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ORIGINAL ARTICLE

Efficacy of the Silensor for treating obstructive sleep apnea syndrome

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Abstract
Introduction Although mandibular repositioning devices were found to be very effective for treating obstructive sleep apnea (OSAS), they can cause side effects such as temporomandibular joint disorder and occlusal deviation. A semi-rigid device with a low frequency of side effects, the Silensor, (Erkodent Gmbh, Tuttlingen, Germany) was reported previously. The purpose of this study is to determine whether the Silensor is effective for treating OSAS.
Materials and methods Thirty-five OSAS patients (27 males and 8 females) who were treated with the Silensor were enrolled in this study. The mean age and body mass index of the patients were 52.2 years (23–72 years) and 24.5 kg/m^2 (19.3–31.6 kg/m^2), respectively. The patients were classified into two groups based on the length of the apparatus connector: 0–2 or 3–4 mm. A polysomnography test was performed twice, at the first visit and after the improvement of subjective symptoms. These data were statistically analyzed using the Wilcoxon signed-rank test.
Results The apnea–hypopnea index significantly improved in all OSAS patients, the mild to moderate OSAS patients, severe OSAS patients, 0- to 2-mm group, and the 3- to 4-mm group (91.4 %; $p<0.01$, 88.9 %; $p<0.01$, 100 %; $p<0.05$, 86.4 %; $p<0.01$, 100 %; $p<0.01$, respectively). The only side effects of the Silensor were broken apparatus and damage to the buccal mucosa.
Discussion The Silensor is useful for the treatment of OSAS. In particular, the Silensor is suitable for the first phase of OSAS treatment with oral appliances because the efficacy of the Silensor was equal to that of other oral appliances and had few side effects.

Keywords Obstructive sleep apnea syndrome · Oral appliances · The Silensor

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Introduction

Excessive daytime sleepiness can be caused by obstructive sleep apnea syndrome (OSAS), which could lead to automobile accidents and hence reduce survival [1, 2]. In Japan, oral appliances for treating OSAS have been covered by the national insurance system since 2004. Oral appliances can be classified into mandibular repositioning devices (MRD) and tongue-retaining devices (TRD).

MRD generally attach to the dental arches and mechanically protrude the mandible. TRD use suction pressure to keep the tongue in a protruded position during sleep. MRD therefore requires the patient to have a sufficient number of teeth, whereas TRD can be used by edentulous patients. Most previous studies have examined the use of MRD, as they are the most common type of oral appliance [3]. In addition, MRD can be separated into rigid MRD and semi-rigid MRD. Although MRD are very effective for treating OSAS, they can cause side effects such as temporomandibular joint disorder and occlusal deviation [4–7]. A semi-rigid device that displays a low frequency of side effects, the Silensor (Erkodent Gmbh, Tuttlingen, Germany; Fig. 1), was reported previously [8]. Therefore, the Silensor is suitable for the first phase of oral appliance treatment for OSAS if the Silensor is effective for the treatment of OSAS. The purpose of this study is to determine whether the Silensor is effective for the treatment of OSAS.

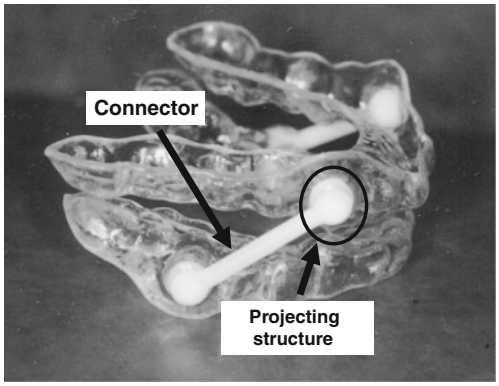

Fig. 1 A semi-rigid device, the Silensor (Erkodent Gmbh, Tuttlingen, Germany). The upper and lower elements of the Silensor were joined by plastic straps running from the upper canine to the lower molar regions, thus allowing some mouth opening during sleep

Materials and methods

Thirty-five OSAS patients (27 males and 8 females) who were treated with the Silensor at Yamaguchi University Hospital from September 2004 to April 2011 were enrolled in this study. Their mean age and body mass index were 52.2 years (23–72 years) and 24.5 kg/m^2 (19.3–31.6 kg/m^2), respectively. The upper and lower elements of the Silensor were joined by plastic straps running from the upper canine to the lower molar regions, thus allowing some mouth opening during sleep. This connector orientation permitted only forward movement of the mandible during opening, thus avoiding the reduction of the airway normally associated with mandibular opening. A further advantage of the Silensor is the ease of its adjustment. The buccal connectors are available in four different lengths, and the mandible can be readily advanced by replacing the original connector with a shorter one [8]. Therefore, the patients were classified into two groups based on the length of the connector used: 0–2 and 3–4 mm. In addition, the patients were classified according to the severity of their condition [2]: mild, an apnea–hypopnea index (AHI) of 5–15/h; moderate, an AHI of 15–30/h; severe, an AHI of more than 30/h. To evaluate the patients' responses, the achievement of an AHI of less than 10/h and the degree of the reduction in AHI (more than 75 %, complete response; 50–75 %, partial response; 25–50 %, weak response; less than 25 %, no response) were evaluated. A polysomnography test was performed twice, at the first visit and after the improvement of subjective symptoms. Using the Alice 5 Diagnostic Sleep System (Respironics; Murrysville, PA), AHI was measured together with the number of apnea episodes (absence of airflow for ≥10 s) and the number of hypopnea episodes (reduction of airflow by 50 % for ≥10 s with at least 3 % desaturation). These data were statistically analyzed using the Wilcoxon signed-rank test with SPSS software (version 11.0; SPSS, Inc, Chicago, IL). Values of $p<0.05$ were considered statistically significant.

Results

Thirty-two of the 35 patients (91.4 %) showed improvement after using the Silensor ($p<0.01$). The mean AHI of the patients treated with the Silensor significantly improved from 22.5 to 9.8/h in (Fig. 2).

When the patients were classified according to the severity of their condition, 24 of the 27 mild to moderate OSAS patients (88.9 %, $p<0.01$) and all of the severe OSAS patients showed improvements (100 %, $p<0.05$). The AHI of these patients significantly improved from 17.7 to 7.4/h and from 38.8 to 17.8/h, respectively.

When the patients were classified according to the connector length of the apparatus, 19 of the 22 patients (86.4 %) in the 0–2-mm group and all patients (100 %) in the 3–4-mm group improved, respectively. The AHI of these patients improved significantly from 20.7 to 9.7/h and from 25.5 to 9.9/h, respectively (Fig. 3).

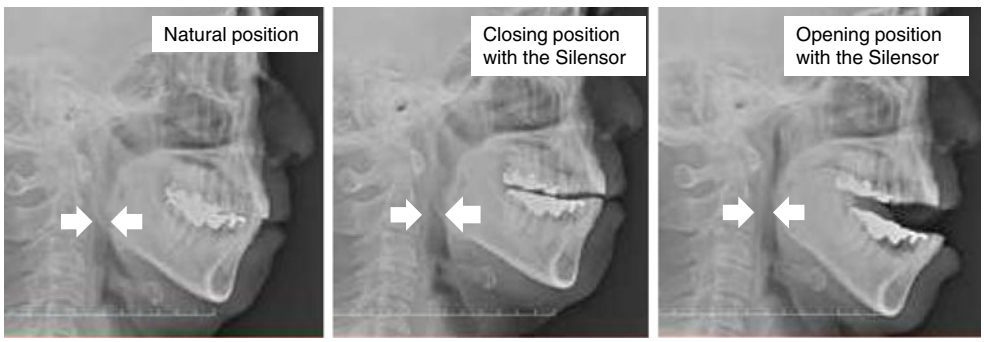

Fig. 2 The change in AHI from pre- to post-treatment. The mean AHI of the patients treated with the Silensor significantly improved from 22.5 to 9.8/h. Twenty-four of the 27 mild to moderate OSAS patients (88.9 %, $p<0.01$) and all of the severe OSAS patients showed improvements (100 %, $p<0.05$). The AHI of these patients significantly improved from 17.7 to 7.4/h and from 38.8 to 17.8/h, respectively

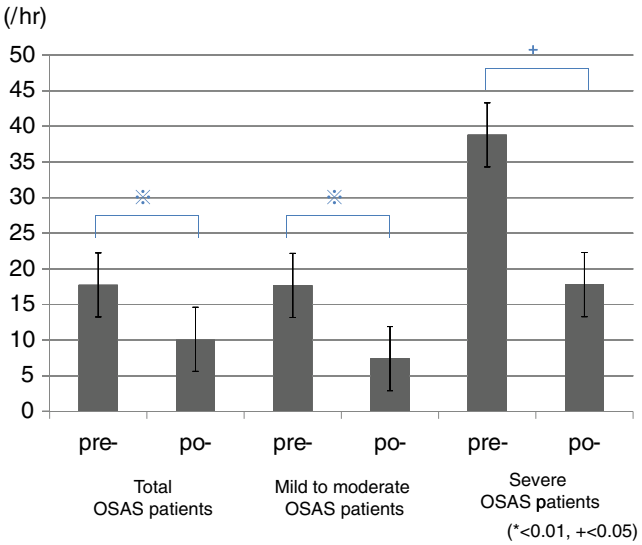

Fig. 3 The change in AHI from pre- to post-treatment in the 0–2 and 3–4 mm. Nineteen of the 22 patients (86.4 %) in the 0–2-mm group and all patients (100 %) in the 3–4-mm group improved, respectively. The AHI of these patients improved significantly from 20.7 to 9.7/h and from 25.5 to 9.9/h, respectively

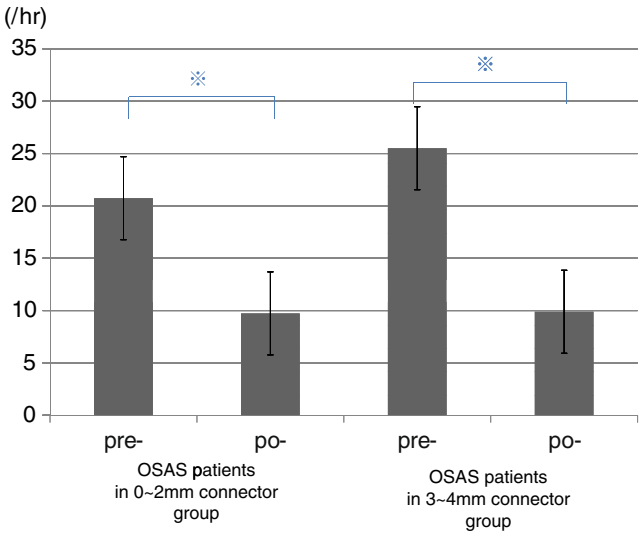

Fig. 4 Case (lateral cephalogram). The airway at the base of the tongue is narrowed, when the mouth is kept open and the mandible is moved anteriorly using the Silensor

Reduction in AHI to less than 10/h

Twenty-four of 35 patients (68.6 %) managed to reduce their AHI to less than 10. When the patients were classified according to the severity of their condition, 22 of the 27 mild to moderate OSAS patients (81.5 %) and 2 of the 8 severe OSAS patients (25 %) managed to reduce their AHI to less than 10/h. When the patients were classified according to the connector length of the apparatus, 15 of the 22 patients (68.2 %) in the 0–2-mm group and 9 of the 13 patients (69.2 %) in the 3–4-mm group managed to reduce their AHI to less than 10/h. When the patients in the 0–2-mm group were classified according to the severity of their condition, 13 of the 17 (68.2 %) mild to moderate OSAS patients and 2 of the 5 (40 %) severe OSAS patients managed to reduce their AHI to less than 10/h. When the patients in the 3–4-mm group were classified according to the severity of their condition, nine of the ten (90 %) mild to moderate patients and none of the three (0 %) severe OSAS patients managed to reduce their AHI to less than 10/h (Table 1).

Evaluation of the degree of improvement

Of the 35 OSAS patients, 13 patients (37.1 %) achieved a complete response, 10 patients (28.6 %) achieved a partial response, 7 patients (20 %) displayed a weak response, and 4 patients (11.4 %) displayed no response. Among the 27 mild to moderate OSAS patients, 11 patients (40.7 %)

Table 1 Evaluation of the improvement rate from pre- to post- treatment. Of the 35 OSAS patients, 13 patients (37.1 %) achieved a complete response, 10 patients (28.6 %) achieved a partial response, 7 patients (20 %) displayed a weak response, and 4 patients (11.4 %) displayed no response

		AHI reduced to less than 10/h	Evaluation of improvement rate			
			Complete response	Partial response	Weak response	No response
Total	Total	24/35 (68.6 %)	13/35 (37.1 %)	10/35 (28.6 %)	7/35 (20.0 %)	4/35 (11.4 %)
	Mild to moderate	22/27 (81.5 %)	11/27 (40.7 %)	8/27 (29.6 %)	5/27 (18.5 %)	3/27 (11.1 %)
	Severe	2/8 (25 %)	2/8 (25.0 %)	2/8 (25.0 %)	4/8 (50.0 %)	0/8 (0.0 %)
In 0–2 mm connector group	Total	15/22 (68.2 %)	8/22 (36.4 %)	5/22 (22.7 %)	6/22 (27.3 %)	3/22 (13.6 %)
	Mild to moderate	13/17 (76.5 %)	8/22 (36.4 %)	5/22 (22.7 %)	3/22 (17.6 %)	3/22 (17.6 %)
	Severe	2/5 (40.0 %)	2/5 (40.0 %)	3/5 (60.0 %)	0/5 (0.0 %)	0/5 (0.0 %)
In 3–4 mm connector group	Total	9/13 (69.2 %)	5/13 (38.5 %)	5/13 (38.5 %)	3/13 (23.1 %)	0/15 (0.0 %)
	Mild to moderate	9/10 (90.0 %)	5/10 (40.0 %)	3/10 (30.0 %)	2/10 (20.0 %)	0/12 (0.0 %)
	Severe	0/3 (0.0 %)	0/3 (0.0 %)	2/3 (66.7 %)	1/3 (33.3 %)	0/3 (0.0 %)

achieved a complete response, 8 patients (29.6 %) achieved a partial response, 5 patients (18.5 %) displayed a weak response, and 3 patients displayed no response (11.1 %). Among the eight severe OSAS patients, two patients (25.0 %) achieved a complete response, two patients (25.0 %) achieved a partial response, and four patients (50 %) displayed a weak response. Among the 22 patients treated with a 0–2-mm connector, 8 patients (36.4 %) achieved a complete response, 5 patients (22.7 %) achieved a partial response, 6 patients (27.3 %) displayed a weak response, and 3patients (13.6 %) displayed no response. Among the 13 patients treated with a 3–4-mm connector, 5 patients (38.5 %) achieved a complete response, 5 patients (38.5 %) achieved a partial response, and 3 patients (23.1 %) displayed a weak response (Table 1).

Side effects

None of patients developed temporomandibular joint disorder or occlusal deviation. However, the treatment method was changed in eight cases because the apparatus connector was broken. The buccal mucosa of one patient was damaged.

Discussion

Following a review of the available literature, the American Sleep Disorders Association recommended that MRD are an appropriate therapeutic option for selected subjects: those with mild to moderate OSA, non-apneic snorers, and subjects who were unable to tolerate nasal continuous positive airway pressure [9]. When reducing the patient's AHI to less than 10/h was used as the post-treatment goal in previous reports, the mean reductions in AHI produced by the mandibular advancement devices being examined ranged from 37 % [10] to 75 % [11] with between 40 and 71 % of subjects achieving a post-treatment AHI of less than 10/h [9, 12, 13]. Both one- and two-piece appliances have been described in previous reports. Although there were no statistically significant differences in the efficacy of the two types of MAS, this may have been due to the small number of subjects involved and should be confirmed in a larger study [8]. In this report, the Silensor reduced the AHI to less than 10/h in 68.6 % of cases, which was similar to the results obtained in previous reports. In the clinical setting, semi-rigid MRD are thought to be mildly effective. One possible reason for this is that the airway at the base of the tongue is narrowed, when the mouth is kept open and the mandible is moved anteriorly using the Silensor (Fig. 4).

The side effects of oral devices included excessive xerostomia, temporomandibular joint pain, dental pain, myofacial pain, and occlusal changes [7]. Irreversible side effects should be viewed with suspicion. Furthermore, these side effects can sometimes lead to the cessation of MRD treatment. A total of nine patients reported side effects in this study. These included breakage of the connector in eight cases and damage to the buccal mucosa in one case. The breakage of the connector occurred frequently, especially in patients with bruxism or clenching. This was due to the fact that the connector was dynamically weak. On the other hand, the buccal mucosa was only damaged in one patient. This side effect was caused by a section of the connector that projected towards the buccal mucosa. In the future, modification of the device will be necessary to prevent such complications.

Although the Silensor was less effective in severe OSAS patients, it was highly effective in mild to moderate OSAS patients. Compared to the incidence of side effects during rigid MRD treatment, the Silensor is associated with a low rate of side effects. As a result, we conclude that the Silensor is suitable for the first phase of oral appliance treatment for OSAS.

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