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Biomimetic Oral Appliance Therapy in Adults with Severe Obstructive Sleep Apnea

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Abstract

Introduction: While Continuous Positive Airway Pressure (CPAP) is widely used to manage Obstructive Sleep Apnea (OSA), compliance can be problematic in some cases. These patients are often referred for Mandibular Advancement Devices (MADs) but there is less evidence of their efficacy in severe cases. We investigated the use of biomimetic oral appliance therapy (BOAT) to test the hypothesis that severe cases of OSA can be addressed using BOAT.

Materials and Methods: 15 consecutive adults aged >21 yrs with severe OSA that were unable to comply with CPAP according to a medical physician were treated using BOAT with or without primary mandibular advancement by a dentist with advanced training in dental sleep medicine. The mean Apnea-Hypopnea Index (AHI) of the sample was calculated prior to and after BOAT with no appliance in the mouth during the sleep studies. The findings were subjected to statistical analysis, using paired t-tests.

Results: Prior to treatment the mean AHI of the study sample was 45.9 hr^{-1} ± 10.5. A follow-up sleep study at 9.7 mos. ± 1.9 showed a 64% decrease in AHI to a mean value of 16.5 hr^{-1} ± 8.8 after BOAT ($p<0.01$) with no appliance in the mouth during the post-treatment sleep studies. Results for those without primary mandibular advancement were: 46.6 hr^{-1} ± 12.9 pre-treatment vs. 13.9 hr^{-1} ± 10.5 after BOAT ($p<0.01$); and for those treated with initial mandibular advancement: 45.2 hr^{-1} ± 8 pre-treatment vs. 19.5 hr^{-1} ± 6 after BOAT ($p<0.01$).

Conclusions: BOAT may be a useful method of managing severe cases of OSA in adults, and represents an alternative to CPAP and MADs. However, long-term follow up is needed to reach more definitive conclusions on these initial findings.

Keywords: Biomimetic; Oral appliance therapy

Introduction

Continuous Positive Airway Pressure (CPAP) is the treatment of choice in patients diagnosed with Obstructive Sleep Apnea (OSA). However, it is prone to intolerance, and compliance is typically less than optimal [1]. As an alternative, it was thought that mandibular advancement devices (MADs) would be an effective treatment in patients with mild to moderate OSA who have failed treatment with CPAP therapy. It was also assumed that MADs would not be as effective as CPAP, and that complications would not occur; but occlusal changes with MADs are more common than previously thought [2]. Despite these findings, MADs have become a common treatment for OSA, and their primary use is in patients with mild to moderate OSA. In fact, recent studies indicate that MADs are also effective in controlling OSA in patients with severe OSA [3]. In a study of adults intolerant to CPAP, the respiratory disturbance index (RDI) decreased by about 50% with a MAD in the patients' mouth during sleep [4]. But, the role of MADs in the treatment of severe OSA is still not well defined.

One study [5] investigated a thermoelastic MAD, and reported an increase in velopharyngeal airway size, as well as a reduction in the RDI, in patients with moderate to severe OSA when the device was worn while asleep at night. In view of these types of findings, the practice parameters of the American Academy of Sleep Medicine recommend MADs for mild to moderate cases of OSA, or for patients with severe OSA who are unable to tolerate or refuse treatment with CPAP [6]. However, other reports suggest that only 50% of the patients will be compliant with MAD therapy after about 3 years of use [7]. Therefore, we tested the hypothesis that severe cases of OSA can be addressed using biomimetic oral appliance therapy (BOAT; DNA appliance® system), which might mitigate long-term use and side effects of MADs, as no previous using this technique have been reported in the literature.

Methods and Samples

After obtaining informed consent, we included 15 consecutive adults that had been diagnosed with severe OSA following an overnight sleep study, but were unable to comply with CPAP according to a medical physician. The rights of the subjects were protected by following the Declaration of Helsinki. Inclusion criteria were: subjects

aged >21 yrs. diagnosed with severe OSA following an overnight sleep study that had been interpreted by a physician; documented failure/intolerance to CPAP therapy; good oral appliance compliance; no history of hospitalization for craniofacial trauma or surgery; no congenital craniofacial anomalies, and dentate upper and lower arches. The exclusion criteria included: age <21 yrs.; lack of oral appliance compliance; active periodontal disease; tooth loss during treatment; poor oral hygiene, and systemic bisphosphonate therapy. The study protocol (#121310) was reviewed and approved by the institution's review board.

Following a confirmed diagnosis of severe OSA by a medical physician, careful history-taking and craniofacial examination was undertaken for each subject by a dentist with advanced training in dental sleep medicine, and each subject was treated using BOAT. BOAT differs from the conventional MADs as it aims to remodel the upper airway through combined maxillo-mandibular correction with or without primary mandibular repositioning. Therefore, a bite registration was obtained in the upright-sitting position with the jaw posture corrected in the antero-posterior and vertical axes specific for each subject, using a sibilant phoneme registration protocol or 'phonetic bite' [8]. Upper and lower polyvinylsiloxane impressions were also obtained. The upper model was then mounted on an articulator and the lower model was mounted relative to the upper model, using the bite registration captured. Blinded to two investigators (SC and GDS), a biomimetic oral appliance without primary mandibular repositioning (Daytime-Nighttime Appliance: DNA appliance®; Figure 1) was prescribed for half of the study population (8 subjects).

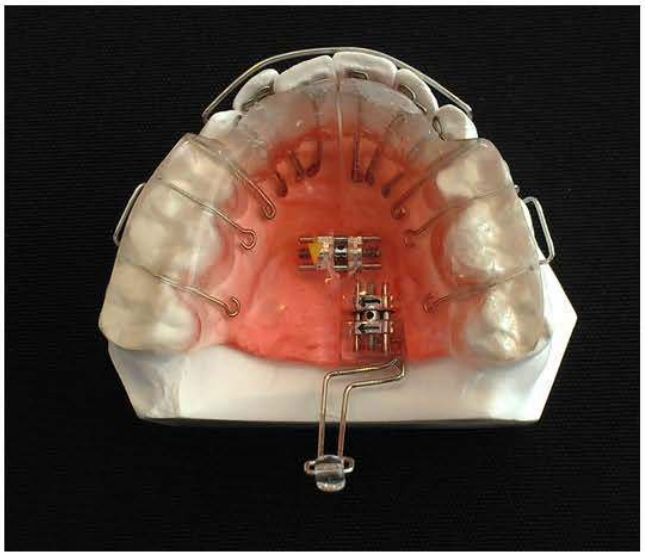

Figure 1: An upper biomimetic appliance (DNA appliance®) that was prescribed for the non-mandibular advancement half of the study population with: anterior 3D axial springs™, a beaded pharyngeal extension, a midline screw, bilateral occlusal coverage, retentive clasps, and a labial bow.

Blinded to two investigators (TG and GDS), a biomimetic oral appliance with mandibular repositioning (mandibular Repositioning Nighttime Appliance: mRNA appliance®; Figure 2) was prescribed for the other half of the sample (7 subjects). Therefore, all authors were blinded in terms of appliance allocation. BOAT is designed to address upper airway deficiencies and to correct maxillo-mandibular hypoplasia in both children and adults [9-17]. All biomimetic oral appliances used in this study had: 6 anterior 3-D axial springs™, a beaded pharyngeal extension, a midline screw, bilateral occlusal coverage, retentive clasps, and a labial bow (Figure 1), but only half of the biomimetic appliances incorporated a mandibular repositioning nighttime component (Figure 2).

Figure 2: The mandibular repositioning nighttime appliance (mRNA appliance®) that was prescribed for the other half of the sample with: anterior 3-D axial springs™, a midline screw, bilateral occlusal coverage, retentive clasps, a labial bow and a lower mandibular advancement component.

All subjects were instructed to wear the appliances during the evening and at nighttime (for approx. 12-16 hrs. in total), but not during the day time and not while eating, partly in line with the circadian rhythm of tooth eruption [18], although this only occurs in children. Proffit [19] notes that an appliance needs to be worn for at least 8 hrs. in the mouth to have a clinical effect. Written and verbal instructions were given to all subjects.

BOAT requires professional adjustments approximately every 4 weeks, and all subjects reported for review each month. At each monthly follow-up, examination for the progress of craniofacial correction was recorded. Adjustments to the devices were performed to optimize their efficacy. Only gentle pressures were transmitted to the teeth and surrounding tissues and the functionality of the devices was checked with the subject activating a mild force on biting. The subjects were encouraged to maintain their treatment protocol as outlined at the beginning of treatment. Development of the lower arch was implemented using a separate lower appliance (Figure 3) to permit arch re-coordination. A lower appliance (Figure 3) was implemented

between 1 to 3 months after the upper appliance unless the subject was wearing the biomimetic appliance design that incorporated the mandibular repositioning nighttime component at the outset (Figure 2). Every 3 months, the overnight sleep studies were repeated. The post treatment sleep tests were done with no appliance in the mouth and were interpreted by a medical physician. The mean apnea hypopnea index (AHI) of the study sample was calculated prior to and after BOAT, and the findings were subjected to statistical analysis, using paired t tests.

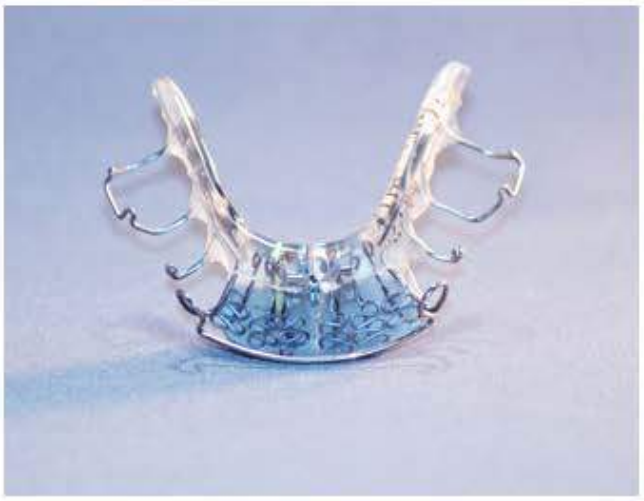

Figure 3: A lower biomimetic appliance (DNA appliance®) with anterior 3 D axial springs™, a midline screw, retentive clasps and a labial bow that was prescribed for the non mandibular advancement half of the study population.

Results

Of the total of 15 adults in this study (Table 1), 8 were treated without primary mandibular advancement (Table 1) and 7 were treated with initial mandibular advancement (Table 1). Prior to treatment the mean AHI of the total study subjects was 45.9 hr^{-1} ± 10.5 with no appliance in the mouth when the sleep studies were done. A follow up sleep study was done at a mean time interval of 9.7 mos. ± 1.9. At this time, the AHI decreased to a mean value of 16.5 hr^{-1} ± 8.8 ($p<0.001$) after BOAT with nothing in the mouth when the post treatment sleep studies were done. This finding represents a fall in the mean AHI by 64% for the total study sample.

For the subjects treated without primary mandibular advancement, there were 8 adults in this part of the study (Table 1). Prior to treatment the mean AHI of the subjects without primary mandibular advancement was 46.6 hr^{-1} ± 12.9. The final sleep study was done at a mean time interval of 10.4 mos. ± 2.6. At this time, the AHI decreased significantly ($p<0.001$) to a mean value of 13.9 hr^{-1} ± 10.5, which represents a fall in the mean AHI by 70% for this sample. Indeed, three subjects had an AHI of between 3 hr^{-1} to 5 hr^{-1} with no appliance in the mouth when the post treatment sleep studies were done.

For the subjects treated with primary mandibular advancement, there were 7 adults in this part of the study (Table 1). There was no statistical difference in the initial AHI between this group and those without primary mandibular advancement. Prior to treatment the mean AHI of these study subjects was 45.2 hr^{-1} ± 8. The final sleep study for this group was done after approximately 9 mos. At this time, the AHI decreased significantly ($p<0.001$) to a mean value of 19.5 hr^{-1} ± 6 after BOAT, which represents a fall in the mean AHI of 57% for this study sample. Therefore, it appears that the upper airway can be improved in adults with severe OSA by targeting craniofacial correction with or without primary mandibular advancement using BOAT.

	Total Sample				Non-mandibular advancement		Primary mandibular advancement	
	Pre AHI	Post AHI	Mths	Age	Pre AHI	Post AHI	Pre AHI	Post AHI
Mean	45.9	16.5	9.7	60.2	46.6	13.8	45.2	19.5
Std	10.5	8.8	1.9	5.6	12.9	10.5	7.9	5.9

Table 1: Summary of findings of subjects treated with BOAT with or without primary mandibular advancement. AHI: Apnea Hypopnea Index, Std: Standard deviation.

Discussion

Although , long term follow up using a larger sample size is needed to make more definitive conclusions on these initial findings, according to Guilleminault and Stoohs [20] there is a distinct interaction between craniofacial morphology and the upper airway, at least in pediatric patients. This present study suggests that combined maxillo mandibular, biomimetic oral appliance therapy (BOAT) with or without primary mandibular advancement may be a useful method of managing severe cases of OSA in adults, and may represent a viable alternative to CPAP and MAD therapy. Lettieri et al. [21] compared the efficacy of adjustable and fixed MADs for the treatment of OSA. About 37% of their sample had severe OSA (AHI ≥ 30) while sleeping with the device. With adjustable MADs the AHI was reduced to <5 hr^{-1} in about 57% cases compared to 47% with non adjustable appliances. For both devices, success was more common in patients with less than severe OSA. Therefore, the severity of AHI should be considered when selecting the type of MAD. But in our present study, no differences in outcome were found when comparing a biomimetic appliance with or without primary mandibular advancement. Presumably, BOAT permits correction of craniofacial components that might not be addressed with MADs alone. In that respect, it would be interesting to analyze the results of the sleep studies performed at 3 months and 6 months, in order to estimate the progress of their improvement, but not all patients were available for this detailed assessment. However, further studies to replicate these current findings, including patients with different disease severity, allowing stratification that might be correlated with the two treatment protocols, are being planned for the future.

Anandam et al. [22] evaluated long-term cardiovascular mortality in patients with severe OSA treated with either CPAP or MAD therapy. They reported that the residual AHI for MAD-treated patients was higher than a CPAP-treated group, but concluded that both CPAP and MAD may be effective therapies to reduce the risk of cardiovascular fatalities in patients with severe OSA. Although CPAP is regarded as the first option for patients with severe OSA, one study [23] investigated whether patients with severe OSA could use a MAD as an alternative treatment to CPAP. In that study, the AHI decreased with MAD use from 30.7 hr^{-1} to 13.2 hr^{-1}, and they concluded that MADs completely reduce sleep disordered breathing in selected patients with severe OSA. Note that for the subjects treated without primary mandibular advancement in our present study, the mean AHI decreased from 46.6 hr^{-1} to a 13.9 hr^{-1} ($p<0.001$), with no appliance in the mouth for this sample. Similarly, for the subjects treated with primary mandibular advancement in our study the mean AHI decreased from 45.2 hr^{-1} to 19.5 hr^{-1} ($p<0.001$) with no appliance in the mouth. Therefore, BOAT appears to correct sleep disordered breathing in subjects with severe OSA possibly using a different corrective mechanism than MADs, such as craniofacial correction and non-surgical, upper airway remodeling or "Pneumopedics". This pneumopedic notion is supported by preliminary work that indicates midfacial bone volume [12] and nasal cavity volume [9] increases in adults undergoing BOAT, as well as morphologic changes in the upper airway [10,13,17], which we refer to as upper airway remodeling or pneumopedics. Pneumopedics may be regarded as an epigenetic phenomenon in the sense that morphologic changes are elicited in craniofacial locations remote from the site(s) of genetic change [24], as predicted by the spatial matrix hypothesis [25].

Phillips et al. [26] compared health outcomes after 1 month of CPAP and MAD therapy in patients with moderate-severe OSA. They reported that while CPAP was more efficacious than MADs in reducing the AHI, compliance was higher with MADs. Surprisingly perhaps, neither treatment improved blood pressure, in contrast to sleepiness and quality of life for both treatments. It was therefore concluded that the similar effectiveness for both treatment modalities may be explained by the greater efficacy of CPAP being balanced by better compliance with MADs. Similarly, Lam et al. [27] assessed the efficacy of MADs in patients with severe OSA and hypertension at 3 months and 1 year intervals. It was found that MADs reduced systolic blood pressure in subjects with hypertension and OSA. In those subjects with retrognathia, MADs reduced the AHI from 47.5 hr^{-1} to 13.1 after 1 year. These AHI results are similar to those noted in our present study; however, although we did not assess blood pressure or hypertension in this present study, our post-treatment sleep studies were performed with no appliance in the mouth while sleeping. Nevertheless, these differences provide further premises for future studies using BOAT. In addition, Tegelberg et al. [28] evaluated the effects of MAD treatment on cognitive functions in patients with moderate-to-severe OSA. After 6 months of MAD treatment, cognitive functioning improved and the AHI decreased with 54% of the patients showing normal breathing during sleep while wearing the MAD. Nevertheless, both treatment modalities presumably represent life-long use if the health outcomes noted above are to be maintained. While we did investigate cognitive function in this current study, BOAT may provide a novel protocol of managing severe cases of OSA and its clinical sequelae in adults, and thus represent an alternative to CPAP and MADs.

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Effects of Biomimetic Oral Appliance Therapy on Epworth Scores in Adults with Obstructive Sleep Apnea

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Introduction: Biomimetic oral appliance therapy (BOAT) differs from conventional mandibular advancement devices (MADs) that are currently deployed for the management of mild and moderate cases of obstructive sleep apnea (OSA) in adults, as it attempts to avoid unwanted tooth movements, temporo-mandibular joint issues and undesired facial profile changes that may be associated with long-term MAD use. Indeed, BOAT aims to correct the upper airway through midfacial redevelopment followed by mandibular correction, which may resolve OSA in adults. In this investigation, we test the hypothesis that perceived daytime sleepiness in adults with mild to moderate OSA can be addressed without primary mandibular advancement using BOAT.

Methods: In this preliminary study, we included 13 consecutive adults aged > 21yrs. that had been diagnosed with mild to moderate OSA, following an overnight sleep study that had been interpreted by a board certified sleep physician. Prior to treatment each subject that participated in this pilot study completed an Epworth sleepiness scale (ESS) questionnaire. Each subject was treated by a dentist with advanced training in dental sleep medicine. At each monthly follow-up visit, examination for progress and adjustments of the devices were performed to optimize their efficacy. Post-treatment, each subject completed a follow-up ESS questionnaire. The mean ESS scores of the study sample was calculated prior to and after BOAT. The findings were subjected to statistical analysis, using paired t-tests.

Results: There were 7 females and 6 males that were included in this preliminary study. The mean age of the sample was 50 yrs. ± 12. Prior to treatment the mean ESS score of the study subjects was 8.2 ± 6. A further follow ESS questionnaire was done at a mean of 29.3 mos. ± 21.5 after BOAT. At this time, the mean ESS score decreased significantly ($p < 0.05$) to a value of 4.2 ± 3.6 after BOAT, which represents a fall in the mean ESS score by 51.4% for the study sample.

Conclusions: BOAT may be a useful method of managing adults with OSA who are seeking an alternative to long-term CPAP and MAD use. Although ESS is a discriminating test of daytime sleepiness, further data on specificity and sensitivity on these initial findings will be obtained using a larger sample size in long-term future studies.

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Facial enhancement using biomimetic oral appliance therapy in adults

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Abstract

Biomimetic oral appliance therapy (BOAT) has been shown to increase midfacial bone volume in adults non-surgically. This study tests the hypothesis that facial enhancement can also be achieved using BOAT. In this investigation, 12 adults underwent BOAT by a dentist with advanced training in BOAT. The following craniofacial parameters were measured on standardized lateral photographs; frontonasal angle; nasolabial angle; labiomental angle, and thyromandibular angle. The mean configurations were also subjected to statistical analyses, principal components analysis (PCA), and finite-element analysis (FEA). The results showed that the mean labiomental angle improved from 126.3˚ to 134.0˚ ($p<0.01$) and the mean thyromandibular angle improved from 126.5˚ to 118.6˚ ($p<0.01$). The mean, pre- and post-treatment craniofacial configurations, however, were not statistically different when tested using PCA ($p>0.05$), with the first two principal components accounting for approx. 70% of the total shape change. But, using FEA, the submandibular region showed a relative 32% decrease in size and the labiomental region also showed a 20% relative size-decrease. Therefore, this study supports the notion that BOAT may enhance facial appearance non-surgically in adults.

Introduction

Currently, much emphasis is being placed on understanding the process of human facial aging, and patients often request enhancement of their facial esthetics from dental personnel. For example, since loss of muscle tone and supportive fat promotes wrinkling and sagging of the skin, dermal filling agents for soft tissue augmentation have been used in the past [1]. But, individuals age at different rates, and these changes become apparent as wrinkles, accentuation of facial lines, laxity and dependency of the facial skin [2]. Thus, repeated applications of moisturizing creams, oils, and cosmetics may be helpful in hydrating the facial skin and improving its appearance, while chemosurgery (peeling) and dermabrasion may also reduce facial lines and wrinkles [3]. In addition, collagen implants may improve facial contours. However, the collagen later migrates into subcutaneous planes, which explains the loss of correction [4]. Alternatively, Botox (botulinum neurotoxin) may be used, but despite its ubiquity in cosmetic circles and broad general awareness, there is a dearth of studies on botulinum regarding facial cosmesis [5].

On the other hand, the non-Caucasian face has various unique attributes, including skin tone and subcutaneous fat content, and these differences may place a patient at increased risk of post-operative scarring and pigmentation. Therefore, it is important to discuss both surgical and non-surgical treatment options for rejuvenation of the non-Caucasian midface, including the periorbital region to meet a patient's expectations [6]. For example, Korean women prefer an ideal eyebrow of middle height with an arched shape [7]. In fact, from an Asian esthetic point of view, a soft facial appearance seems to be more attractive, especially in the gonial angle and mental region from the lateral view to obtain a more slender, oval face. Therefore, Li *et al.* [8] undertook a combination of surgical osteotomies to reshape the face to make it look more harmonious, particularly in the middle and lower one-third of the face. But, Asians increasingly seek non-surgical facial esthetic treatments, especially at younger ages. In addition, Asians differ from Caucasians in terms of attitudes to beauty, structural facial anatomy, as well as signs and rates of aging. Presumably, these treatment requests to improve facial shape reflect a desire to correct underlying facial structural deficiencies that detract from cultural ideals of facial beauty [9]. For example, Chinese women, who have a characteristic flattened facial contour prefer enhanced projection of the nose, including the nasal dorsum, nasal tip and columella [10].

As noted above, an improved understanding of the anatomy and physiology of the face provides a foundation for a more comprehensive approach to facial rejuvenation, using a holistic approach that considers the entire facial structural framework to provide more natural outcomes [11]. But, the associated phenomena that take place in the underlying bone of the facial skeleton are often overlooked. Skeletally, the maxilla changes its form due to remodeling in a downward direction over time. These bony changes result in a thinner upper lip and result in more tooth-show during smiling, due to an increase in vertical maxillary dimension [12]. The reduced maxillofacial bone volume results also in the deepening of the nasolabial grooves. Thus, retrusion of the facial skeleton below the soft tissue of the nasolabial fold causes the nasolabial fold to appear more prominent in both males and females [12]. Until more recently, some dental professionals have concerned themselves largely with facial development in children, while the esthetic concerns of adults have been somewhat neglected. Recently, however, an increased midfacial bone volume in adults

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treated with a non-surgical, biomimetic oral device was demonstrated [13]. Biomimetic oral appliance therapy (BOAT) was also shown to have beneficial effects in adults with mild, moderate and even severe obstructive sleep apnea [14,15]. But, in addition, this non-surgical, pain-free technique, which does not use drugs or injections, may have other effects, such as improving facial appearance. Therefore, the aim of this study is to test the hypothesis that facial enhancement can be achieved using BOAT in Korean adults.

Materials, methods and sample

After obtaining informed consent, 12 consecutive patients were recruited for this study (9 females; 3 males; mean age = 29 yrs ± 3). The rights of the subjects were protected by following the Declaration of Helsinki. Inclusion criteria were: adults over age 16yrs; good compliance; no history of hospitalization for craniofacial trauma or surgery; no congenital, craniofacial anomalies, and a fully-dentate upper arch. The exclusion criteria included: age <16 yrs; lack of compliance; active periodontal disease; tooth loss during treatment; poor oral hygiene, and systemic bisphosphonate therapy. After careful history-taking and craniofacial examination, standardized, pre-treatment lateral photographs were taken for subjects that met these criteria.

Following diagnostics, an upper, biomimetic oral appliance (DNA appliance®) was constructed specifically for each individual. This biomimetic device has 6 (patented) 3D axial springs and a labial bow (Figure 1). It includes a midline expansion screw that is advanced approx. 0.25 mm per week; a width, which is consistent with sutural homeostasis [16]. All subjects who underwent biomimetic oral appliance therapy (BOAT) were treated by a general dentist (KYK) with advanced training in this technique. All subjects were instructed to wear the appliance 12 to16hrs per day, starting in the late afternoon and throughout the night. The appliance was not worn during the day, and was removed for eating and cleaning.

All subjects reported for review each month. At each monthly follow-up, examination for the progress of midfacial development was recorded. Adjustments to the devices were performed to optimize their efficacy. The fitting surface acrylic/posterior border was adjusted gradually to permit palate to remodel inferiorly. The device was selectively equilibrated and the occlusal acrylic reduced to permit the lower teeth to track the occlusion. Only gentle pressures were transmitted to the teeth, and the functionality of the device was checked with the subject activating a mild force on biting. The subjects were encouraged to maintain their treatment regimen as outlined. Development of the lower arch was implemented using a lower biomimetic appliance to permit arch re-coordination. A lower appliance was implemented after 1-3 months, depending on the patient's progress. On completion of treatment, standardized, post-treatment lateral photographs were taken for all subjects.

Figure 1. A biomimetic, upper oral appliance (DNA appliance®) that was customized for each individual. This biomimetic device has 6 (patented) 3D axial springs and a labial bow.

Using appropriate software, 12 homologous landmarks (Table 1; Figure 2) were digitized on the pre- and post-treatment lateral photographs. The following mean craniofacial parameters were measured: frontonasal angle; nasolabial angle; labiomental angle, and thyromandibular angle. The measurement parameters are summarized in Figure 2. The findings were subjected to statistical analysis, using paired t-tests. In addition, the mean, pre- and post-treatment craniofacial configurations were computed using Procrustes superimposition. These configurations were subject to principal components analysis (PCA) and finite-element analysis (FEA).

Table 1. Definitions of homologous landmarks digitized on the pre- and post-treatment lateral photographs.

Landmark	Name	Definition
1	Submandibulare	Most concave point of the junction of the mandible with the neck
2	Soft pogonion	Most prominent point of the chin
3	Soft B point	Most concave point of the labiomental groove
4	Prolabiale inferior	Most prominent point of the lower lip
5	Oral commissure	Junction of the upper and lower lips at the corner of the mouth
6	Prolabiale superior	Most prominent point of the upper lip
7	Base of columella	Most concave point of the junction of the columella and the upper lip
8	Pronasale	Most prominent point on the tip of the nose
9	Soft tissue nasion	Most concave point of the frontonasal suture on the bridge of the nose
10	Soft tissue glabella	Most prominent point of the frontal bone on the forehead
11	Laryngeal prominence	Most prominent point of the thyroid cartilage in the neck

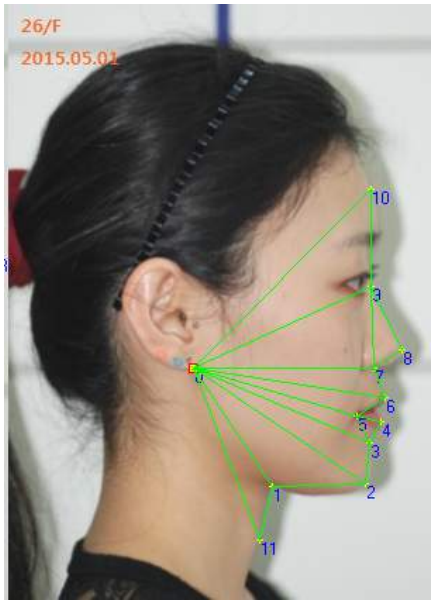

Figure 2. The craniofacial parameters that were measured in this study were:
Frontonasal angle: Angle between 10-9-8
Nasolabial angle: Angle between 8-7-6
Labiomental angle: Angle between 4-3-2
Thyromandibular angle: Angle between 2-1-11.

Results

The 12 adults that participated in this study had a mean age of 29 yrs ± 8. The mean treatment time was 11.2 mos. ± 7. Figure 3 shows the pre- and post-treatment facial features. Overall, the midface appears fuller with less pronounced labiomental and thyromandibular angles. The mean changes in the craniofacial parameters measured are summarized in Table 2. Specifically, the mean labiomental angle improved from 126.3° ± 11.3 to 134.0° ± 7.3 ($p<0.01$), and the mean thyromandibular angle improved from 126.6° ± 11.2 to 118.6° ± 14.3 ($p<0.05$).

The mean, pre- and post-treatment craniofacial configurations were not statistically different when tested using PCA ($p>0.05$), with the first two principal components accounting for approx. 70% of the total shape change (Figure 4). Using FEA, the submandibular region showed a relative 32% decrease in size (blue coloration, Figure 5). The direction of change was mostly horizontal (green coloration, Figure 6). The labiomental region also showed a 20% relative size-decrease (blue coloration, Figure 5).

Discussion

The popularity of cosmetic procedures for rejuvenating the face has undergone enormous growth over the past few years. However, pain and potential adverse events are challenges for patients undergoing surgical facelifts and other rejuvenating procedures. For example, patients being treated with calcium hydroxyapatite experienced increased pain, erythema, swelling, bruising and redness in the needle-treated side compared to using a blunt cannula [17]. Therefore, the current trend is away from surgical interventions and toward non-invasive cosmetic procedures. Non-invasive procedures for achieving a "non-surgical face-lift" include radiofrequency (RF) and infra-red light devices, which stimulate collagen production, as well as electro-stimulation of facial muscles. Taub [18] evaluated eye-lift and neck-lift achieved at 12 months, and concluded that an electrical, facial muscle-stimulating procedure yields significant improvements of the face and neck. In another study, RF in non-ablative skin tightening for skin

Figure 3. The pre- and post-treatment facial features of subjects that participated in this study. Note that the midface appears fuller with less pronounced labiomental and thyromandibular angles.

Table 2. The findings of craniofacial parameters measured in this study.

	Frontonasal angle		Nasolabial angle		Labiomental angle		Thyromandibular angle	
Subject	**Pre Tx**	**Post Tx**	**Pre Tx**	**Post Tx**	**Pre Tx**	**Post Tx**	**Pre Tx**	**Post Tx**
1	145.8	149.5	137.4	105.1	126.5	134.2	130	124.5
2	135.4	139.7	87.4	81.3	138.5	128.5	110.5	95.6
3	138.1	139.1	82.7	90.5	118.5	128	147.4	131.4
4	134.9	137.3	88.2	86.8	131.8	139	125.7	106.5
5	131.2	127.7	95.2	86.5	130.2	135.8	115.8	117.7
6	122	116.2	101.2	101.7	150.9	147.4	110.5	106.3
7	138.6	144.8	71.1	78.8	119	132.9	132	109.2
8	143.2	141.6	90.1	83.9	131.7	145.9	134.7	148
9	138	137.9	78.9	81.8	114.7	132.7	122.2	115.4
10	139.8	135.4	89.6	88.7	113.3	121.5	140.6	133.5
11	142.4	143.7	76	81.4	127.7	132.7	123.8	122.4
12	135.2	137.4	68.1	66.8	113.1	129.4	125.7	112.8
Mean	137	137.5	86.8	86.1	126.3	134	126.6	118.6
Std	5.9	8.2	12.6	10.1	11.3	7.3	11.2	14.3
P Value	NS		NS		**0.004**		**0.009**	

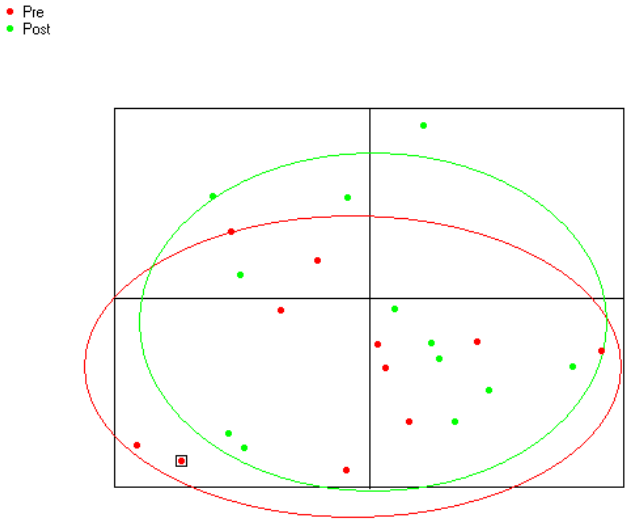

Figure 4. Principal components analysis, showing that the mean, pre- and post-treatment craniofacial configurations were not statistically different when tested using PCA ($p > 0.05$), with the first two principal components accounting for approx. 70% of the total shape change.

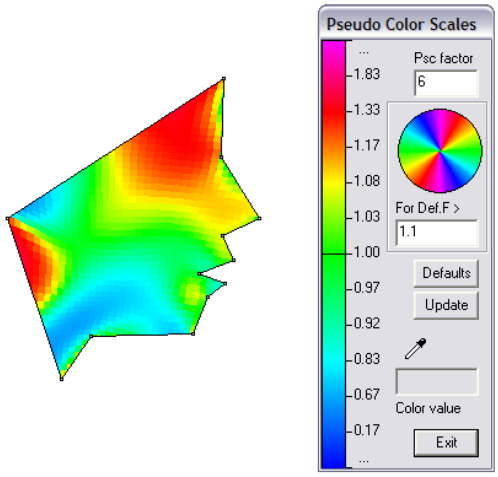

Figure 5. Using FEA, the submandibular region shows a relative 32% decrease in size (blue coloration). The labiomental region also shows a 20% relative decrease in size (blue coloration).

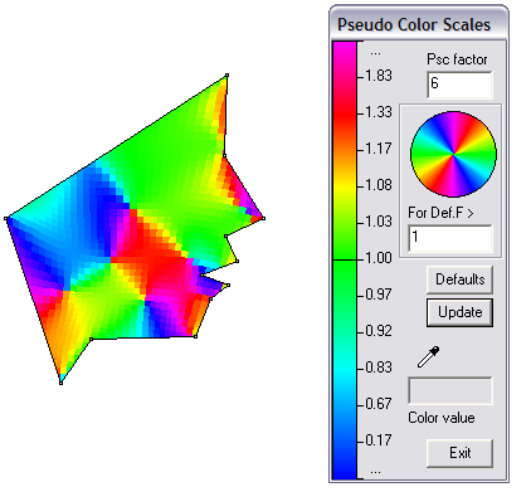

Figure 6. The direction of the facial change was mostly forwards in the horizontal axis, using the circular, pseudocolor scale (green coloration).

laxity was assessed in Asians. The investigators judged treatment of nasolabial folds, marionette lines, and sagging jowls. The RF treatment was found to be effective at the 6-month evaluation [19]. In this regard, the mean treatment time this present study was approx. 11 months, thus it is important for the clinician to help their patient understand and select the most appropriate rejuvenating treatment based on a variety of factors, such as timing, age, ethnicity, motivating factors, area to be addressed, and desired outcome [20].

Restoration of facial volume by surgically-redistributing the facial fat compartments may assuage the effects of ageing. But, research continues to suggest the importance of bony remodeling in facial aging [21]. The results of this particular study highlight the importance of skeletal remodeling in improving the soft-tissue contours of the face (Figure 3). Facial wrinkles, however, are not a single groove, but comprise a functional unit, which participates in facial functions responsible for expression, protection, and communication. Thus,

while wrinkles are related to increased muscle tone or contraction [22], the effect of BOAT appears to diminish the appearance of some facial contours, such as the labiomental groove, while enhancing others such as the thyromandibular angle.

Owsley [23] reported on the surgical correction of prominent nasolabial folds by undermining the malar fat pad and fixation by sutures. In contrast, the findings of this particular study suggest that improvements in the nasolabial folds can be also achieved non-surgically (Figure 3). The biomimetic oral device that was worn to promote an increase in midfacial bone volume also achieved overall facial enhancement (Figure 3). The biomimetic device widened the smile by remodeling the maxilla and likely increased maxillary volume [13]. Aging also affects the skin, the facial contour, the dentition and periodontium, the facial and masticatory muscles, the facial skeleton and the temporomandibular joints. Using this novel biomimetic device, however, dental professionals may be able to assist cosmetic/esthetic facial plastic surgeons and other cosmetology professionals by providing patients with a biomimetic appliance to wear overnight that aims to increase midfacial volume, and remodel the maxilla upward and outwards to prevent and retard the premature aging of the face. Indeed, the mean nasolabial angle improved from 86.7° ± 12.6 to 86.1° ± 10.1 in our study but marginally failed to reach statistical significance ($p=0.07$).

In addition to addressing the aging changes of the forehead, nose, eyes and cheeks, the natural progression of these endeavors are to understand aging of the lower one-third of the face and aging of the neck (24). In this present study, we found the mean labiomental angle improved from 126.3° ± 11.3 to 134.0° ± 7.3 ($p<0.01$). A relatively acute labiomental angle indicates not only a deep bite (which may be associated with temporo-mandibular joint issues) but also a retruded mandible. But mandibular retrognathia is associated with an increased risk of OSA (25). In addition, in our study the thyromandibular angle decreased from 126.6° ± 11.2 to 118.6° ± 14.3 ($p <0.01$). Lam *et al.* [26] showed that an increased thyromandibular angle is associated with an increased severity of OSA in both Asian and Caucasian subjects. Thus, we suggest that BOAT might not only be used for facial enhancement but also for the possible prevention of undiagnosed OSA. Therefore, further studies are planned to correlate 3D facial changes with the outcomes of overnight sleep studies to determine whether non-surgical facial enhancement can be used to prevent OSA in both children and adults.

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NON-SURGICAL UPPER AIRWAY REMODELING AS A TREATMENT FOR OBSTRUCTIVE SLEEP APNEA

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Introduction: Obstructive sleep apnea (OSA) is a sleep disorder that involves cessation or significant decrease in airflow in the presence of breathing effort during the sleep period. Commonly, long term therapy, such as continuous positive airway pressure (CPAP) and/or oral appliance therapy, such as mandibular advancement appliances, have been utilized as treatment. However, a recent form of treatment, biomimetic oral appliance therapy (BOAT), offers and alternative non-surgical method, which can putatively resolve OSA by combined maxilla-mandibular correction, and addressing craniofacial deficiencies. The aim of this study is to determine whether changes induced by BOAT produce a more favorable upper airway, which might result in a reduction in the severity of sleep disordered breathing.

Methods: After obtaining informed consent, five adults (1 male, 4 females; mean age 44.2 yrs. ± 9) diagnosed with mild to moderate OSA were started on treatment with FDA-cleared BOAT (mRNA appliance®). After 6 months of treatment, the apnea-hypopnea index (AHI), without the appliance in the mouth during sleep, of each study subject was reassessed by means of a home sleep study. (HST). The findings were analyzed by paired t-tests.

Results: The mean AHI for the sample prior to treatment was 18.5 hr ± 6.2. Following 6 months of BOAT, the mean AHI decreased significantly ($p = 0.015$) to 7.1 hr ± 4.2 with no appliance in the mouth when the follow-up HST was performed. Thus, a mean decrease in the AHI of 38% was achieved with no appliance in the mouth in the follow-up sleep study. These results are similar to BOAT findings reported elsewhere.

Conclusion: Biomimetic oral appliance therapy may provide a useful form of therapy for the resolution of OSA. While the mid-treatment results of this pilot study look promising, long term follow-up of this cohort, as well as further studies using larger sample sizes are warranted.

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Resolution of Pediatric Chronic Rhinitis using Biomimetic Oral Appliance Therapy: A Case Report

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Abstract

There are several methods of addressing chronic rhinitis (CR), including the use of various drugs and medications. However, other non-pharmacological methods of improving paranasal function have recently become available, such as balloon sinuplasty. This case report describes the resolution of CR in a 12 yr. old girl, using biomimetic oral appliance therapy (BOAT). In this case, treatment was completed over a period of 24 months. During this time, the patient showed less rhinorrhea, improved nasal breathing and regression of adenoidal hypertrophy. In addition, the patient's head posture, facial appearance and dental occlusion improved along with better sleep. Biomimetic oral appliance therapy may be beneficial in young patients with chronic rhinitis.

Keywords

Pediatric chronic rhinitis; Oral appliance therapy

Introduction

Common pathologies of the pediatric nasal and paranasal sinuses are typically inflammatory in nature. These diseases include acute and chronic rhinosinusitis, allergic rhinitis, and adenoidal hypertrophy. Chronic rhinosinusitis (CRS) can be defined as inflammation of the nasal and sinus mucosae for over 12 weeks. However, nasal obstruction can also cause disturbed facial growth. Therefore, descriptions of diseases of the nose and paranasal sinuses might also take midfacial growth into account [1].Chronic rhinitis (CR) is a common disorder and allergic rhinitis (AR) is a risk factor for CR [2]. It is known that AR is an allergen-driven, mucosal, inflammatory disease, which is modulated by immunoglobulin E (IgE). Clinically, pediatric and adult patients with AR present with sneezing, rhinorrhea, nasal itching, nasal congestion and postnasal drainage. The most effective drugs for the treatment of AR are antihistamines and topical glucocorticoids, including intra-nasal formulations, such as azelastine hydrochloride and fluticasone propionate [3]. But, despite the availability of several pharmaceutical options, relief of symptoms such as nasal obstruction is often limited, and local adverse reactions are not uncommon [4]. However, recently, Hopkins et al. [5] reported that over 60% of patients treated with balloon sinuplasty note subjective improvement in AR symptoms. On the other hand, Saunders et al. [6] reported that specific structural changes can occur in CRS. For example, adults with CRS are more likely to develop it on the side with a more laterally-positioned uncinate process. Thus, structural modulation of the nasal cavity might be an alternative method of addressing various nasal

diseases, including CR. Therefore, a case report of biomimetic oral appliance therapy (BOAT) to address a pediatric case of CR is presented.

Case Report

This case report refers to a 12 yr. old Korean female (Fig. 1) whose parents gave informed consent and signed a patient release form, and her rights were protected by the Declaration of Helsinki (1964). She initially presented to our dental office where a medical screening evaluation revealed a history of CR and rhinorrhea. Further history-taking discovered a history of mouth breathing; chronic, fever-like symptoms, and poor academic performance in school due to "brain fog".

Examination and Assessment

Physical and radiographic evaluations were undertaken, including facial and intra-oral photography, which revealed the following findings;

Long face phenotype (Fig. 1)
Forward head posture (Fig. 2) with counterclockwise rotation of the head (Fig. 2).
Anterior crowding of the maxillary teeth with mild torus palatinus and bilateral torus mandibularis (Figs. 3a and 3b).
Nasal obstruction (Fig. 4).
Adenoidal hypertrophy (Fig. 5).

Diagnosis

The working and differential diagnoses in this case included;

- Adenoid facies
- Class I malocclusion with anterior crossbite
- Maxillary hypoplasia
- Sleep bruxism
- Obstructive sleep apnea with hypersomnia

Therefore, a comprehensive treatment plan was formulated as noted below.

Treatment

The patient was advised to improve her sleep hygiene, including going to bed by 10pm. She was also instructed on keeping her lips closed as much as possible, particularly while at rest. In addition, nutritional counseling was implemented. Next, a biomimetic, upper appliance was prescribed (DNA appliance®, Fig. 6). This appliance system is designed to correct maxillo-mandibular development in both children and adults [7-13]. The patient was instructed to wear the device during the late afternoon after school, during the early evening and at nighttime during sleep (for approx. 12-16hrs. in total), but not during the day and not while eating, partly in line with the circadian rhythm of tooth eruption [14]. The patient reported for review every 4 weeks, approximately. At each monthly follow-up, examination for the progress of midfacial development was recorded. Adjustments to the device were also performed to optimize its efficacy. Only gentle pressures were transmitted to the teeth, and the functionality of the device was checked with the subject activating a mild force on biting. The patient was encouraged to maintain the protocol until the end of treatment.

Results

After 18 months of active treatment, the patient reported a resolution of CR and rhinorrhea, better nasal breathing, better sleep and no more "brain fog". In addition, she noticed an improved facial appearance and smile esthetics (Fig. 7). Therefore, after a further 12 months we found;

Improved facial phenotype (Fig. 7)
Improved head posture (Fig. 8)
Resolution of malocclusion and anterior crossbite (Figs. 9a and 9b)
Decreased nasal obstruction (Fig. 10), suggesting an improved upper airway.
Resolution of adenoidal hypertrophy (Fig. 11), suggesting an improved upper airway.

Discussion

Studies evaluating 2D cephalographs for the effects of rapid maxillary expansion (RPE) in actively-growing children report both a widening of the maxilla and the base of the nose, so that the nasal cavities are larger at the end of treatment [15]. However, during RPE the sutures that unite the two halves of the midface are split apart, and the process of bone fracture healing ensues. In contrast, the BOAT protocol used in this study maintained sutural integrity, whilst simultaneously producing craniofacial enhancement (Figs. 7-8). It is likely that BOAT promotes circum-maxillary sutural remodeling (induced midfacial morphogenesis) by inducing a biomolecular response that deploys the same physiologic mechanisms used in passively-growing adults, undergoing an osteogenetic-orthodontic protocol [16]. In osteogenetic-orthodontics, we suggest that the mechanisms of sutural homeostasis are evoked that produce an enhanced midfacial complex as evidenced by the growth of the nasal cavity in adults [17]. The changes in facial growth and development that BOAT putatively induces is a phenomenon that is in line with the spatial matrix hypothesis [18]. These changes in the functional space of the nasal cavity include dento-alveolar and midpalatal responses associated with a wider maxillary arch and a broader smile, which also enhances facial esthetics. Therefore, improved facial form (esthetics) and functional spaces (such as the nasal airway) are evident (Figs. 7-8 and 10-11). Thus, BOAT may be an alternative treatment choice for pediatric cases of CR. However, Evcimik et al. [19]noted that adenoidal hypertrophy may be associated with comorbid conditions, including sleep apnea and chronic sinusitis. Furthermore, these conditions are more common among children with allergic diseases. Han et al. [20] identified novel risk factors for the development of allergic rhinitis in Korean schoolchildren. On the other hand, Stenner [1] suggested that adenoids might actas a reservoir for recurrent infections of thenose and nasal sinus, and nearly 70% of children with rhinosinusitis benefit from adenoidectomy. Not surprisingly, Warman et al. [2] reported improvements in rhinitis secondary to adenoidectomy in children. In our study, we noted regression of adenoidal hypertrophy (Fig. 11) and this finding may have helped in the resolution of CR in this case. Therefore, further research is required to ascertain the relationship between CR and adenoidal hypertrophy, including the mechanism by which adenoidal hypertrophy is resolved.

Conclusion

Biomimetic oral appliance therapy may be considered in pediatric patients with chronic rhinitis.

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Figures

Figure 1

Figure 7

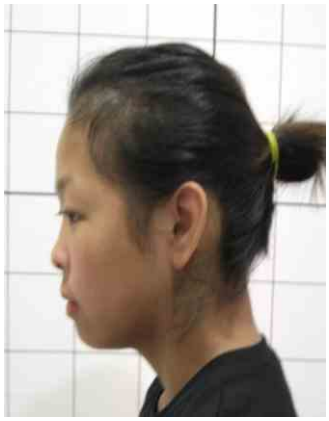

Figure 2

Figure 8

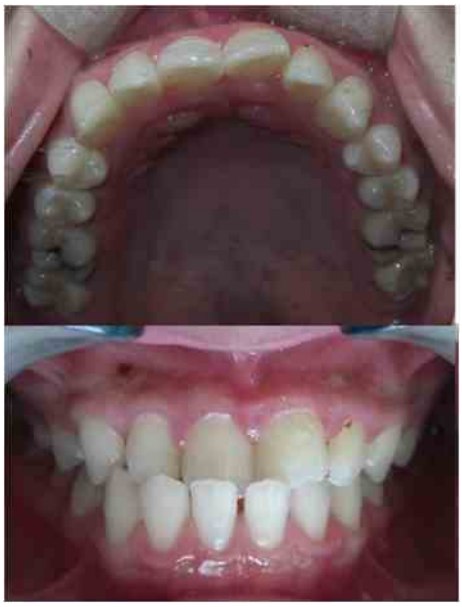

Figure 3a & 3b

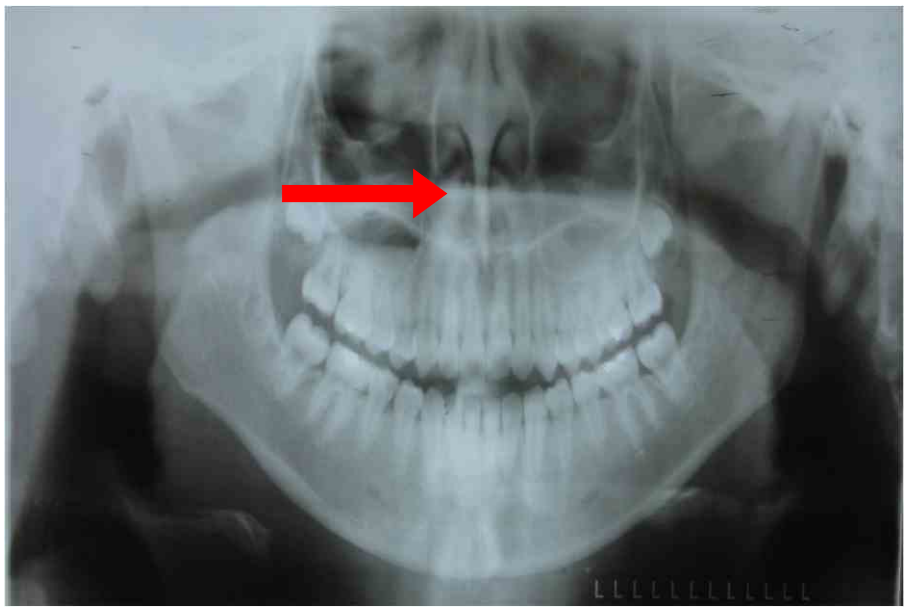

Figure 4

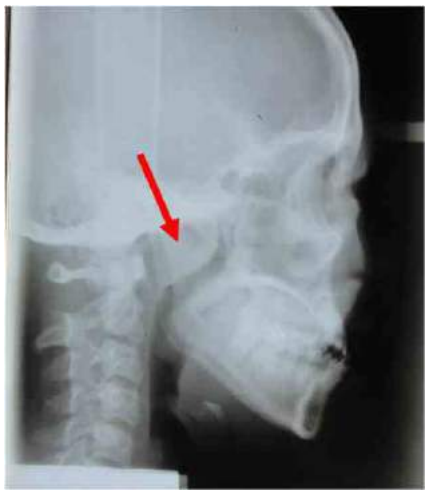

Figure 5

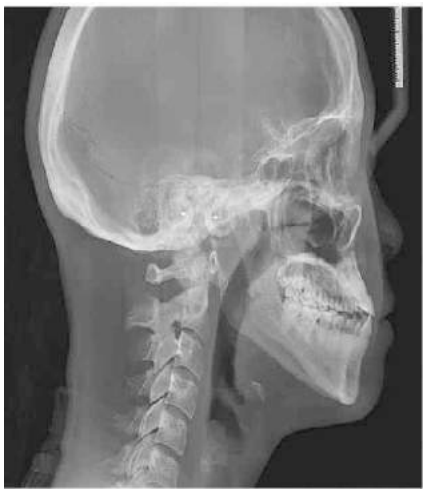

Figure 11

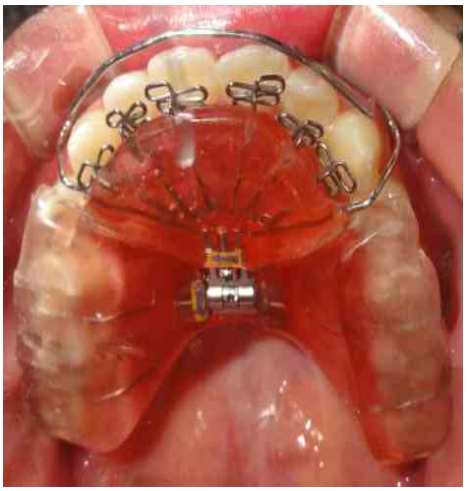

Figure 6

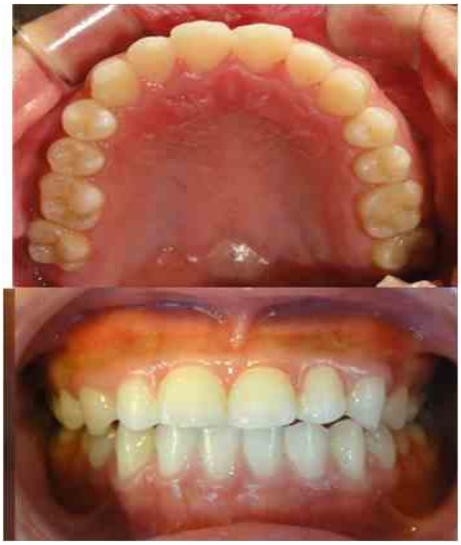

Figure 9a & 9b

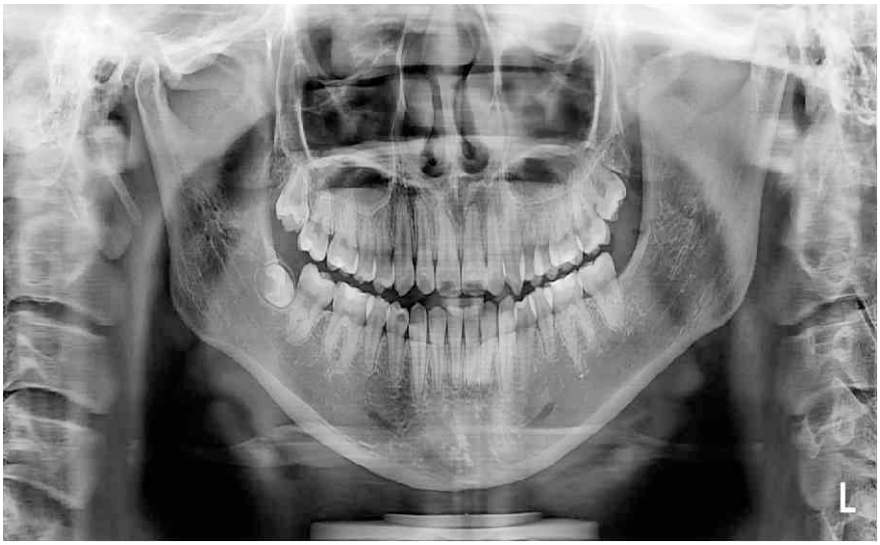

Figure 10

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