

Microimplant-based mandibular advancement therapy for the treatment of snoring and obstructive sleep apnea: a prospective study

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ABSTRACT

Objective: To investigate the efficacy of orthodontic microimplant-based mandibular advancement therapies for the treatment of snoring and obstructive sleep apnea (OSA) in adult patients.

Materials and Methods: Ten adult OSA patients (seven men, three women; mean age 60.00 ± 9.25 years) were each treated with two mandibular orthodontic microimplants attached to a customized reverse face mask for mandibular advancement. Pretreatment and posttreatment outcome measures of microimplant mobility, apnea-hypopnea index, snoring, respiratory movement, and Epworth sleepiness scores were evaluated after 6 months.

Results: Highly significant reductions in the apnea-hypopnea index, snoring, and sleep variables were observed. Sixteen of the 20 (80%) microimplants were stable and showed no mobility, and four (20%) demonstrated grade 1 or 2 mobility and required removal and reinsertion of a new microimplant.

Conclusions: Favorable reductions in sleep variables highlight the potential of microimplant-based mandibular advancement therapy as an alternative treatment modality for OSA patients who cannot tolerate continuous positive airway pressure and oral appliance therapy. (*Angle Orthod.* 2012;82:978–984.)

KEY WORDS: Obstructive sleep apnea; Snoring; Microimplant-based mandibular advancement

INTRODUCTION

Sleep-disordered breathing (SDB) describes a spectrum of abnormal breathing during sleep that may range from primary snoring to hypopneas to periods of obstructive sleep apnea (OSA), during which there is complete cessation of breathing.¹ OSA is characterized by repetitive periods of partial or complete airway obstruction during sleep, which result in oxygen desaturation, sleep fragmentation, and frequent arousals. This common sleep disorder has been implicated in hypertension,² stroke,³ and carotid atherosclerosis.⁴ Although continuous positive airway pressure (CPAP) therapy remains the gold standard treatment,⁵ more recently the use of oral appliances (OAs) to treat SDB

has increased. OAs act primarily by mechanically advancing the mandible and tongue, thereby increasing the size of the pharyngeal lumen.⁶

The efficacy of OAs is variable, depending on appliance design and host factors.⁷ Contraindications have been found to be as high as 34% of potential patients because of dental factors, including insufficient teeth and periodontal disease.⁸ Side effects, although transient in nature, range from occlusal alteration to temporomandibular joint and muscular pain.⁹ Although adverse effects are thought to occur in the first 2 years of use, irreversible changes in jaw and dental relationships have been reported.^{8,10}

Descriptions of SDB via prosthetic implant treatment are sparse in the literature. High cost and surgical morbidity present as limiting factors.¹¹ Recently, we reported the use of orthodontic microimplants in the treatment of a dentate severe OSA patient.¹² Two microimplants anchored to the mandible enabled skeletal anchorage for mandibular advancement (MA). A customized face mask provided extraoral anchorage, to which the microimplants were connected for titratable MA. Microimplant-based mandibular advancement (MiMA) therapy resulted in reductions in OSA symptoms and snoring.

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To avoid the need for tooth anchorage of OAs and reduce the costs and morbidity associated with endosseous implants, the present prospective study investigated the use of orthodontic microimplants as an alternative method of MA. We hypothesized that microimplants can provide skeletal anchorage for MA for the treatment of snoring and OSA. The potential advantages of this novel treatment modality include the ability to treat patients with excessive missing teeth, an exaggerated gag reflex, or CPAP/OA intolerance. The added benefit of increased oral volume because of their small size and ease of placement increase the attractiveness of microimplants as a novel method of skeletal anchorage for MA.

This study furthers our investigations into the efficacy of orthodontic MiMA therapy for the treatment of snoring and OSA in adult patients.

MATERIALS AND METHODS

Subjects

Ten adult OSA patients (seven men, three women) referred by sleep physicians to a dental sleep clinic were recruited. Six of the patients had previously rejected CPAP therapy, and all patients were OA intolerant. Overnight sleep studies were used to quantify baseline sleep characteristics for all subjects. Inclusion criteria were the presence of at least two symptoms of OSA (snoring, fragmented sleep, witnessed apneas, and excessive daytime sleepiness), and evidence of OSA on sleep study with an apnea-hypopnea index (AHI) of ≥ 10 events/hour. Patients were excluded if there was evidence of bone disorders or regular use of sedatives. Ethical human research approval was not required. Written informed consent was obtained from all participants.

Microimplants

At T1, two orthodontic microimplants (1.6 mm diameter \times 10 mm length; Absoanchor, Dentos Inc, Daegu, Korea) made of titanium alloy (titanium-aluminum-vanadium [Ti-6Al-4V]) (Figure 1) were placed in the mandible under light anesthesia (0.5 mL lidocaine). The microimplants were inserted bilaterally with the self-tapping method, with the sites of insertion based on factors such as bone quality, root proximity, and soft tissue thickness. A 1.3-mm pilot drill was used under copious saline irrigation. Each microimplant was inserted manually, and loading was delayed for at least 2 weeks.

Intraoral Attachment

Two customized "shepherd's hook" attachments (Figure 2) were fabricated with 0.18-inch stainless



Figure 1. Two microimplants with mushroom head for comfort (1.6 mm diameter, 10 mm length).

steel wire. The attachments engaged the microimplants posteroanteriorly (Figure 3) and were extended extraorally with 60-lb fishing line (Seven Oceans, Inc, Mukilteo, WA, USA) to the midsagittal plane, where they connected to a customized reverse-pull face mask (Figure 4). An adjustable screw device on the face mask enabled titration to 70% of maximum protrusive capability. The two microimplants provided skeletal anchorage for the hook attachments to "pull" and effect MA.

Outcome Measurements

A follow-up Sonomat sleep study (Sonomedical, Balmain, Australia) of MiMA therapy was performed at 6 months (T2). Microimplant mobility and sleep variables were recorded and defined as follows.

Microimplant mobility. Visual and tactile assessments were used to measure microimplant stability. Implants were characterized as: grade 0, no mobility; grade 1, less than 0.5 mm of lateral mobility but able to withstand force loading; or grade 2, greater than 1 mm of lateral mobility, partial/total mobility, or loss as a result of force loading.

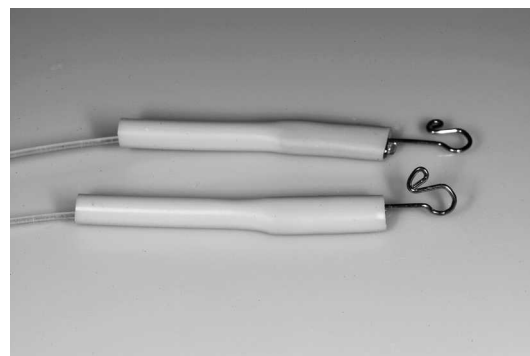


Figure 2. Two customized "shepherd's hook" attachments fabricated of 0.18-inch stainless steel.



Figure 3. The attachments engage both microimplants in a posteroanterior direction.

Apnea-hypopnea index. AHI was defined as the number of apnea and hypopnea events per sleep hour. Apneas were defined as a complete cessation of breathing for a period ≥ 10 seconds. Hypopneas were defined as episodes $>50\%$ reduction of respiratory airflow, as determined by an increase in respiratory effort. The index time was calculated as total recording time minus total movement time, including time out of bed.

Frequency of snoring. This was expressed as total snore percentage (TS%), calculated as a percent of index time. It was defined as the amount of time spent snoring during the sleep study, excluding periods of arousals or movement.

Respiratory movement index. The respiratory movement index (RMI) was defined as the number of individual movements of a period >3 seconds that occurred per hour as the result of a respiratory event.



Figure 4. The attachments extend extraorally to customized face mask.

Table 1. Study Sample Characteristics at Baseline (n = 10)

Variable ^a	Baseline value
Sex	7 M, 3 F
Age, y	60.00 \pm 9.25
BMI, kg/m ²	26.7 \pm 2.9
ESS score	13.0 \pm 3.3
AHI, events/h	36.8 \pm 16.5
RMI, events/h	19.7 \pm 18.0
TS%	41.6 \pm 22.1

^a BMI indicates body mass index. Data are presented as means \pm SDs.

Epworth Sleepiness Scale. The Epworth Sleepiness Scale¹³ (ESS) assessed the level of daytime sleepiness.

Statistical Analysis

Statistical calculations were performed with SPSS version 17.0 statistical software (SPSS software, Chicago, Ill) for Windows. Data are presented as percentages or means \pm standard deviations (SDs) for variables demonstrating normal distribution. To assess the statistical significance of treatment changes, paired Student *t* tests were used for parametric variables to compare baseline and treatment measures. A value of $P < .05$ was established as a statistically significant level.

RESULTS

The overall microimplant survival rate was 80%. Patient characteristics are outlined in Tables 1 and 2. Sixteen of the 20 microimplants (80%) were stable and showed no mobility at T2. One microimplant (patient 6), which exhibited mild inflammation and grade 1 mobility, was left in situ following oral hygiene instruction. Three microimplants (15%) demonstrated grade 2 mobility and required removal; a new microimplant was placed in all cases.

A highly significant reduction in the AHI, from 36.8 ± 16.5 to 10.0 ± 4.5 events/hour ($P = .005$), was observed (Tables 3 and 4; Figure 5). All 10 patients had $>50\%$ reduction in AHI. Using the American Academy of Sleep Medicine classification of OSA severity, there were initially five subjects with severe OSA, four with moderate OSA, and one with mild OSA. Following MiMA therapy, there were no patients with severe OSA, one with moderate OSA, and nine with mild OSA. All five severe OSA subjects improved remarkably, with four of them (80%) having AHI <15 events/hour. The most severe OSA patient (patient 7) decreased from 63.5 to 15.7 events/hour. Four moderate OSA patients reduced their AHI to <15 events/hour and were reclassified as mild OSA.

Table 2. Individual Patient Microimplant Characteristics After MiMA Therapy (T2)

Patient	Sex	Age, y	Dentition	MI location	Mobility
1	M	75	FE	33, 43	R2, L0
2	M	59	PE	34/35, 44/45	R0, L0
3	M	55	PE	37, 46/47	R0, L0
4	M	42	FD	35/36, 44/45	R0, L0
5	M	66	PE	33D, 43D	R0, L0
6	F	56	FD	33/34, 43/44	R1, L0
7	M	59	PE	35/36, 46D	R0, L2
8	F	65	PE	35/36, 44/45	R0, L0
9	M	69	PE	36/37, 45/46	R0, L0
10	F	54	PE	34/35, 45/46	R2, L0

^a FE indicates full edentulism; FD, fully dentate; PE, partial edentulism; MI location, microimplant location; /, interradicular space; D, distal; No. of MI, number of microimplants inserted; ST, self-tapping method; D, delayed (loading); mobility grades: 0, no mobility; 1, less than 0.5 mm of lateral mobility, screw stable able to withstand orthodontic force loading; and 2, greater than 1 mm of lateral mobility, partial/total mobility, or loss as a result of force loading.

TS% values are shown in Tables 3 and 4 and Figure 6. Statistically significant reductions in snoring, from $41.6\% \pm 22.1\%$ to $21.8\% \pm 14.4\%$ ($P = .005$) of total sleep time, were observed. All patients reduced their snoring frequency, with five (50%) reducing their snore time by $>50\%$. Patients 5 and 8 had an $>80\%$ reduction in snoring.

Highly significant reductions in RMI (19.7 ± 18.0 versus 6.9 ± 7.3 events/hour; $P = .005$) and ESS (13.0 ± 3.3 versus 8.1 ± 3.1 ; $P < .0001$) were observed (Tables 3 and 4). All 10 patients reduced their RMI, with eight (80%) reducing their RMI $>50\%$ during total sleep time.

Overall, initial side effects included soft tissue irritation caused by the prominence of the microimplant's mushroom-shaped head and a "morning-after" bite alteration effect. Similar to OA use, these effects were transient and resolved within 2 weeks. No dental

side effects of the dentition or temporomandibular joint were seen. In contrast to OA therapy, we observed pressure sores in the area of the zygomatic pads. These areas of soft tissue compression resolved uneventfully following enlargement of the zygomatic pad area with thicker silicone material.

DISCUSSION

This prospective study introduced the novel concept of using orthodontic microimplants for the treatment of snoring and OSA. Two microimplants were placed bilaterally in the mandibles of each patient. MiMA provided an alternative to CPAP and OA therapy. Poor CPAP compliance frequently occurs as a result of side effects; hence, patients prefer OAs to CPAP therapy.¹⁴ However, Pantin et al.¹⁵ noticed that occlusal changes occurred in the first 2 years of OA use, with 7.5% of patients discontinuing treatment. Longer-term occlusal alterations have also been documented.¹⁶ Despite their increasing popularity, the compliance rate after 1 year ranges from 55% to 82% and appears to decline over time.¹⁷ This decline may be in part the result of a perceived lack of therapeutic benefit and side effects, as individual patient response to OAs can be variable and may depend on appliance design.⁷

Although prosthetic implants for edentulous OSA treatment have been documented,^{11,18} their high cost and surgical morbidity present as limiting factors. Of note, de Carlos et al.¹⁹ documented microimplant treatment of an edentulous OSA patient. To our knowledge, our study is the first to document orthodontic microimplants for the treatment of dentate and one edentulous OSA patient. At 6 months, 16 of 20 (80%) microimplants were stable, with no mobility. Poor oral hygiene and inflammation resulted in the first failure. The second failure occurred as a result of overloading, jiggling, and lateral forces from an overdenture (patient 1). Microimplant fracture during primary insertion caused the third failure. This was

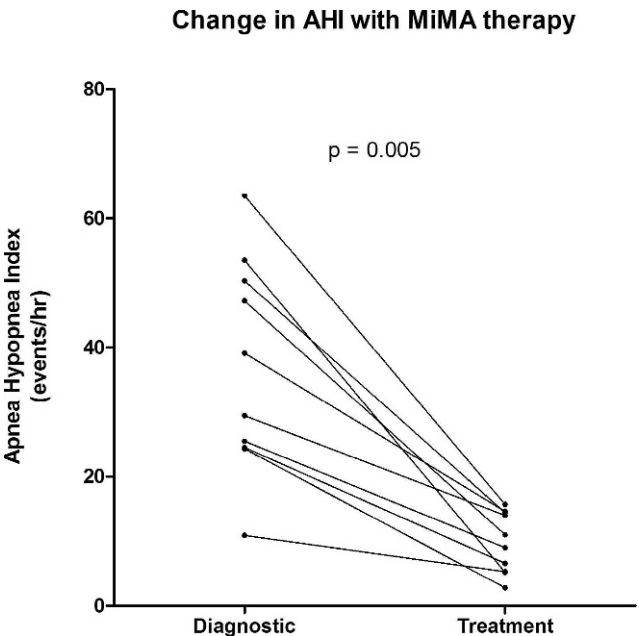


Figure 5. Change in AHI with MiMA therapy.

Table 3. Summary of Measurements at Baseline and After MiMA Therapy

Patient	BMI		AHI		TS%		RMI		ESS	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	24.6	24.8	39.1	14.6	55.6	36.8	17.0	8.5	18	13
2	28.7	28.4	29.4	14.0	42.2	36.5	10.1	3.1	15	9
3	27.8	27.8	50.3	14.4	56.8	32.5	34.0	10.8	16	8
4	33.4	33.3	47.2	11.0	77.2	35.5	31.5	4.9	8	4
5	27.6	27.9	53.5	5.2	46.8	9.1	15.4	3.6	15	9
6	25.6	26.0	24.5	6.6	32.0	10.7	4.2	2.5	15	13
7	26.4	26.8	63.5	15.7	42.2	33.5	61.5	25.6	9	6
8	25.4	25.1	10.9	5.3	4.5	0.2	6.2	1.1	12	4
9	23.0	22.9	24.3	3.8	8.1	7.6	13.3	7.1	11	8
10	24.3	24.7	25.5	9.0	50.3	15.4	4.2	1.5	11	7

^a BMI indicates body mass index; T1, baseline; and T2, MiMa therapy.

attributed to dense cortical bone and excessive insertion torque, despite the use of a 1.3-mm pilot drill prior to manual insertion with the self-tapping method.

In dentate patients, root proximity and cortical bone levels warrant special consideration. Studies report thicker cortical bone in the mandible, with densities dependent on the region of placement.²⁰ Areas of cortical bone at least 1 mm thick are thought to increase microimplant stability and success.²¹ When evaluating dental implants, axial pull-out strength, quantifying the resistance to bone rupture in the long axis of the screw, is often used.²² However, the microimplants used for MiMA therapy are subjected to lateral loading. Additionally, torsional stress has been argued to generate a moment to the implant in the unscrewing direction.²³ To minimize the counter-clockwise moment, our intraoral attachments rotated freely when connected to the microimplant head.

Although the precise mechanisms for MA are unclear, imaging studies have revealed improvements in airway patency in the velopharynx, particularly in the lateral dimension.²⁴ Dose-dependent decreases in AHI with increasing MA have been reported.²⁵ Furthermore, a dose-dependent effect, with each 2 mm of forward positioning resulting in a 20% improvement in the number/severity of nocturnal oxygen desaturation events, has been demonstrated.²⁶

With increasing MA, reciprocal forces are dissipated through the dentition in tooth-supported OAs, poten-

tially causing undesirable dental side effects. In contrast, with MiMA therapy, these forces we hypothesize are skeletally supported and dissipated through the microimplants and face mask. Extraoral anchorage was provided by the face mask, with principal compressive forces noted on the zygomatic pads. During MA, we observed a rotational moment pivoting around the zygomatic pads. As the frontal pad of the face mask rotated clockwise, stringent fastening of the frontal headstraps was required to counter this rotational effect, in addition to increasing the surface area and padding on the zygomatic pads.

Importantly, the authors acknowledge the possibility that additional placement of two microimplants between the maxillary anterior teeth with interarch connectors to the mandibular microimplants for MA would negate the need for a face mask. However, only two “hidden” posterior mandibular microimplants were required when a face mask was used. Numerous clinical challenges encountered with maxillary microimplant use for MA have included thinner cortical bone and high aesthetic and soft tissue requirements and will be presented in a later publication by the authors.

Our study documented highly significant reductions in AHI, from 36.8 ± 16.5 to 10.0 ± 4.5 events/hour ($P = .005$). All patients had $>50\%$ reduction in AHI, with nine (90%) exhibiting AHI <15 events/hour and therefore being reclassified with mild OSA. Significant reductions in snoring, from $41.6\% \pm 22.1\%$ to $21.8\% \pm 14.4\%$ ($P = .005$) of total sleep time, were noted. However, it is noteworthy that, with the exception of patient 8, full resolution of snoring was not attained in the other nine patients. As snoring may not be directly reflected in the AHI, it is tempting to categorize low-AHI patients as low risk despite the presence of residual snoring. Increasingly, snoring is no longer thought to be a benign condition but a vibratory insult that leads to pharyngeal inflammation.²⁷ Recent evidence associates this symptom with endothelial dysfunction as a prelude to atherosclerosis and stroke in asymptomatic mild OSA patients.⁴

Table 4. Summary of Changes in Sleep Variables After MiMA Therapy (n = 10)

Variable	T1	T2	P
AHI, events/h	36.8 ± 16.5	10.0 ± 4.5	.005*
TS%	41.6 ± 22.1	21.8 ± 14.4	.005*
RMI, events/h	19.7 ± 18.0	6.9 ± 7.3	.005*
BMI, kg/m ²	26.7 ± 2.9	26.8 ± 2.9	NS
ESS score	13.0 ± 3.3	8.1 ± 3.1	.0001**

^a BMI, body mass index; NS, not significant.

* Highly statistically significant. Data are presented as means \pm SDs.

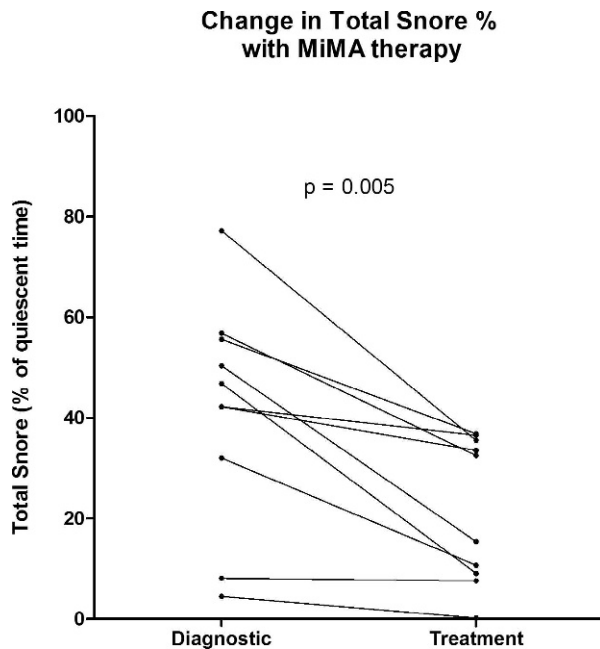


Figure 6. Change in TS% with MiMA therapy.

Clinical objectives in OSA treatment should thus strive to reduce symptoms, with goals of eliminating both apneas and snoring.

Favorable improvements in RMI depict a reduction in compensatory respiratory movements and sleep fragmentation and are relevant, as decreases in slow-wave and the rapid-eye-movement sleep phase have been shown to impair function, cognition, and mood.²⁸ The reduction in ESS scores further supports the improvements in daytime vigilance and alertness.

There are important limitations to this study. We observed only 10 patients with a diversity of dentition over a 6-month period. Longer-term studies that account for skeletal and dental changes are warranted. There was a potential for selection bias, as the referred patients had previously rejected CPAP/OA therapy and hence represented a select group of care-seeking volunteers rather than de novo OSA patients.

Given the multifactorial nature of SDB, it is prudent to note that MA poses as only one possible solution to a complex disorder. Despite recent advances in OA design and titration protocols that aim to predict success, current practice typically involves great financial expenditure without any guarantee of success. In this respect, orthodontic microimplants may, given their low cost and ease of placement, serve as a potential screening device to assess the feasibility of MA therapy. Longer-term studies in larger cohorts to assess microimplant stability and mandibular retraction forces during a complete sleep cycle are warranted.

This study introduces MiMA therapy as a novel treatment modality that can be applied clinically in

patients who have insufficient teeth for OA therapy, periodontal concerns, an exaggerated gag reflex, or unresolved OA side effects. Patient selection should take into account previous OSA treatment history and local factors for successful microimplant therapy.

CONCLUSION

- A customized titratable face mask attached to two microimplants was used to achieve mandibular advancement for the treatment of snoring and OSA.
- The MiMA device is effective for mandibular advancement; favorable reductions in the AHI, snoring, and other sleep variables were attained.
- MiMA therapy can provide an alternative treatment modality for adult patients who cannot tolerate CPAP and OA therapy.

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