39–152.82)	0.001
Soreness of jaw/jaw joint	9.39 (1.11–79.61)	0.04
Difficulty in breathing	1.23 (1.05–1.37)	0.01
Non-retention	1.44 (1.17–1.78)	0.0001

95% CI: 95% confidence interval.Odds ratios (OR) comparing nonusers to users.

with greater improvements in symptoms reported by patients and partners. Stopping MRS use was associated significantly with higher side effects score. Table 5 shows odds ratios relating nonusers to users for these variables where there was a significant difference between the two groups.

The effects of CPAP failures/refusal on the usage and success of MRS:

Usage of MRS was not significantly affected by whether a patient was a CPAP failure or refuser ($P>0.3$). Of 50 CPAP failures/refusers, as 46% (23) indicated that they were still using their MRS at least occasionally, and in these usage averaged 3% (3) h/night. Those CPAP failures/refusers who continued to use MRS benefited from it. ESS scores, rated by these patients, improved significantly after MRS therapy, with pre- and post-MRS ESS scores of 10 (6) and 9 (6), respectively ($P<0.02$). However, ESS scores, rated by their partners, did not change with MRS therapy.

Discussion

This is a retrospective and self-reported follow-up study, on an individual mandibular repositioning device. Despite these limitations, the results suggest that MRS helped patients' daytime and nocturnal symptoms and partners' sleep quality as evidenced by symptomatic improvement from patient and partner reports and greater improvements in MRS users than non-users. However, continuing use of the MRS by patients a median of 7 (IQR 5–11) months after fitting was low. Half the patients had abandoned the MRS completely and only one quarter of the total sample used the MRS nightly.

The present results, though using a different MRS device, closely agree with this of a similar study in a slightly smaller patient group.[28] However, we have extended their outcome measures by examining marital satisfaction and a more extensive range of side-effects and asked which of these prevented MRS usage.

Compliance rate with OA treatment differs, depending on the appliances' design, the particular study and the duration of treatment. Our compliance rate, 51% of patients wearing MRS average 5 h/night at a median 7 months after fitting, is consistent with previous studies.[5,23,28] However, survival analysis showed that this percentage decreased to 12% at the end 12 months. McGown et al. for instance, reported that 55% of their patients claimed to have used their splint on average 6.6 h/night regularly over 1 year.[28] In another study, patients' compliance at the end of one year was 60%, but dropped to 48% at the end of second year.[23] In contrast, however, Marklund et al. reported a higher compliance rate (76%) in a long term study.[34] In addition, Pancer et al. reported that compliance was 86% followed for almost 1

year.[24] In comparison with CPAP, patient compliance with OAs can not be proved objectively. As reported by Engleman et al. subjective CPAP compliance (5.8SD2 h/night) is higher than objective compliance (5.1SD2.5 h/night).[7] The compliance can also change over time. In a large follow-up CPAP study, compliance rate decreased from 84% to 68% in 4 years (a median usage of 5.7 h per night).[8]

The effectiveness and patient satisfaction of OA was compared to CPAP [6,17–21] in a recent systematic review[6] and several randomised controlled trials.[6,17–21] These studies showed that OAs had greater satisfaction and lesser side effects compared to CPAP.[17–21] Although both OA and CPAP were effective in the studies, OAs did not decrease AHI,[17–21] daytime[17–19] or nocturnal symptoms[17,18,21] as much as CPAP. However, patients' preference were for OAs in four studies[17,18,20,21] and was for CPAP in one study.[19]

It is not known exactly why such a large number of patients abandoned MRS in present study. Our results showed that the main reasons for stopping MRS usage are related to lack of benefit and side effects from MRS cited by patients, but these were by nature subjective and not confirmed by objective tests. In the current study, problems preventing MRS use in 70 non-users included: non-retention ($n = 12$), sore mouth ($n = 13$) or jaw ($n = 7$), difficulties falling asleep ($n = 10$) or breathing ($n = 7$), excessive salivation ($n = 4$), dental damage ($n = 4$) and other problems ($n = 3$). Primary side effects stopping MRS usage were difficulty with retention, sore mouth and jaw, falling asleep and breathing. The results from previous studies related to side effects conflict with one another. Schmidt–Nowara et al. in the meta-analysis reported that TMJ pain and occlusal changes are rare and that oral discomfort is a common side effect but subside with regular use and adjustment of fit.[5] In a study using a mandibular advancement splint, it was reported that side effects were dryness of mouth (21%), excessive salivation (19%), bruxism (9%), and gum irritation (7%). However, mild jaw discomfort on waking was present during initiation of treatment in 37 (65%) of the 57 as patients.[27] Pantin et al. showed on minor or temporary dental side effects in patients who had worn OAs for a mean of 31 (SD18) as months. Nevertheless, they detected occlusal changes in 14% of their patients.[25] Pancer et al. reported that the most common side effects with an appliance, the Thornton anterior positioner, were teeth or jaw discomfort occurring in 83% and 81% of 121 patients, respectively.[24] In a recent evaluation of 22 patients treated with a removable mandibular advancement appliance, Fritsch et al. also found a significant decrease in intermolar position and a decrease in overjet and overbite after 12–30 as months.[22] In this study, even though side effects, such as mucosal dryness, hypersalivation, transient tooth, or jaw pain were common, occurring in 32–86% of patients, they were not so severe that patients discontinued treatment.[22] Thus, side effects were less frequent but reported MRS discontinuation more common in our study than in others.

In the analysis of continued MRS use, the outcome indicated that a relief of clinical symptoms are major factors to support MRS use. Specially, improvement in snoring, breathing pauses and sleep quality noticed by patients and partners, and partner's sleep quality were associated with continuing MRS usage. Our results confirmed the previous study which tried to establish the factors influencing OA usage with variable results.[28] Additionally, our findings demonstrated that the number of teeth ($\geqslant 12$) when OA was fitted and poor marital satisfaction before commencing MRS were factors associated with continuing MRS usage. Thus number of teeth may well be an important clinical consideration in this type of MRS. It has been previously suggested that 8 teeth should be in each jaw to aid sufficient retention for a permanent mandibular protrusion with an OA.[9] In our study, the number of teeth can be an important factor stopping MRS usage.

The device's design, anatomical skeletal factors influencing the degree of vertical and sagittal opening, possible displacement of the mandible, the enlargement of the pharyngeal airway-space, and sleep position might play important role in treatment efficacy with OA.[5,9,11,15,16] In the randomised controlled trial the best outcome for OA achieved with an adjustable appliance.[26] MRSs used in this audit were not titratable and adjustable expressly by design. However, the MRS designed by the same dentist (JMcD) accomplished a decrease in subjective daytime and nocturnal symptoms in current study and a previous study and many patients also obtain good results for objective efficacy in this previous study.[19] Bloch et al. compared two different custom-fitted MRS devices in a randomised control trial. The simpler model resembling those used in the current study achieved better efficacy.[35] In another study, Mayer et al. were able to treat patients with mild to severe OSAHS effectively using Esmarch devices similar to ours.[10] Furthermore, Marklund et al.[34] used an individually designed, one-piece device throughout the entire 10.5-year period, even when they changed the material from hard acrylic to soft elastomer in the middle of the study. The results

did not show any differences in treatment effect between these two appliances.

This low rate of MRS usage may be explained by differences in patient selection or survey methods. For example, while OAs have been commonly recommended for mild OSAHS,[4,5,9] our study included a wide spectrum of patients with non-apneic snoring to severe OSAHS (AHI range from 1–164). However, in our study severity of disease was not related to MRS usage and some studies also showed that patients with severe OSAHS benefited reasonably from OAs treatment.[5,10,11,24,26,36] In the current study, there were only 23 patients with clinically significant sleepiness (ESS $>$ 10) and an AHI $>$ 30/h. Eighteen of 23 patients had failed or refused to use CPAP. In addition, our survey was carried out by the sleep centre and not by the orthodontic service, and thus the patients were not in a dependent role with their questioner as far as their MRS was concerned.

There was no evidence from our study that MRS resulted in improved marital satisfaction. This is consistent with results from a randomised crossover trial with CPAP versus placebo, which showed that CPAP did not improve marital as satisfaction.[3] In another recent controlled study, which examined the relationship between untreated men with OSAHS and their partners' marital satisfaction,[37] they found OSAHS was not associated with reduced marital satisfaction although co-sleeping was impaired. If OSAHS or snoring were not the primary cause of marital disharmony, then either MRS or CPAP usage would not be expected to have a major effect on marital satisfaction. In other words, snoring or apnoeas could be secondary explanations for a pre-existing primary problem. O'Sullivan and co-workers made first reporting that OA use resulted in couples being able to sleep in the same room.[27] Our results concurred with theirs; namely that patients and their partners reported that sharing the same room improved after MRS usage. This may be connected with our other finding that improvement in patients' snoring could be a positive reinforcement from their partners. However, when partners do not see benefits this may discourage patients from using their device.[28] In the current study, only the frequency of cuddling and of sharing the same room correlated with MRS usage. Also, as mentioned above, low marital satisfaction perceived by partners before using MRS was associated with continuing MRS use. Thus a partner annoyed by snoring may encourage their partner to use OA.

Limitations of our own study include its retrospective, questionnaire-based character, the lack of objective assessment of the effect of MRS and the type of MRS used. Questionnaires have limitations but these were minimised by ensuring a high (81%) response rate. It would have been preferable to measure compliance objectively, but techniques for this remain in a developmental stage. The other limitation is that this is based on a single MRS device, as mentioned above. Additionally, the device did not cover all the teeth, a fact which could have contributed to the problems with retention,although patients not benefiting from the MRS were offered revision or provision of a new device at no cost. Nevertheless these results cannot be generalised to all devices, but they raise the challenge to users of other devices to prove greater efficacy and better use.

In conclusion, MRS may offer a simple and effective alternative treatment of non-apnoeic snoring to severe OSAHS in selected patients who are unwilling or unable to use nasal CPAP. However, patients' use of MRS devices and their therapeutic response to this treatment was disappointing.

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