

Changes in respiratory and cardiac functions of patients with mandibular deficiency after treatment with a removable functional appliance

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Review Article

Abstract

BACKGROUND AND AIM: There is no study on respiratory or cardiac function of patients with mandibular deficiency before or after treatment. This preliminary trial was conducted for the first time to assess respiratory/cardiac parameters of such patients before and after treatment (compared to healthy controls) with a removable functional appliance.

METHODS: This before-after clinical trial was performed on 20 patients with class II division 1 malocclusion (mandibular deficiency with normal maxilla) and 20 matched control subjects at the peak of the mandibular growth spurt. Bionator removable functional appliance was used for 9 months to treat class II cases. Capnography and pulse oximetry were used to record respiratory parameters [end-tidal carbon dioxide pressure (PETCO₂), respiration rate (RR), oxygen saturation (SPO₂), and pulse rate (PR)]. Groups were compared using paired and unpaired t-tests ($\alpha = 0.05$).

RESULTS: Carbon dioxide (CO₂) and oxygen (O₂) did not change significantly after treatment ($P > 0.50$, paired t-test). However, RR and PR reduced significantly after the treatment ($P < 0.001$, paired t-test). CO₂ in healthy subjects was not different from pre-treatment or post-treatment values in class II patients ($P = 0.100$). O₂ in healthy subjects was not different from pre-treatment or post-treatment values in class II patients ($P = 0.200$, independent samples t-test). The RR in healthy controls differed from pre-treatment ($P < 0.001$) but not post-treatment values in class II patients ($P = 0.541$). The PR in the healthy controls differed marginally significantly from pre-treatment ($P = 0.067$) but not post-treatment values ($P = 0.752$).

CONCLUSION: In patients with mandibular deficiency, treatment with a Bionator functional appliance improves RR and PR back to normal levels. O₂ and CO₂ levels were not affected in class II patients.

KEYWORDS: Respiratory Function Tests; Heart Function Tests; Functional Appliance; Orthodontics; Corrective; Quality of Life

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Class II malocclusion is among the most common problems in orthodontics, and it is seen in about one third of the population. The most common diagnostic finding in patients with class II malocclusion is mandibular deficiency.¹ Functional appliance therapy is usually the first choice of treatment in patients with mandibular deficiency who are still in growth age.² Removable functional

appliances are used to treat this anomaly by creating a set of functions that encourage a new morphological pattern in skeletal and dental structures.^{3,4}

Class II skeletal discrepancy with mandibular deficiency is intended as a risk factor for disorders of the upper airway and oropharyngeal airway (OPA) deficiency.⁵ Computerized tomography (CT) studies indicate that the nasopharyngeal airway

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(NPA) volume in patients with mandibular retrognathia is significantly smaller compared to those with mandibular prognathism.⁶ Mandibular deficiency is observed in children and adolescents with a history of respiratory obstruction as well as in children with sleep apnea.⁷ Functional devices can increase the size of the OPA and create a forward posture in the mandible, hyoid bone, tongue, and soft palate.⁵ The morphological diversity of the airway space does not necessarily imply a greater respiratory efficacy or vice versa.⁸

Respiration consists of two components of oxygenation and ventilation. There are different methods of checking the status and pattern of respiration, including polysomnography (PSG) and capnography.^{9,10} Capnography is a non-invasive method which provides accurate measurements of the arterial pressure of carbon dioxide (PCO₂).⁹ In a capnograph device, the carbon dioxide (CO₂) concentration is determined by the infrared light detector. By increasing the concentration of CO₂, there will be an increase in the amount of infrared light absorption and the device will be able to measure the pressure of end-tidal CO₂ (PETCO₂). Several studies have shown that expiratory CO₂ pressure reflects PCO₂. Therefore, capnography can be regarded as a comprehensive assessment of respiratory function.^{9,11} There is no significant difference between PCO₂ and the PETCO₂.¹² Capnography can be used to detect respiratory depression or obstructive changes with high sensitivity.¹³ Pulse oximetry is mainly used to assess oxygenation. The pulse oximeter is equipped with a microprocessor that estimates the presence of hemoglobin saturated by oxygen (SPO₂) based on the absorption of light by oxyhemoglobin which is present in the vascular bed.¹⁴

Although anatomical airway alterations after functional therapy have been assessed in patients with mandibular deficiency,¹⁵⁻²⁰ to our knowledge, respiratory functions have not been assessed in such patients. Therefore, this preliminary before-after clinical trial was

conducted for the first time to compare the respiratory and cardiac functions in patients with mandibular deficiency before and after treatment with a removable functional appliance, and in comparison to a control group.

Methods

This preliminary before-after clinical trial was performed on 20 healthy subjects and 20 patients. The inclusion criteria were patients with class II division 1 malocclusion [mandibular deficiency with a normal maxilla, Frankfurt-mandibular plane angle (FMA) in the range of 20-25 degrees and more than 5 mm overjet],^{19,21} who were referred to private clinics in Ahvaz, Iran. All patients were at the peak of their mandibular growth spurt based on the cervical vertebral maturation (CVM) method (CS-3 to CS-4).²² Patients with a previous orthodontic treatment history, anterior open bite, severe proclination of the anterior teeth [incisor mandibular plane angle (IMPA) > 20], psychological disorder inhibiting cooperation, as well as systemic diseases that affect the general bone growth, craniofacial syndromes, and any respiratory problems were excluded from this study.^{19,21} The inclusion criteria for healthy subjects were matched in terms of demographics and growth phases (according to the CVM) with patients, but without skeletal anomalies of the jaws. The exclusion criteria for all subjects were the lack of any history of respiratory disease, history of asthma in subject's family, any recent acute respiratory disease, and any systemic disease. Protocol ethics were approved by the Ethics Committee of the Ahvaz Jundishapur University of Medical Sciences, in accordance with the Declaration of Helsinki (ethical code: IR.AJUMS.REC.94.643). An international reviewing body also approved the method [Iranian Registry of Clinical Trials (IRCT) code: IRCT20160927030014N2]. All subjects could leave the study even without giving any reason, and the treatment would be delivered to them freely anyway. All subjects

were briefed about the study and had signed written consent forms.

Functional appliance:^{19,23} In this study, the “Bionator” removable functional appliance was used. All devices were made by the same technician. Acrylic resin was spread on the surface of the anterior teeth to prevent the labial tipping of the anterior teeth. Single-step mandibular advancement was performed during the bite registration; it was comfortable for the patients and did not move the incisors past an edge-to-edge incisor relationship. The patients were advised to wear the appliance 24 hours/day (also during sleep), except when eating, doing exercise with the risk of injury, and while brushing their teeth. All the subjects were followed once every 4 weeks until the end of active appliance therapy. The appliance use was stopped when the excess overjet disappeared.

Capnography and pulse oximetry:⁹ The parameters were measured before the commencement of treatment at T0 and after treatment (about 9 months later) at T1; they were also measured in healthy controls. The capnograph device measures the PETCO₂ and reports the output with percentage. The PETCO₂ of the subjects was recorded by a capnograph device (Viamed, VM-2500-S Sidestream Capnograph, England). Patients were placed in an upright position on the dental chair and an oxygen (O₂) mask was placed on their face. After a few moments, when patients became used to the mask, the PETCO₂ and respiration rate (RR) were recorded for 6 minutes. The device was calibrated for each subject, prior to the recording of the data. The patients were

asked to breathe normally through the mouth and nose during the recording of data, without any speaking and movement. The SPO₂ and pulse rate (PR) were recorded simultaneously, using a pulse oximeter probe on the index finger. Patients who had been absent for more than two appointments (once every 4 weeks) and did not cooperate properly were excluded.

Sample size and statistical analysis: The sample size was calculated based on the standard deviation (SD) of a previous study²⁴ regarding Bionator effects on skeletal and dental components (SD = 2.19) and a d = 1.5 as 22 patients in order to provide powers above 90%. Two patients were later dropped out, making the number of patients 20; and a similar number of healthy subjects was enrolled as well.

Descriptive statistics and 95% confidence intervals (CIs) were calculated for all parameters. The normality of groups was confirmed using Kolmogorov-Smirnov test (K-S test). To compare the parameters before and after the treatment, paired t-test of SPSS software (version 25, IBM Corporation, Armonk, NY, USA) were used. Pre- and post-treatment parameters were compared with the control (healthy) subjects using independent samples t-test. The level of significance was set at 0.05.

Results

Patient flow is illustrated in figure 1. Patients' mean age was 10.0 ± 0.4 years. There were 10 boys and 10 girls in class II patients; also there were 10 boys and 10 girls in controls.

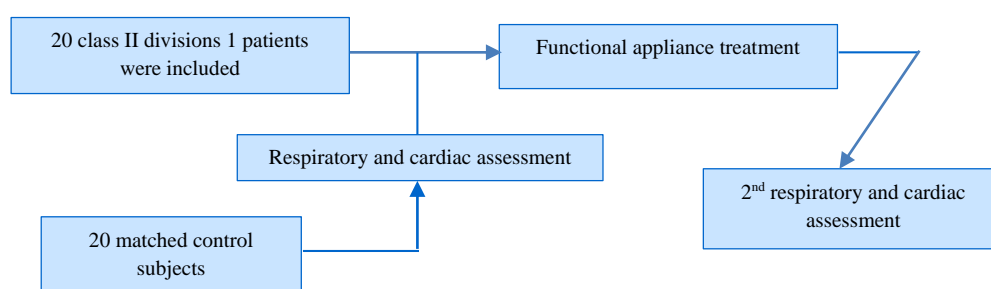


Figure 1. Flowchart of patient inclusion and assessment

Table 1. Descriptive statistics and 95% confidence intervals (CIs) for all measurements

| | Parameter | Mean \pm SD | 95% CI | Minimum | Q1 | Median | Q3 | Maximum |
|----------------|-----------------------|-------------------|-------------|---------|-------|--------|--------|---------|
| Baseline | ETCO ₂ (%) | 4.51 \pm 0.41 | 4.32-4.70 | 3.88 | 4.12 | 4.51 | 4.88 | 5.17 |
| | RR (per minute) | 20.98 \pm 1.60 | 20.24-21.73 | 18.69 | 19.82 | 20.18 | 22.54 | 23.74 |
| | SPO ₂ (%) | 97.14 \pm 1.11 | 96.62-97.66 | 94.21 | 96.47 | 97.43 | 97.85 | 98.92 |
| Post-treatment | PR (per minute) | 95.48 \pm 6.52 | 92.43-98.53 | 83.11 | 90.87 | 95.65 | 100.60 | 107.40 |
| | ETCO ₂ (%) | 4.45 \pm 0.39 | 4.27-4.63 | 3.91 | 4.05 | 4.55 | 4.70 | 5.10 |
| | RR (per minute) | 16.95 \pm 1.51 | 16.25-17.66 | 14.85 | 16.03 | 16.81 | 17.94 | 20.09 |
| Control | SPO ₂ (%) | 97.29 \pm 1.20 | 96.73-97.86 | 94.63 | 96.78 | 97.39 | 98.32 | 99.00 |
| | PR (per minute) | 88.32 \pm 7.44 | 84.84-91.80 | 77.13 | 80.98 | 87.77 | 95.28 | 100.80 |
| | ETCO ₂ (%) | 4.33 \pm 0.38 | 4.15-4.51 | 3.89 | 4.02 | 4.20 | 4.65 | 5.06 |
| | RR (per minute) | 16.66 \pm 1.48 | 15.97-17.36 | 14.02 | 15.56 | 16.78 | 17.36 | 19.70 |
| | SPO ₂ (%) | 96.90 \pm 1.22 | 96.33-97.46 | 95.09 | 95.99 | 96.87 | 98.10 | 98.88 |
| | PR (per minute) | 89.38 \pm 12.91 | 83.34-95.42 | 69.15 | 79.79 | 89.67 | 100.00 | 118.30 |

SD: Standard deviation; CI: Confidence interval; Q1: First quartile; Q3: Third quartile; ETCO₂: End-tidal carbon dioxide; RR: Respiration rate; PR: Pulse rate; SPO₂: Oxygen saturation

Their body mass index (BMI) was normal (20%-70%). The paired t-test showed that levels of CO₂ and O₂ did not change significantly after treatment (P for CO₂ = 0.616, P for O₂ = 0.698) (Table 1). However, RR and PR reduced significantly after the treatment (both P < 0.001) (Table 1). Levels of CO₂ in healthy subjects (Table 1) were not different from pre-treatment (unpaired t-test, P = 0.160) or post-treatment (P = 0.347) values in class II patients. Similarly, levels of O₂ in healthy subjects were not different from pre-treatment (P = 0.514) or post-treatment (P = 0.304) values in class II patients. The RR in healthy controls differed from pre-treatment (P < 0.001) but not post-treatment (P = 0.541) values in class II patients. The PR in the healthy controls differed marginally significantly from pre-treatment (P = 0.067) but not post-treatment (P = 0.752) values in class II patients (Tables 1 and 2) (Figure 2).

Discussion

Since there was no previous study in this

regard, we are limited to discussing more general aspects. The normal values of end-tidal CO₂ (ETCO₂), SPO₂, RR, and PR are 4%-6%, 96%-98%, 12-20 per minute, and 60-100 per minute, respectively.^{25,26} There was no significant change in the levels of ETCO₂ and SPO₂ before and after treatment. This finding showed that patients with mandibular deficiency could compensate for their anatomical airway deficiencies by other measures such as increasing their RRs, and therefore, the amounts of CO₂ and O₂ gases in patients with mandibular deficiency are at a desirable level compared to the normal value, and mandibular deficiency does not reduce the blood levels of these gases. Also, patients are capable of maintaining a proper concentration of these gases in the blood. The other parameter was RR, which showed a significant change in pre-treatment compared to post-treatment. This may be due to the fact that in patients with mandibular deficiency, the RR increases as a compensation to provide desirable levels of CO₂ and O₂.

Table 2. Comparison of means in different groups using paired t-test between pre- and post-treatment and using unpaired t-test between healthy controls and either of pre- or post-treatment

| Parameter | Baseline | Post-treatment | P | Baseline | Control | P | Post-treatment | Control | P |
|-----------------------|----------|----------------|---------|----------|---------|---------|----------------|---------|-------|
| ETCO ₂ (%) | 4.51 | 4.45 | 0.616 | 4.51 | 4.33 | 0.160 | 4.45 | 4.33 | 0.347 |
| RR (per minute) | 20.98 | 16.95 | < 0.001 | 20.98 | 16.66 | < 0.001 | 16.95 | 16.66 | 0.541 |
| SPO ₂ (%) | 97.14 | 97.29 | 0.698 | 97.14 | 96.90 | 0.514 | 97.29 | 96.90 | 0.304 |
| PR (per minute) | 95.48 | 88.32 | < 0.001 | 95.48 | 89.38 | 0.067 | 88.32 | 89.38 | 0.752 |

ETCO₂: End-tidal carbon dioxide; RR: Respiration rate; PR: Pulse rate; SPO₂: Oxygen saturation

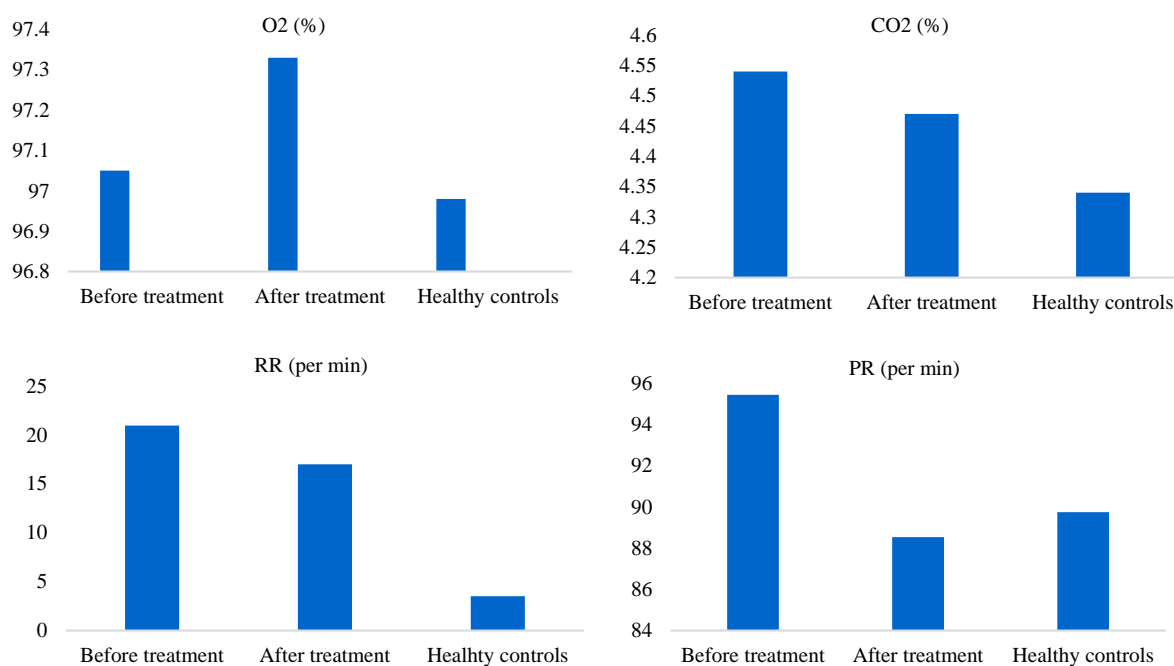


Figure 2. Means and standard deviations (SDs) of all parameters in all groups

After treatment with functional appliances, patients present a more normal respiratory pattern; hence, they are able to maintain a favorable concentration of respiratory gases in the blood with lower RRs. In this study, ETCO₂ was measured by means of an O₂ mask (as a non-aggressive method) which caused the dilution of exhaled air with ambient air and consequently reduced the values of the parameter compared to the standard method. However, since this method was used for all subjects, the results are reliable. Another parameter that was evaluated in our study was PR, which showed a significant reduction after treatment. This could indicate that the cardiovascular system would be able to preserve hemostatic, physiological, and metabolic conditions with the lower heart rate and regulate the level of respiratory gases. Of course, the physiological and hemostatic control and respiratory pattern is a complex subject, with many involved factors. In the present study, the changes were assessed before and after treatment in each patient to reduce the role of the confounding factor. Also, the changes that

occurred were more likely as a result of the functional treatment. Swift et al. showed that breathing through the nose could increase blood circulation, O₂ and CO₂ levels, reduce the rate of respiration, improve the overall volume of the lung, and increase the resistance twice as much as oral respiration.²⁷ The pattern of changes in O₂, CO₂, and RR parameters was similar to our study. Such evidence suggests that functional devices can change the breathing pattern from the mouth to the nose, by reducing airway resistance. It seems reasonable to think that mandibular advancement with functional appliance has a positive effect on the upper airway.²² Several studies have reported the increase in airway dimensions by treatment with functional devices¹⁵⁻¹⁸ and several studies have shown that changes in the dimensions of the pharyngeal airways remain in the long term.^{19,20} Of course, the morphological variation of airway space does not necessarily imply more respiratory function or vice versa. This matter emphasizes the need for such studies that measure respiratory function and blood gas levels after treatment with a functional appliance. Other treatments

such as rhinoplasty have been shown to alter respiratory efficacy.^{28,29}

This preliminary clinical trial was limited by some factors. Although we recruited a group of positive controls (healthy subjects), it was better to also include a group of negative controls (class II patients who were not treated at the same age) to assess whether growth plays any role in improvement of respiratory parameters or not. However, it was not ethical to keep class II patients untreated for the sake of a research. Besides, studies on airway dimensions already suggest that this improvement we observed could be due to effects of the Bionator functional device.¹⁵⁻²⁰ Still, randomized clinical trials (RCTs) are needed to verify our results; however, they would as well face the ethical problem of involving class II patients needing treatment without treating them. As advantages, this study was the first one in the field with a sample size predetermined based on power

calculations. Besides the routine before-after design, we also recruited healthy subjects to confirm our results with a greater reliability.

Conclusion

Treatment with a functional Bionator appliance might improve RR and PR in patients with mandibular deficiency back to normal levels. Blood O₂ and CO₂ of patients with mandibular deficiency do not differ from those of healthy subjects, even before treatment.

Conflict of Interests

Authors have no conflict of interest.

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