university of groningen

University Medical Center Groningen

University of Groningen

Oral-appliance therapy obstructive sleep apnea-hypopnea syndrome

Hoekema, Aarnoud

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2007

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Hoekema, A. (2007). *Oral-appliance therapy obstructive sleep apnea-hypopnea syndrome: a clinical study on therapeutic outcome*. [Thesis fully internal (DIV), University of Groningen]. [s.n.].

Copyright
Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment.

Take-down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Download date: 08-08-2024

Chapter 6

Applications for oral appliances in specific cases

Chapter 6.1

Oral appliances and maxillomandibular advancement surgery: an alternative treatment protocol for the obstructive sleep apnea-hypopnea syndrome

This chapter is based on the following publication:
* Hoekema A, de Lange J, Stegenga B, de Bont LGM. Oral appliances and maxillomandibular advancement surgery: an alternative treatment protocol for the obstructive sleep apnea-hypopnea syndrome. *Journal of Oral and Maxillofacial Surgery* 2006;64:886-891.

Summary

Background Despite a variety in treatment protocols for maxillomandibular advancement (MMA) surgery, the precise indication for this surgical procedure in the management of obstructive sleep apnea-hypopnea syndrome (OSAHS) is currently undefined. The present study comprises a retrospective evaluation of the potential application of mandibular repositioning appliance (MRA) therapy preceding MMA surgery. Our initial experiences with a new surgical protocol, in which MRA therapy serves as a predictor for success of MMA surgery in OSAHS, are reported.

Methods Forty-three consecutive OSAHS patients treated with MRA therapy were considered for inclusion (mean ± standard deviation; apnea-hypopnea index (AHI) = 27 ± 20, age = 53 ± 9 yrs). All patients displaying a substantial improvement in their AHI with MRA therapy (*i.e.*, >50% reduction), who preferred surgical rather than "prosthetic" advancement of the mandible, were offered MMA surgery. Accordingly, four out of 43 patients were treated with MMA surgery. The AHI was used as primary outcome measure with MMA surgery being considered successful in case of a postoperative AHI <5.

Results All four patients included displayed a substantial improvement in their AHI following MRA therapy. Moreover, in three patients MRA therapy resulted in a post-treatment AHI ≤5. With respect to the primary outcome measure, successful OSAHS management was attained in all four patients following MMA surgery.

Conclusions Results obtained from the four patients included in the present study suggest that MRA therapy might be a good predictor for the success of MMA surgery in OSAHS management. Although confirmation in a larger study sample is indicated, we conclude that patients with a substantial reduction in baseline AHI with MRA therapy appear candidates for MMA surgery.

Introduction

The obstructive sleep apnea-hypopnea syndrome (OSAHS) is a highly prevalent sleep-related breathing disorder associated with various (serious) neurocognitive and cardiovascular sequelae.[1] OSAHS is characterized by repetitive obstructions of the upper airway during sleep that are either partial (hypopnea) or complete (apnea) and often result in (severe) oxygen desaturations.[2] In order to diagnose OSAHS a sleep registration (*e.g.*, polysomnography) should demonstrate five or more apneas or hypopneas per hour sleep (*i.e.*, apnea-hypopnea index [AHI] >5).[2] Continuous positive airway pressure (CPAP) therapy is regarded the treatment of choice for, especially moderate to severe, OSAHS.[3] Modification of pharyngeal patency by oral appliances that reposition the mandible (mandibular repositioning appliances; MRA's) has been suggested as a viable alternative in, especially mild to moderate, OSAHS.[4] Surgical treatment of OSAHS is principally aimed at enlarging airway dimensions while decreasing airway collapsibility.[5] Maxillomandibular advancement (MMA) surgery is currently regarded as the most effective and acceptable surgical treatment for OSAHS.[6]

MMA surgery in OSAHS patients traditionally consists of a bilateral sagittal split osteotomy of the mandible and a Le Fort I osteotomy of the maxilla. Advancement of the maxillomandibular complex is suggested to displace the soft tissues attached to the maxilla, mandible and hyoid bone anteriorly.[6] Consequently, enlargement of the velo-orohypopharyngeal airway and enhanced tension and decreased collapsibility of the pharyngeal dilator musculature may be accomplished. MMA surgery in OSAHS patients generally involves 10 mm of maxillomandibular advancement.[7,8] Successful OSAHS management following MMA surgery is generally reported in 75 to 100% of patients.[6,9] Two long-term studies have demonstrated that the treatment effect of MMA surgery is relatively stable over a two- and four-year period, respectively.[7,8] However, it should be noted that most MMA surgery studies in OSAHS patients probably incorporate bias due to preoperative patient selection.[10] Evidence for the medium to long-term stability of the skeletal advancements with MMA surgery in OSAHS patients has been corroborated by several cephalometric studies.[8,11-13]

Prerequisites suggested for MMA surgery include "clinically significant" OSAHS that is not susceptible to non-invasive treatment (*e.g.*, CPAP), a medically and psychologically stable condition and the patient's informed consent prior to surgery.[6] Several different protocols for MMA surgery in OSAHS are adopted. Riley *et al.* employ a phased protocol based on the specific site of upper airway obstruction (*e.g.*, soft palate or base of tongue).[14] In the first phase of this protocol patients are treated with a uvulopalatopharyngoplasty (UPPP) and/or a genioglossus advancement with hyoidthyroidpexia. Second phase reconstruction consists of

MMA surgery and is generally preserved for phase one failures. Because the majority of patients failing the first surgical phase tend to have more severe OSAHS, obesity and mandibular deficiency,[14] others directly proceed with MMA surgery in patients with severe OSAHS or craniofacial dysmorphy.[9,15] Prinsell adopts a "site-specific" approach in which OSAHS patients with "orohypypharyngeal narrowing caused by macroglossia with a retropositioned tongue base" are considered eligible for MMA surgery.[16] Finally, both Waite *et al.* and Hochban *et al.* adopt a protocol in which MMA surgery is considered a first surgical option in patients with specific "craniofacial deformities" (*e.g.*, abnormal posterior airway space).[17,18] Despite the variety of treatment protocols, the precise indication for MMA surgery in OSAHS management is currently indefinite.

The present study comprises a retrospective evaluation of the potential application of MRA therapy preceding MMA surgery in the treatment of OSAHS patients. Our initial experiences with a new surgical protocol, in which MRA therapy serves as a predictor for success of MMA surgery, are reported.

Methods

Patient selection

Forty-three consecutive OSAHS patients treated with MRA therapy, in the period of September 1999 to September 2003, were considered for inclusion in the present study (mean ± standard deviation; AHI 27 ± 20, age 53 ± 9 years). All patients had been subjected to diagnostic polysomnography and an upper airway examination (*i.e.*, nasendoscopy or dynamic sleep nasendoscopy).[19] The indication for MRA therapy was either oropharyngeal airway obstruction (*i.e.*, base of tongue) during dynamic sleep nasendoscopy (18 patients) or oropharyngeal airway narrowing during upright nasendoscopic examination (19 patients) that, in addition, responded to mandibular protrusion by a "substantial" increase in airway patency. Moreover, MRA therapy was also indicated in four patients with relatively mild OSAHS not qualifying for CPAP therapy and in two patients requiring alternative treatment because of CPAP nonadherence. Following successful habituation to MRA therapy, a second polysomnographic evaluation was performed. Subsequently, all patients displaying a substantial improvement in their AHI with MRA therapy (*i.e.*, >50% reduction), who preferred surgical rather than "prosthetic" advancement of the mandible, were offered MMA surgery. At present, four out of 43 patients have been treated with MMA surgery according to the protocol described above.

Prosthetic and surgical management

Both MRA therapy and MMA surgery were performed by one surgeon (J. de Lange). MRA therapy was performed with a modified Herbst-appliance.[20] Protrusion of the

TABLE 1. Patient and surgical characteristics.

Patient	Age (yr)	Baseline AHI (no/hour)	Body-mass index (kg/m²)	Blood* loss (ml)	Hospital† stay (days)	Orthodontic‡ treatment
1	42	81	35	1200	5	postoperative
2	51	54	29	600	3	pre- and postoperative
3	54	37	29	900	3	pre- and postoperative
4	54	26	25	800	3	pre- and postoperative

* Blood loss during maxillomandibular advancement surgery.
† Postoperative hospital stay following maxillomandibular advancement surgery.
‡ Fixed appliance therapy.
Abbreviations: AHI = apnea-hypopnea index.

mandible with the MRA was set at approximately 75% of the patient's maximum protrusion. The degree of interincisal bite opening imposed by the appliance was at least 4 to 6 mm. Preceding MMA surgery, all patients were subjected to a clinical and standardized lateral cephalometric examination.[16] Surgical treatment consisted of maxillomandibular advancement surgery performed under general anesthesia. Except for possible recontouring of the anterior nasal spine, no adjunctive surgical procedures were performed. The (planned) advancement of the mandible was approximately 10 mm whereas maxillary advancement was aimed at accomplishing a postoperative class I occlusion. Fixation of the mandible and maxilla was achieved with monocortical miniscrews and miniplates. The polysomnographic evaluation was repeated within four to eight months following surgery. Moreover, the lateral cephalometric examination was repeated four weeks after surgery. Orthodontic treatment (*i.e.*, fixed appliance therapy) was performed in the pre- and postoperative period if required.

Outcome measures

The AHI was used as primary outcome measure with MMA surgery being considered successful in case of a postoperative AHI <5. Secondary outcome measures with respect to both MRA therapy and MMA surgery included changes in the lowest oxyhemoglobin saturation during sleep ($minSaO_2$) and the desaturation-index (*i.e.*, the mean number of oxyhemoglobin desaturations >4% per hour sleep). Furthermore, changes in patient's propensity to fall asleep were

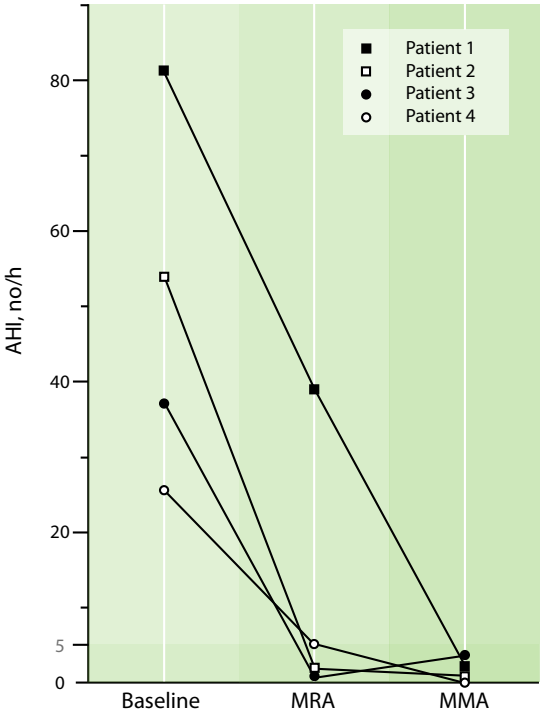

FIGURE 1. Individual AHI values.

Individual AHI values at baseline and following MRA therapy and MMA surgery, respectively. All four patients displayed a substantial improvement in their AHI following MRA therapy (*i.e.*, >50% reduction). Subsequently, successful obstructive sleep apnea-hypopnea syndrome management (*i.e.*, AHI <5) was attained in all four patients following MMA surgery.
Abbreviations: AHI = apnea-hypopnea index, MMA = maxillomandibular advancement, MRA = mandibular repositioning appliance.

evaluated with the Epworth sleepiness scale (ESS) at baseline and following MRA therapy and MMA surgery, respectively.[21] In addition, pre- and postoperative lateral cephalometric radiographs were used to evaluate the amount of maxillomandibular advancement,[18] and changes in the posterior airway space (PAS) [22] and the posterior uvular space (PUS) [23] as a result of MMA surgery.

Results

Characteristics of the four male patients completing the protocol are outlined in Table 1. All four patients had moderate to severe OSAHS (AHI range; 26–81). Two of the four patients had undergone previous (*i.e.*, >3 years ago) upper airway

TABLE 2. Polysomnographic and questionnaire outcomes following MRA therapy and MMA surgery.

Patient	AHI (no/hour)			$minSaO_2$ (%)			desaturation-index (no/hour)			Epworth sleepiness scale		
	baseline	MRA	MMA	baseline	MRA	MMA	baseline	MRA	MMA	baseline	MRA	MMA
1	81	39	2	49	53	79	62	43	13	11	5	0
2	54	2	1	81	80	82	6	4	3	7	4	2
3	37	1	3	83	92	91	15	1	2	9	4	3
4	26	5	0	87	93	90	11	0	0.5	10	4	0

Abbreviations: AHI = apnea-hypopnea index, $minSaO_2$ = lowest oxyhemoglobin saturation during sleep, MMA = maxillomandibular advancement, MRA = mandibular repositioning appliance.

surgery for the treatment of snoring. Treatment had consisted of a nasal septal reconstruction, turbinate outfracture and a UPPP in one patient (patient 2) and a nasal septal reconstruction in the second patient (patient 3).

Polysomnographic and Epworth sleepiness scale outcomes at baseline and following MRA therapy and MMA surgery are outlined in Table 2. All four patients displayed a substantial improvement in their AHI following MRA therapy. Moreover, in three patients MRA therapy resulted in a post-treatment AHI ≤5 (Figure 1). With respect to the primary outcome measure, successful OSAHS management was attained in all four patients following MMA surgery (Figure 1). When compared with baseline values, the minSaO_2 improved in three patients following MRA therapy and in all four patients following MMA surgery. Likewise, the desaturation-index improved in all four patients following both MRA therapy and MMA surgery when compared with baseline values. Despite "normal" baseline values an improvement in the Epworth sleepiness scale was noted in all four patients following MRA therapy and MMA surgery.

Cephalometric outcomes with respect to MMA surgery are outlined in Table 3. The amount of mandibular and maxillary advancement with MMA surgery ranged from 6.6 to 9.7 mm and 6.3 to 11.7 mm, respectively. Compared with preoperative values, both the posterior airway space and posterior uvular space increased in all four patients as a result of MMA surgery. Cephalometric changes in upper airway morphology as a result of MMA surgery are illustrated in Figure 2.

Discussion

Results obtained from the four patients included in the present study suggest that MRA therapy might be a good predictor for the success of MMA surgery in the treatment of OSAHS patients. Patients with a substantial reduction in baseline AHI with MRA therapy, therefore, appear candidates for MMA surgery.

Out of the four patients included, MRA therapy did not result in an AHI ≤5 in one patient. The latter patient was characterized by more severe OSAHS (*i.e.*, AHI of 81). This finding corresponds to results observed in other studies that suggest a decline in effectiveness of MRA therapy with increasing AHI levels.[4] Despite the "sub-optimal" (but substantial) reduction in AHI with MRA therapy in the latter patient, MMA surgery was successful in all four patients included. The success of MMA surgery corresponds with results obtained in other studies.[14,16,17] However, contrary to these favorable reports, failure meeting the (polysomnographic) criterion for success has been reported in over 25% of patients undergoing MMA surgery.[9,15,18,24] Moreover, criteria for the definition of success in MMA surgery are generally not uniform and sometimes less stringent. In accordance with previously

TABLE 3. Cephalometric outcomes of MMA surgery.

Patient	Advancement (mm)		PAS (mm)		PUS (mm)	
	mandible	maxilla	pre-operative	post-operative	pre-operative	post-operative
1	9.2	6.3	10.3	14.3	3.9	8.3
2	9.7	11.7	4.3	15.1	1.3	12.4
3	6.6	9.4	14.2	20.8	7.1	14.3
4	8.4	8.1	8.4	12.9	4.2	8.5

Abbreviations: PAS = posterior airway space (defined as the minimum distance between the base of the tongue and the posterior pharyngeal wall along the line from the supramentale to gonion),[22] PUS = posterior uvular space (defined as the minimum distance from the posterior border of the uvula to the posterior pharyngeal wall).[23]

reported recommendations for syndrome definition in clinical research, treatment success of MMA surgery was defined quite rigidly in the present study (*i.e.*, AHI <5).[2] Based on the results of the four patients included in the present study, MRA therapy appears a predictor for the success of MMA surgery that is competitive with CPAP therapy.

Most surgical treatment protocols for MMA surgery in OSAHS patients adopt rather abstract selection criteria for surgical candidates (*e.g.*, presence of "severe craniofacial dysmorphy" or "craniofacial deformities").[9,15,17,18] Other surgical treatment protocols addressing the specific site of disproportionate upper airway anatomy offer a logic for the selection of a specific surgical procedure.[14,16] However, physical and fiberoptic examination techniques to determine the site of disproportion require specific expertise and are open to misinterpretation and inconsistencies. Moreover, since upper airway examination is usually performed in the wake state, possible changes in airway morphology that occur during sleep are not taken into account (*e.g.*, thickening of the lateral pharyngeal walls).[25] The phased protocol described in the present study does not employ morphological selection criteria for MMA surgery. Instead, only patients with a substantial improvement in their AHI following MRA therapy qualify for MMA surgery. MRA therapy was used to simulate the effects of surgical mandibular advancement. As reported in a previous case study,[26] it was reasoned that a favorable response to MRA therapy (*i.e.*, a >50% reduction in AHI), would predict successful OSAHS management with MMA surgery. Since all four patients included in the present study had a class I occlusion, maxillomandibular advancement was performed. The "additional" maxillary advancement with MMA surgery might explain why in one patient MRA therapy obtained a "sub-optimal" result, whereas surgery

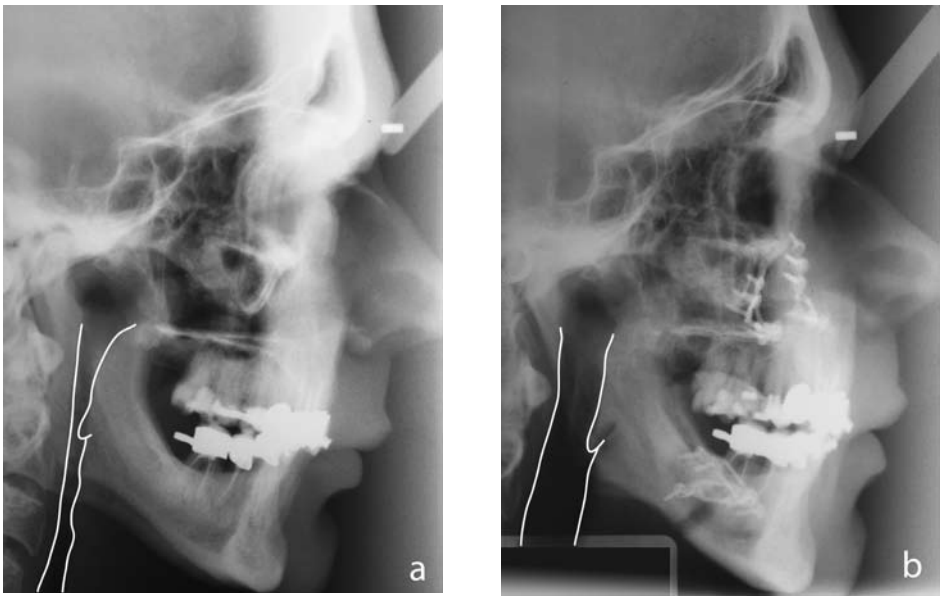

FIGURE 2. Changes in upper airway morphology following MMA surgery in patient 2.

(a) preoperative lateral cephalometric radiograph; (b) postoperative lateral cephalometric radiograph following MMA surgery.
Abbreviations: MMA = maxillomandibular advancement.

resulted in an AHI <5. A reduction in the baseline AHI exceeding 50% with MRA therapy, therefore, appears a legitimate predictor for successful MMA surgery in OSAHS patients.

Besides the apparent predictive value of MRA therapy for successful MMA surgery, the phased employment of both treatment modalities may offer some additional advantages. The subgroup of OSAHS patients directly qualifying for MMA surgery has been reported to represent less than 2.5% of patients recruited in a sleep laboratory.[9] MRA therapy has been reported successful in a substantial subset of OSAHS patients.[4] By offering MMA surgery to patients with a substantial improvement in their AHI following MRA therapy, a considerable greater proportion of OSAHS patients would qualify for this procedure. Although OSAHS management should not be aimed at treating all patients by means of MRA therapy followed by MMA surgery, the present surgical protocol offers the clinician a greater variety of treatment options that can be tailored to the individual patient. Moreover, MRA therapy preceding (possible) MMA surgery allows patients to accustom to the idea of surgical advancement of the (maxillo)mandibular complex. In addition, because the advancement of the maxillomandibular complex is generally somewhat

arbitrarily defined, MRA therapy may also be used as an estimate for the amount of mandibular advancement required with MMA surgery.

When compared with the phased surgical protocol proposed by Riley *et al.*,[14] the treatment protocol reported in the present study may be more efficacious. For example, MRA therapy is considered a reversible and non-invasive treatment modality,[4] whereas phase one treatment according to Riley *et al.* is an irreversible and invasive procedure. Disadvantages of these surgical procedures include the fact that a significant proportion of up to 75% of patients fail to respond adequately.[9] In addition, only 25% of treatment failures decided to proceed with the second phase of their protocol (*i.e.*, MMA surgery).[14] These limitations may hamper the overall efficacy of this phased surgical protocol. In contrast, failures in the first phase of the present study may discontinue MRA therapy without having endured an invasive and uncomfortable surgical procedure. Moreover, patients with a sub-optimal but substantial reduction in their AHI following MRA therapy, or patients preferring surgical over prosthetic advancement of the mandible, may proceed with MMA surgery in the second phase of the protocol.

Except for a more substantial improvement in one patient following MMA surgery, no marked differences in saturation indices were noted following MRA therapy and MMA surgery. However, despite "normal" baseline values, MMA surgery resulted in more pronounced improvements in the Epworth sleepiness scale when compared with MRA therapy. Although 10 mm mandibular advancement was planned presurgically, the cephalometric analyses indicated less. These findings may be related to postsurgical skeletal relapse.[14] Despite the fact that maxillomandibular advancement was somewhat smaller than reported in other studies,[7,8,18] MMA surgery was still effective in all four patients included.

The present study describes our initial experiences with an alternative treatment protocol for MMA surgery in OSAHS patients. The phased protocol is aimed at minimizing unwarranted surgery while serving as an efficacious alternative in OSAHS management. Results obtained from the four patients included in the present study suggest that MRA therapy might be an adequate predictor for successful MMA surgery. OSAHS patients with a substantial reduction in their baseline AHI with MRA therapy, therefore, appear candidates for MMA surgery. When compared with other (well-established) protocols for MMA surgery, similar improvements in subjective and objective parameters were observed in the present study. In addition, patient selection for MMA surgery may be more practical with the present phased protocol when compared with others. Despite the favorable results, an equally sized study sample is indicated for ascertaining the precise value of the present protocol relative to other treatment protocols for MMA surgery.

Acknowledgement The authors wish to thank drs. J. de Graaf from the Department of Neurology of the Isala Clinics Zwolle (The Netherlands) for performing the polysomnographic studies and disposing of the relevant data.

REFERENCES

1. Malhotra A, White DP. Obstructive sleep apnoea. *Lancet* 2005;360:237-245.
2. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep* 1999;22:667-689.
3. Giles T, Lasserson T, Smith B, White J, Wright J, Cates C. Continuous positive airways pressure for obstructive sleep apnoea in adults. *Cochrane Database Syst Rev* 2006;1: CD001106.
4. Hoekema A, Stegenga B, De Bont LGM. Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review. *Crit Rev Oral Biol Med* 2004;15:137-155.
5. Sher AE, Schechtman KB, Piccirillo JF. The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep* 1996;19:156-177.
6. Prinsell JR. Maxillomandibular advancement surgery for obstructive sleep apnea syndrome. *J Am Dent Assoc* 2002;133:1489-1497.
7. Conradt R, Hochban W, Brandenburg U, Heitmann J, Peter JH. Long-term follow-up after surgical treatment of obstructive sleep apnoea by maxillomandibular advancement. *Eur Respir J* 1997;10:123-128.
8. Riley RW, Powell NB, Li KK, Troell RJ, Guilleminault C. Surgery and obstructive sleep apnea: long-term clinical outcomes. *Otolaryngol Head Neck Surg* 2000;122:415-421.
9. Bettega G, Pepin JL, Veale D, Deschaux C, Raphael B, Levy P. Obstructive sleep apnea syndrome. fifty-one consecutive patients treated by maxillofacial surgery. *Am J Respir Crit Care Med* 2000;162:641-649.
10. Sundaram S, Bridgman SA, Lim J, Lasserson TJ. Surgery for obstructive sleep apnoea. *Cochrane Database Syst Rev* 2005;4:CD001004.
11. Louis PJ, Waite PD, Austin RB. Long-term skeletal stability after rigid fixation of Le Fort I osteotomies with advancements. *Int J Oral Maxillofac Surg* 1993;22:82-86.
12. Miles PG, Nimkarn Y. Maxillomandibular advancement surgery in patients with obstructive sleep apnea: mandibular morphology and stability. *Int J Adult Orthod Orthognath Surg* 1995;10:193-200.
13. Nimkarn Y, Miles PG, Waite PD. Maxillomandibular advancement surgery in obstructive sleep apnea syndrome patients: long-term surgical stability. *J Oral Maxillofac Surg* 1995;53:1414-1418.
14. Riley RW, Powell NB, Guilleminault C. Obstructive sleep apnea syndrome: a surgical protocol for dynamic upper airway reconstruction. *J Oral Maxillofac Surg* 1993;51:742-747.
15. Hendler BH, Costello BJ, Silverstein K, Yen D, Goldberg A. A protocol for uvulopalatopharyngoplasty, mortised genioplasty, and maxillomandibular advancement in patients with obstructive sleep apnea: an analysis of 40 cases. *J Oral Maxillofac Surg* 2001;59:892-897.
16. Prinsell JR. Maxillomandibular advancement surgery in a site-specific treatment approach for obstructive sleep apnea in 50 consecutive patients. *Chest* 1999;116:1519-1529.
17. Hochban W, Conradt R, Brandenburg U, Heitmann J, Peter JH. Surgical maxillofacial treatment of obstructive sleep apnea. *Plast Reconstr Surg* 1997;99:619-626.
18. Waite PD, Wooten V, Lachner J, Guyette RF. Maxillomandibular advancement surgery in 23 patients with obstructive sleep apnea syndrome. *J Oral Maxillofac Surg* 1989;47:1256-1261.
19. Hessel NS, de Vries N. Diagnostic work-up of socially unacceptable snoring. II. Sleep

endoscopy. *Eur Arch Otorhinolaryngol* 2002;259:158-161.
20. Bloch KE, Iseli A, Zhang JN, Xie X, Kaplan V, Stoeckli PW, et al. A randomized, controlled crossover trial of two oral appliances for sleep apnea treatment. *Am J Respir Crit Care Med* 2000;162:246-251.
21. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep* 1991;14:540-545.
22. Riley R, Guilleminault C, Herran J, Powell N. Cephalometric analyses and flow-volume loops in obstructive sleep apnea patients. *Sleep* 1983;6:303-311.
23. Yao M, Utley DS, Terris DJ. Cephalometric parameters after multilevel pharyngeal surgery for patients with obstructive sleep apnea. *Laryngoscope* 1998;108:789-795.
24. Goh YH, Lim KA. Modified maxillomandibular advancement for the treatment of obstructive sleep apnea: a preliminary report. *Laryngoscope* 2003;113:1577-1582.
25. Schwab RJ. Imaging for the snoring and sleep apnea patient. *Dent Clin North Am* 2001;45:759-796.
26. Patel D, Ash S, Evans J. The role of orthodontics and oral and maxillofacial surgery in the management of obstructive sleep apnoea - a single case report. *Br Dent J* 2004;196:264-267.

Chapter 6.2

Implant retained oral appliances: a novel treatment for edentulous patients with obstructive sleep apnea-hypopnea syndrome

This chapter is based on the following publication:
* Hoekema A, de Vries F, Heydenrijk K, Stegenga B. Implant retained oral appliances; a novel treatment for edentulous patients with obstructive sleep apnea-hypopnea syndrome. *Clinical Oral Implants Research* (in press).

Summary

Background Mandibular repositioning appliances (MRA's) are a viable treatment alternative in patients with obstructive sleep apnea-hypopnea syndrome (OSAHS). Because these appliances require retention in the patient's dentition, edentelous patients generally do not qualify for this treatment. This study describes our experiences with an implant retained MRA in the treatment of edentulous OSAHS patients.

Methods Six edentulous OSAHS patients were included in this study. Standard treatment consisted of the placement of four endosseous dental implants in the mandible and the construction of a new maxillary denture and a mandibular overdenture. Subsequently an MRA was made. After a habituation and adjustment period, the effect of treatment was evaluated with polysomnography. Treatment was aimed at a correction of the apnea-hypopnea index to normal levels (*i.e.*, <5).

Results Of the six patients included, two did not tolerate the MRA because of pressure-induced discomfort on the labial mucosa in the maxilla. These two patients were offered an implant retained overdenture and MRA in the maxilla. One of the two patients proceeded with this secondary treatment. Of the five patients completing the follow-up polysomnography, a correction of the apnea-hypopnea index <5 was attained in four.

Conclusions Results obtained from this study suggest that an implant retained MRA in the mandible is a viable treatment modality in edentulous OSAHS patients. Because therapeutic effectiveness of this treatment may be compromised by excessive pressure of the MRA on the labial mucosa in the maxilla, we suggest that an implant retained MRA in the maxilla is offered as a secondary treatment in selected patients.

Introduction

The obstructive sleep apnea-hypopnea syndrome (OSAHS) is a common sleep-related breathing disorder, affecting approximately 4% of the male and 2% of the female adults in the North-American population.[1] The condition is characterized by disruptive snoring and repetitive obstructions of the upper airway during sleep. Airway obstructions in OSAHS patients are either partial (hypopnea) or complete (apnea) and often result in (severe) oxygen desaturations. Patients have recurrent arousals from sleep as an attempt to restore upper airway patency. This results in activation of the sympathetic nervous system and sleep fragmentation.[2] Neurobehavioral consequences of sleep fragmentation include excessive sleepiness, an increased risk of accidents, and impairment of the quality of life.[3-5] Cardiovascular sequelae of OSAHS include hypertension and an increased risk for ischemic heart disease, congestive heart failure and stroke.[6-8] Because obesity is a risk factor for OSAHS, it should be considered a serious and increasing public health problem.[9] In order to diagnose OSAHS a sleep registration (*e.g.*, polysomnography) should demonstrate five or more apneas or hypopneas per hour sleep (*i.e.*, apnea-hypopnea index ≥5).[10]

Continuous positive airway pressure (CPAP) prevents upper airway obstruction during sleep, and is currently regarded as the treatment of choice for OSAHS.[5] However, poor compliance may compromise the effect of CPAP due to its obtrusive nature.[11,12] Over the past decade, oral-appliance therapy has emerged as an increasingly popular alternative to CPAP therapy.[13] Oral appliances that reposition the mandible (mandibular repositioning appliances [MRA's]) are currently considered a viable treatment modality, in particular for mild to moderate OSAHS.[14] In up to 34% of cases an MRA cannot be inserted because of dental limitations.[15] Factors of consideration include (extensive) periodontal disease and dental decay, active temporomandibular joint disorders, and restrictions in mobility of the mandible. In the majority of cases, however, there are an insufficient number of teeth to support and retain the appliance.[14,15] This is especially the case in edentulous patients.

Several types of oral appliances have been described for managing OSAHS in edentulous patients.[16-21] Full-night application of these appliances is generally compromised by discomfort or poor retention. In order to stabilize and retain an MRA in the edentulous mandible osseointegrated implants may be used.[16] However, clinical studies of this technique have not been reported to date. This study describes our experiences with an implant retained MRA in the treatment of edentulous OSAHS patients.

TABLE 1. Patient characteristics.

Patient	Age (years)	Baseline AHI (no/hour)	Body-mass index (kg/m²)	Implantological procedure
1	55	6	25	- 4 implants mandible - 6 implants maxilla (2nd treatment)
2	48	11	24	- 4 implants mandible
3	53	13	25	- 4 implants mandible
4	57	18	29	- 4 implants mandible
5	63	14	31	- transmandibular implant
6	58	18	28	- 4 implants mandible

Abbreviations: AHI = apnea-hypopnea index.

Methods

Patient selection

All edentulous OSAHS patients treated with an MRA at the Medical Center Leeuwarden (The Netherlands) in the period January 2003 to January 2005 were included in this study (Table 1). Before treatment, all patients had been subjected to polysomnography and an upper airway examination. MRA therapy was indicated in mild OSAHS cases not qualifying for CPAP therapy (four male patients) or in patients declining CPAP therapy (two male patients). Written informed consent was obtained from each patient before treatment was initiated.

Treatment procedure

Except for one patient, all subjects received four endosseous dental implants (Straumann AG, Waldenburg, Switzerland) in the interforaminal region of the mandible. Because one patient had previously (more than ten years ago) received a transmandibular implant (M+R Haren b.v., Haren, Groningen, The Netherlands), placement of endosseous implants was not required in this subject. The implants were placed by one surgeon (K. Heydenrijk) under local anesthesia.[22] After a two-month osseointegration period, the MRA could be constructed.

Before the MRA was constructed, a new maxillary denture and a mandibular overdenture were made.[23] A bar construction was screwed onto the implants (Figure 1A). This construction provided support for a clip attachment that was incorporated in the mandibular overdenture. When the denture was finished, it was duplicated in transparent acrylic.

MRA therapy was performed with a modified version of the Thornton adjustable positioner (Airway Management Inc., Dallas, TX, USA).[24] This MRA consists of an adjustable construction that allows patients to titrate the amount of mandibular advancement. The construction was incorporated in the duplicated denture. In the maxilla, the MRA was retained by the suction force of the duplicate of the upper denture. In the mandible the MRA was retained by the bar construction and a clip attachment that was incorporated in the duplicate of the lower overdenture (Figure 1A & 2A). Patients were instructed to wear the MRA instead of their dentures whenever they slept. When initiating MRA therapy, the mandible was adjusted to approximately 50% of the patient's maximum advancement. Patients could accustom to this position during a two-week period. Subsequently, patients were instructed to advance the mandible with one to two increments (*i.e.*, 0.2 to 0.4 mm) each night. This titration was continued until symptoms of OSAHS (*e.g.*, snoring, apneas and hypopneas or excessive sleepiness) abated or until further advancement of the mandible resulted in discomfort. After the MRA was titrated, a second polysomnographic study was performed.

Polysomnography

Polysomnography at baseline and follow-up evaluations was conducted ambulatory in the patient's home situation (Embla® A10 digital recorder, Medcare, Reykjavik, Iceland). Standardized criteria were used to score apneas and hypopneas.[10] All polysomnographic studies were evaluated and scored by one neurophysiologist.

Outcome measures

The apnea-hypopnea index (AHI) was used as primary outcome measure. MRA therapy was aimed at a correction of the AHI to normal levels (*i.e.*, AHI <5). Secondary outcomes were changes in the lowest oxyhemoglobin saturation during sleep (minSaO_2) and the desaturation-index (*i.e.*, the mean number of oxyhemoglobin desaturations >4% per hour sleep).

Results

The time interval between placement of the implants and initiation of MRA therapy varied from six months (patient 2, 3, 4 and 6) to ten months (patient 1). In the sixth patient, who already had an implant retained overdenture in the mandible (patient 5), MRA therapy could be initiated within a month. Besides the loss of one of the implants (patient 6), no complications were encountered after placement of the implants.

MRA therapy was well tolerated by four of the six patients. In the remaining two patients (patient 1 and 6), the MRA was not tolerated because of pressure induced discomfort of the labial mucosa in the maxilla. Moreover, advancement of the

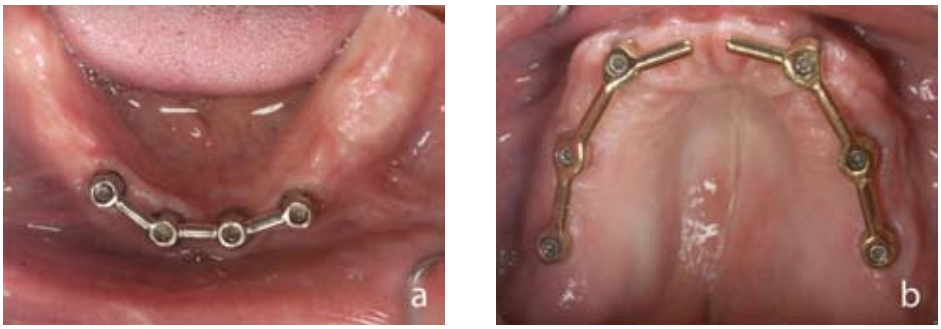

FIGURE 1. Features of the bar constructions that provide retention for the MRA in patient 1.

(a) bar construction screwed onto the implants in the mandible; (b) bar construction screwed onto the implants in the maxilla.
Abbreviations: MRA = mandibular repositioning appliance.

mandible was limited for the same reason in three patients who did tolerate the MRA (patient 2, 3 and 5). Attempts to relieve the labial mucosa by trimming the acrylic of the upper appliance or by applying a silicone lining were unsuccessful in the two patients who did not tolerate the MRA. In order to resolve the pressure problems, these two patients were offered an implant retained overdenture and MRA in the maxilla. Because this would require additional surgery, one patient declined further treatment (patient 6). The other patient was treated under general anesthesia with a bone augmentation of the maxillary sinuses using autologous grafts from the right anterior iliac crest. After three months, six endosseous implants were placed in the posterior region of the maxilla, and after another three months two bar constructions were screwed onto the maxillary implants. These bar constructions provided retention for an overdenture and MRA in the maxilla (Figure 1B & 2B). The pressure on the labial mucosa was relieved and the further course of MRA therapy was uncomplicated in this patient.

All five patients who completed the follow-up review displayed an improvement in the AHI as a result of MRA therapy (Table 2). A correction of the AHI <5 was attained in four patients. The minSaO_2 showed a small improvement in three out of five patients. The desaturation-index improved in all five patients. The deterioration in minSaO_2 and modest improvement in desaturation-index in one patient (patient 4) could be explained by his chronic obstructive pulmonary disease.

Four out of the five patients who completed the follow-up review of MRA therapy reported a satisfactory improvement of their symptoms (*e.g.*, snoring, excessive sleepiness). Despite an adequate improvement of the AHI, the remaining patient

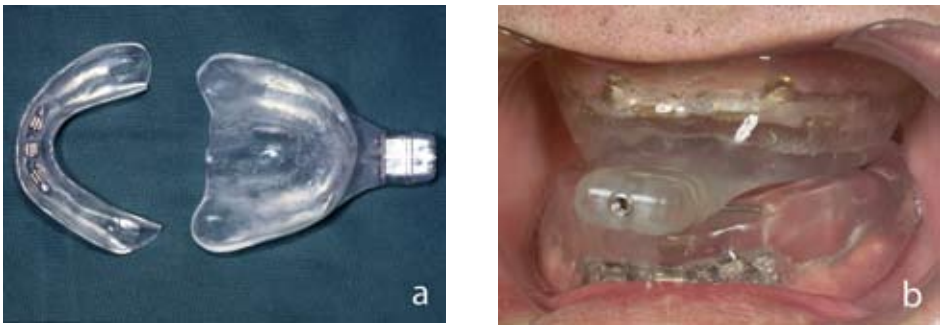

FIGURE 2. Features of the MRA in patient 1.

(a) upper and lower part of the MRA before placement of implants in the maxilla, note the clip attachment in the mandibular part of the MRA; (b) intraoral view with MRA after placement of implants in the maxilla.
Abbreviations: MRA = mandibular repositioning appliance.

complained of persistence in socially disruptive snoring (patient 2). To resolve these complaints additional advancement of the mandible was necessary. Because this again caused excessive pressure on the labial mucosa in the maxilla, an implant retained MRA in the maxilla, as described earlier, was offered. This patient is currently contemplating this secondary treatment.

Discussion

Edentulous OSAHS patients are generally excluded from MRA therapy.[14] In the general Dutch population up to 35% of subjects aged 20 or older are edentulous.[25] Therefore, in theory a considerable proportion of OSAHS patients do not qualify for MRA therapy. This study demonstrates that it is worth consideration to place endosseous implants, in order to stabilize and retain an MRA, in edentulous OSAHS patients. After implant placement, MRA treatment can generally be initiated within a six-month period. By adopting the technique described in this study, a larger proportion of OSAHS patients qualify for MRA therapy. Moreover, edentulous OSAHS patients may be offered a greater variety of treatment options when CPAP therapy is not indicated or has failed.

Four out of the six patients tolerated the implant retained MRA well. However, in five of the six patients the therapeutic effectiveness was compromised by pressure of the MRA on the labial mucosa in the maxilla. In two patients, this phenomenon made it impossible to wear the MRA. We have successfully treated one of these patients with six implants in the maxilla retaining the upper part of an MRA. We

TABLE 2. Polysomnographic outcomes.

Patient	Follow-up* (months)	AHI (no/hour)		$minSaO_2$ (%)		desaturation-index (no/hour)	
		baseline	MRA	baseline	MRA	baseline	MRA
1	24	6	0	90	92	14	1
2	8	11	4	85	83	6	2
3	7	13	4.7	90	91	11	2
4	6	18	3	84	79	22	12
5	10	14	12	86	88	14	4
6	-	18	-	84	-	5	-

* Follow-up period from treatment initiation until follow-up polysomnography of MRA therapy.
Abbreviations: AHI = apnea-hypopnea index, $minSaO_2$ = lowest oxyhemoglobin saturation during sleep, MRA = mandibular repositioning appliance.

suggest that this solution is offered to patients failing the primary treatment due to pressure discomfort of the upper appliance. When compared with the mandible, placement of implants in the posterior region of the maxilla is generally associated with more morbidity and more prolonged treatment periods.[26] To overcome these limitations, we currently offer patients requiring an implant retained MRA in the maxilla two implants in the canine regions. These two implants can be provided with ball attachments that subsequently may be used for retention of an overdenture and MRA. By doing so, surgical intervention is minimized and secondary treatment may be initiated more quickly.

In four out of five patients, the MRA therapy resulted in an AHI <5. In the fifth patient therapy was not effective. This may be related to the limitation in mandibular advancement that resulted from pressure of the MRA on the labial mucosa in the maxilla. Despite the disappointing effect on the AHI, the desaturation-index improved substantially in this patient. Because the patient experienced a satisfactory improvement in symptoms, he refused secondary treatment.

Results obtained from this study suggest that an implant retained MRA in the mandible is a viable treatment modality in edentulous OSAHS patients. However, therapeutic effectiveness of this treatment may be compromised by excessive pressure of the MRA on the labial mucosa in the maxilla. To overcome this limitation we suggest that an implant retained MRA in the maxilla is offered as a secondary treatment in selected patients. Additional studies evaluating the feasibility of this secondary treatment and the feasibility of an implant retained MRA in OSAHS patients with more severe disease are of interest. It is advised that treatment with

an implant retained MRA is performed by an oral and maxillofacial surgeon and dentist experienced in treating patients with sleep-related breathing disorders.

Acknowledgement The authors wish to thank the Department of Neurology and the Center for Sleep and Wake Disorders of the Medical Center Leeuwarden (The Netherlands) for performing the polysomnographic studies and providing the relevant data.

REFERENCES

1. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med* 1993;328:1230-1235.
2. Malhotra A, White DP. Obstructive sleep apnoea. *Lancet* 2002;360:237-245.
3. Patel SR, White DP, Malhotra A, Stanchina ML, Ayas NT. Continuous positive airway pressure therapy for treating sleepiness in a diverse population with obstructive sleep apnea: results of a meta-analysis. *Arch Intern Med* 2003;163:565-571.
4. Teran-Santos J, Jimenez-Gomez A, Cordero-Guevara J. The association between sleep apnea and the risk of traffic accidents. Cooperative Group Burgos-Santander. *N Engl J Med* 1999;340:847-851.
5. Giles T, Lasserson T, Smith B, White J, Wright J, Cates C. Continuous positive airways pressure for obstructive sleep apnoea in adults. *Cochrane Database Syst Rev* 2006;1: CD001106.
6. Wolk R, Kara T, Somers VK. Sleep-disordered breathing and cardiovascular disease. *Circulation* 2003;108:9-12.
7. Marin JM, Carrizo SJ, Vicente E, Agusti AG. Long-term cardiovascular outcomes in men with obstructive sleep apnoea-hypopnoea with or without treatment with continuous positive airway pressure: an observational study. *Lancet* 2005;365:1046-1053.
8. Yaggi HK, Concato J, Kernan WN, Lichtman JH, Brass LM, Mohsenin V. Obstructive sleep apnea as a risk factor for stroke and death. *N Engl J Med* 2005;353:2034-2041.
9. Newman AB, Foster G, Givelber R, Nieto FJ, Redline S, Young T. Progression and regression of sleep-disordered breathing with changes in weight: the Sleep Heart Health Study. *Arch Intern Med* 2005;165:2408-2413.
10. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep* 1999;22:667-689.
11. Barbe F, Mayoralas LR, Duran J, Masa JF, Maimo A, Montserrat JM, et al. Treatment with continuous positive airway pressure is not effective in patients with sleep apnea but no daytime sleepiness. a randomized, controlled trial. *Ann Intern Med* 2001;134:1015-1023.
12. Barnes M, Houston D, Worsnop CJ, Neill AM, Mykytyn IJ, Kay A, et al. A randomized controlled trial of continuous positive airway pressure in mild obstructive sleep apnea. *Am J Respir Crit Care Med* 2002;165:773-780.
13. Cistulli PA, Gotsopoulos H, Marklund M, Lowe AA. Treatment of snoring and obstructive sleep apnea with mandibular repositioning appliances. *Sleep Med Rev* 2004;8:443-457.
14. Hoekema A, Stegenga B, de Bont LGM. Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review. *Crit Rev Oral Biol Med* 2004;15:137-155.
15. Petit FX, Pepin JL, Bettega G, Sadek H, Raphael B, Levy P. Mandibular advancement devices: rate of contraindications in 100 consecutive obstructive sleep apnea patients. *Am J Respir Crit Care Med* 2002;166:274-278.
16. Meyer JB, Knudson RC. Fabrication of a prosthesis to prevent sleep apnea in edentulous patients. *J Prosthet Dent* 1990;63:448-451.
17. Cartwright R, Stefoski D, Caldarelli D, Kravitz H, Knight S, Lloyd S, et al. Toward a treatment logic for sleep apnea: the place of the tongue retaining device. *Behav Res Ther* 26: 1988;121-126.
18. Robertson CJ. Obstructive sleep apnoea. Part II: Treatment with a customised dental appliance. *N Z Dent J* 1997;93:4-9.

19. Kingshott RN, Jones DR, Taylor DR, Robertson CJ. The efficacy of a novel tongue-stabilizing device on polysomnographic variables in sleep-disordered breathing: a pilot study. *Sleep Breath* 2002;6:69-76.
20. Eskafi M, Ekberg E, Cline C, Israelsson B, Nilner M. Use of a mandibular advancement device in patients with congestive heart failure and sleep apnoea. *Gerodontology* 2004;21:100-107.
21. Nayar S, Knox J. Management of obstructive sleep apnea in an edentulous patient with a mandibular advancement splint: a clinical report. *J Prosthet Dent* 2005;94:108-111.
22. Sutter F, Schroeder A, Buser D. New ITI implant concept–technical aspects and methods (I). *Die Quintessenz* 1988;39:1875-1890.
23. Batenburg RH, Reintsema H, van Oort RP. Use of the final denture base for the intermaxillary registration in an implant-supported overdenture: technical note. *Int J Oral Maxillofac Implants* 1993;8:205-207.
24. Pancer J, Al-Faifi S, Al-Faifi M, Hoffstein V. Evaluation of variable mandibular advancement appliance for treatment of snoring and sleep apnea. *Chest* 1999;116:1511-1518.
25. van den Berg J. Dentures in the Dutch population. *Monthly Report in Health Statistics* nr. 1. Central Bureau for Statistics (The Netherlands); 1982.
26. Raghoebar GM, Timmenga NM, Reintsema H, Stegenga B, Vissink A. Maxillary bone grafting for insertion of endosseous implants: results after 12-124 months. *Clin Oral Implants Res* 2001;12:279-286.