RESEARCH ARTICLE

THE TREATMENT EFFECTS OF THE COMBINED APPROACH: BRACES WITH PREFABRICATED MYOFUNCTIONAL APPLIANCE FOR GROWING CLASS II PATIENT

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Abstract

Objective: To evaluate the effect of combined treatment approach: braces with myofunctional appliance (trainer-T4B) on dentoalveolar, sagittal and vertical skeletal level in growing individuals with Skeletal and Dental Class II.

Methods: Twenty teenagers with permanent dentition were treated with fixed appliance-braces in combination with myofunctional appliance (trainer-T4B). All patient completed the treatment with occlusal Class I molar relationship. The patients made initial and final profile X-rays with cephalometric analysis. The evaluation of the treatment effects was made by comparing the initial and the final cephalometric analysis.

Results: Significant sagittal skeletal changes were observed on all sagittal skeletal parameters, except for SNA°. A high positive association was found between the ANB angle change and Wits change. The changes in the rest of the vertical skeletal measurements were significant for two, including SN-M° and Go°. The dentoalveolar measurements showed significant changes in all parameters, except for i/M° where the change was marginally significant.

Conclusion: The chosen treatment approach was effective for growing skeletal and dental Class II patients with permanent dentition.

Introduction:

The Class II malocclusions are one of the most common orthodontic diagnosis in the everyday orthodontic practice. The diagnosis of Class II malocclusion consists of different skeletal and dentoalveolar configuration¹. McNamara² stated that most Class II patient present a deficiency in the anteroposterior position of the mandible. One of the preferred treatment options for Class II growing patients with mandibular deficiency is functional orthodontic appliances³. Several types of these functional appliances are currently in use for Class II correction in growing individuals. One of their contemporary variations are prefabricated myofunctional appliances⁴. There main effects are: increase of mandibular growth, improvement of sagittal skeletal and dental relationship, altering the muscles balance etc.

Numerous studies discuss effectiveness of treatment with functional appliances on skeletal and dentoalveolar level⁵. Some of them introduce their mode of action in the treatment of Class II malocclusions, other mention their ability to correct disfunctions that may have caused disturbance of the facial development. But with these appliances were notable to control precisely the movements of each tooth⁶. Braces, as mechanically acting fixed appliances,
provide optimal leveling and alignment of the teeth in the dental arches. Thus, it has been a trend to combine a two-phase system to obtain the best of functional and fixed appliance treatment modalities. The simultaneous application of the two treatment appliances in single-phase treatment aims optimal alignment of the teeth, while achieving balanced occlusal contacts.

The purpose of this research was to evaluate by cephalometric analysis the possible effects of the combined treatment with: braces and myofunctional appliance on the skeletal and dentoalveolar components in patients with Class II malocclusion.

Materials and Methods:
The study observed twenty-five Skeletal Class II patients with ANB angle values greater than 4° and Dental Class II. They all underwent orthodontic treatment with the following treatment protocol: initial leveling of the upper dental arch with braces, adjusting the trainer T4B (Myobrace®, Myofunctional Research Co, Australia) (Fig. 1) on 0.016” NiTi archwire and three months later leveling of the lower dental arch with braces. Among them, nine were male (45%) and eleven (55%) female. The patients’ age ranged between 10 and 20 years, with a mean age of 13.80±2.98 years. The patients had no previous orthodontic treatment. They were observed until completion of the treatment with Dental Class I.

The 40 lateral cephalograms were analyzed with AudaxCeph® software. The cephalometric measurements are shown in Figure 2.

Statistical Analysis:
The data was analyzed with the statistical software IBM SPSS version 26 (2018) and Minitab version 19 (2019). Continuously measured and normally distributed variables were described through the mean values and standard deviations (±SD). Categorical data was processed in frequencies and percentages. A paired-samples t-test was used to compare the cephalometric measurements before and after the treatment. Pearson product moment correlation and single linear regression were performed to examine the relationship between the change in the ANB angle, Wits values and the SNB angle. Proportions were compared through Fisher’s exact test. All p-values were two-tailed and interpreted as follows: p < 0.05 a significant trend (*); p < 0.01 a strong significant trend (**); p < 0.001 a very strong significant trend (***)
Figure 2: Cephalometric analysis of the initial and final profile X-rays, and the superimposition between both analyses.

Results:
Sagittal skeletal changes:
Sagittal skeletal changes were assessed through paired comparisons of the cephalometric data before and after the treatment (Table 1). Significant changes were observed on all parameters (p < 0.001), except SNA° (p = 0.258).

Table 1: Paired comparisons of sagittal skeletal parameters before and after the treatment.

| Measurement   | Mean±SD | Difference | Mean±SD | Minimum-Maximum | p   |
|---------------|---------|------------|---------|-----------------|-----|
| SNA° before   | 81.20±2.54 | -0.200±0.76 | -2.00 to 1.00 | 0.258           |
| SNA° after    | 81.00±2.61 | -0.200±0.76 | -2.00 to 1.00 | 0.258           |
| SNB° before   | 75.15±3.31 | 1.85±1.14  | 0.00 to 5.00 | 0.000***        |
| SNB° after    | 77.00±3.35 | 1.85±1.14  | 0.00 to 5.00 | 0.000***        |
| ANB° before   | 6.05±1.39  |            |         |                 |     |
| Parameter          | Before       | After        | Difference     | p-Value      |
|--------------------|--------------|--------------|----------------|--------------|
| ANB° after         | 4.05±1.53    | -2.00±1.14   | -5.00 to -1.00 | 0.000***     |
| SNPg° before       | 76.40±3.87   |              |                |              |
| SNPg° after        | 77.90±4.11   | 1.50±1.46    | 0.00 to 1.50   | 0.000***     |
| Wits (mm) before   | 4.50±1.93    |              |                |              |
| Wits (mm) after    | 1.95±0.95    | -2.55±2.52   | -10.00 to 1.00 | 0.000***     |

* - Significant at p < 0.05; ** - Significant at p ≤ 0.01; *** - Significant at p < 0.001

**Figure 3** illustrates the individual and mean sagittal skeletal differences established at the end of the treatment. The mean SNA angle decreased by 0.200±0.76° after the treatment, from 81.20±2.54° to 81.00±2.61°, but the observed decrease was not significant (p = 0.258). The plot of the individual values of the difference in SNA° shows that the majority of the patients (N = 14), constituting 70% of the whole group did not have a change in SNA°, two (10%) had an increase of 1°, and four (20%) had a decrease by 1° or 2°.

The mean SNB angle increased from 75.15±3.31° to 77±3.35°, with a mean difference of 1.85±1.10° (p < 0.001). The individual values of the difference varied between 0° and 5°, with an increase in SNB° in nineteen patients (95%) and a zero change in one patient (5%).

The mean ANB angle decreased by 2.00±1.14°, from 6.05±1.39° to 4.05±1.53° (p < 0.001). A decrease was observed in all patients (100%) with values varying between -5° to -1°.

The mean SNPg° angle increased from 76.40±3.87° to 77.90±4.11°, with a mean difference of 1.50±1.46° (p < 0.001). The individual values of the difference in SNPg° varied between 0° and 1.50°. SNPg° values increased in fourteen of the patients (70%) and did not change in six patients (30%).

The Wits mean of 4.50±1.93mm before the treatment decreased to 1.95±0.95mm after the treatment, with a mean difference of 2.55±2.52mm (p < 0.001). The individual changes in Wits varied between -10mm to 1mm with the following distribution: Seventeen patients (85%) had a decrease in their initial Wits values, in two patients (10%) Wits increased by 1mm and in one patient (0%) there was no change.

Figure 3:- Individual and mean values of the difference in sagittal skeletal parameters before and after the treatment.

We examined the relationship of the change in the ANB angle with the change in Wits values and the SNB angle through Pearson product moment correlation and single linear regression analysis (Fig. 4). A high positive association was found between the ANB angle change and Wits change, r = 0.517, 95% CI: 0.397 to 0.781, p = 0.02 (panel A). According to the R-square, 26.74% of the change in Wits could be accounted for by the change in the
ANB angle (R-square adj = 22.67\%) with the following prediction equation: Wits (dif) = -0.319 + 1.115 ANB° (dif). The ANB angle change showed a very high negative association with the SNB angle change, \( r = -0.752, 95\% \text{ CI: } -0.896 \text{ to } -0.464, p < 0.001 \) (panel B). SNB° change could be accounted for by the change in the ANB° angle up to 56.6\% (R-square adj = 54.1\%) by the equation: SNB° (dif) = 0.3885 – 0.7308 ANB° (dif).

*** - Significant at \( p < 0.001 \)

**Figure 4:**- Panel A: A significant positive association between the change in ANB° and the change in Wits. Panel B: A significant negative association between the change in ANB° and the change in SNB

**Vertical skeletal changes:**
The changes in the vertical measurements before and after the treatment are summarized in Table 2. Significant changes were observed on two of the parameters, including SN-M° (\( p = 0.010 \)) and Go° (\( p = 0.019 \)).

**Table 2:**- Paired comparisons of vertical skeletal parameters before and after the treatment.

| Measurement | Mean±SD | Difference Mean±SD | Minimum-Maximum | p   |
|-------------|---------|---------------------|------------------|-----|
| SN-M° before | 31.70±5.01 | -0.60±0.94 | -2.00 to 1.00 | 0.010** |
| SN-M° after  | 31.10±5.03 |                   |                  |     |
| SN-FH° before| 8.20±1.88 | 0.40±0.99 | -2.00 to 3.00 | 0.088 |
| SN-FH° after | 8.60±2.23 |                   |                  |     |
| SN-SpP° before | 10.05±3.05 | 0.50±1.14 | -1.00 to 3.00 | 0.066 |
| SN-SpP° after | 10.55±3.20 |                   |                  |     |
| SpP-M° before | 21.45±4.61 | -0.25±2.91 | -3.00 to 11.00 | 0.706 |
| SpP-M° after  | 21.20±4.96 |                   |                  |     |
| Go° before    | 121.45±5.38 | -0.35±2.70 | -5.00 to 5.00 | 0.019* |
| Go° after     | 121.10±4.75 |                   |                  |     |
| PFH/AFH before | 66.70±3.85 |                   |                  |     |
The individual and mean vertical skeletal differences are illustrated on Figure 5. The mean SN-M° value decreased by 0.60±0.76° after the treatment, from 31.70±5.01° to 31.10±5.03° with significant difference (p = 0.010). The plot of the individual values of the difference in SN-M° shows a decrease by 1 or 2° in twelve patients (60%), an increase by 1° in three patients (15%) and no change in five patients (25%).

The mean SN-FH° value increased from 8.20±1.88° to 8.60±2.23°, but the mean difference of 0.40±0.99° was not significant (p = 0.088). Nine patients (45%) had no change in SN-FH°, nine patients (45%) had an increase and two patients (10%) had a decrease in SN-FH° after the treatment.

The mean SN-SpP° value increased by 0.50±1.14°, from 10.05±3.05° to 10.55±3.20°, but the observed change was not significant (p = 0.066). The individual values of the difference show no change in seven patients (35%), an increase of 1° to 3° in nine patients (45%) and a decrease by 1° in four patients (20%).

A slight decrease of -0.25±2.91° was observed in the mean SpP-M° value, from 21.45±4.61° to 21.20±4.96°, but the change was not significant (p = 0.706). In thirteen patients (65%) the SpP-M° value decreased by 1°, 2° or 3°. An increase of 1°, 2° or 11° was observed in four patients (20%) and no change in three patients (15%).

The mean Go° value decreased from 121.45±5.38° to 121.10±4.75°, with a significant difference of 0.35±2.70°, p = 0.019. The individual values of the difference showed a decrease from 1° to 5° in ten patients (50%), an increase of 1° to 5° in nine patients (45%) and no change in one patient (1%).

PFH/AFH ratio had a mean value of 66.70±3.85 before the treatment which increased to 67.50±4.05 after the treatment, with a small difference of 0.80±1.39 of no statistical significance (p = 0.569). The individual changes in PFH/AFH ratio varied from -1 to 4 with the following distribution: Twelve patients (60%) had an increase in their baseline PFH/AFH ratio, four patients (20%) had a decrease, and in four patients (20%) there was no change in the value of the PFH/AFH ratio.

| PFH/AFH after | 67.50±4.03 | 0.80±1.39 | -1.00 to 4.00 | 0.569 |
|--------------|-----------|----------|--------------|------|
* - Significant at p < 0.05; ** - Significant at p ≤ 0.01; *** - Significant at p < 0.001

Although the changes in the mean values of the vertical skeletal parameters were small and in most of the cases not significant, the examination of the individual differences showed a wide range of patients with an increase or a decrease in values and only a few with no change. This observation prompted us to carry out an additional analysis by comparing the proportion of the patients with a change, combining patients with an increase and a decrease, vs.
the proportion of the patients with no change through Fisher’s exact test. The results (Fig. 6) showed that a significant proportion of the patients 75% (N=15) had a change in their SN-M° value vs. 25% (N = 5) with no change, (p = 0.004). A change in SN-FH° was observed in 55% of the patients (N = 11) and was not observed in 45% (N = 9), with no significant difference in proportions, p = 0.752. The patients with a change in SN-SpP° constituted 65% (N = 13) of the group vs. no change in 35% (N = 7), with a significant difference (p = 0.047). The patients with a change in SpP-M° were 85% (N = 17) and significantly dominated vs. 15% (N = 3) with no change, p < 0.001. All patients (95%), except one (5%) had a change in the Go° value, with a highly significant dominance, p < 0.001. A change in the PFH/AFH ratio was found in 80% (N = 16) of the patients vs. 20% (N = 4) with no change, with a highly significant difference, p < 0.001.

**Figure 6:** Patients with a change in SN-M°, SN-FH°, SN-SpP°, SpP-M°, Go° and PFH/AFH vs. patients without a change.

**Dentoalveolar changes:**

The dentoalveolar measurements taken before and after the treatment were compared through paired-samples t-tests. The results (Table 3) showed significant changes in all parameters, except for i/M° where the change was marginally significant (p = 0.054).

**Table 3:** Paired comparisons of dentoalveolar measurements before and after the treatment.

| Measurement     | Mean±SD     | Difference |        |        |                  | p   |
|-----------------|-------------|------------|--------|--------|------------------|-----|
| I/SpP° before   | 108.15±9.21 | 3.65±7.34  | -5.00  | 17.00  | 0.039*           |     |
| I/SpP° after    | 111.80±6.23 | 16.80±8.91 | 0.039  |       |                  |     |
| I/NA° before    | 111.80±6.23 | 16.80±8.91 | 0.039  |       |                  |     |

* - Significant at p < 0.05; ** - Significant at p ≤ 0.01; *** - Significant at p < 0.001
The individual and mean values of the differences in the dentoalveolar parameters before and after the treatment are illustrated on Figure 7. The mean I/SpP° value increased significantly by 3.65±7.34° after the treatment, from 108.15±9.21° to 111.80±6.23° (p = 0.039). The plot shows eleven patients (55%) with an increase between 1° to 17°, eight patients (40%) with a decrease of -1° to -5°, and one patient (5%) with no change.

A significant increase was observed in the mean I/NA° value from 16.80±8.91° to 20.55±6.30°, with a mean difference of 3.75±7.85° (p = 0.046). Eleven patients (55%) had an increase of I/NA°, ranging from 2° to 17°. The remaining nine patients (45%) had a decrease between -2° to -7°.

The mean I/i° value decreased significantly by -6.15±9.76°, from 131.40±13.62° to 125.25±8.97° (p = 0.011). A decrease was observed in fifteen patients (75%), with values ranging between -1° to 35°. Four patients (20%) had an increase between 1° and 8°, and one patient (5%) had no change.

A significant increase was observed in the mean i/M° value, from 98.85±6.46° to 101.60±6.71°, however the change was not significant (p = 0.054). An increase was established in thirteen patients (65%) with values ranging between 2° and 20°. Six patients had a decrease (30%) and one patient (5%) had no change.

A significant increase was observed in the mean i/NB° value, from 25.90±6.88° to 30.30±5.93° with a significant difference of 4.30±6.19 (p < 0.006). In twelve patients (60%) the i/NB° increased, with values ranging between 2° to 20°; two (10%) patients had a decrease of -1° and in six patients (30%) there was no change.

A significant increase was observed in the mean I:NA mm value from 2.05±3.21mm to 3.75±2.12mm, with a significant difference of 1.70±2.16mm, p = 0.009. The individual data showed an increase in eleven (55%) patients, ranging between 1mm to 6mm, a decrease in four (20%) patients of -1mm to -3mm and no change in five patients (25%).

The i:NB parameter showed a significant increase of 1.40±1.95mm, from 4.85±2.87mm to 6.25±2.14mm, p = 0.005. Twelve patients (60%) had an increase with values ranging between 1mm and 6mm; two patients (10%) had a decrease of -1mm, and in six patients (30%) there was no change.

The most significant increase was observed in the mean i:APg value, from 0.30±2.67mm to 3.20±2.09mm, with a difference of 2.90±2.42mm, p < 0.001. Nineteen patients (95%) had an increase, ranging between 1mm to 10mm and one patient (5%) had no change.
Discussion:
Sagittal skeletal changes:
The maxillomandibular relationship showed improvement in comparison with the beginning of the treatments. The changes in ANB angle after the treatments were a result of small but cumulative effects on dentofacial structures.

The improved result from anterior positioning of the mandible as a result of treatment and growth changes, displayed by increase in SNB value. Similar findings were shown with bionator by some authors.

Vertical skeletal changes:
The treatment results of removable functional appliances showed statistically significant increase in some of the vertical skeletal parameters in most of the clinical studies. Most of them showed changes mainly in metrical measurement of the facial height or the mandibular angle. This could be explained with the vertical development allowed by the excessive eruption of the mandibular molars.

Other study did not show an evidence for statistically significant vertical skeletal changes during treatment with removable functional appliances.

The slight but statistically significant decrease in SN-M° value and Go° value in the present study could be explained by vertical control of the mandibular molars and incisors. Fixed appliances combined with prefabricated myofunctional appliances T4B in one treatment phase, provides control over mandibular molar vertical position and incisors intrusion, if they were in superposition by using fixed appliance – braces and the horizontal occlusal pad of the T4B. This effect is known as leveling of the Spee curve during fixed appliance treatment.
Dentoalveolar changes:
There is a lack of high-quality evidence in the existing literature regarding combine approach: braces with prefabricated myofunctional appliance for the treatment of Class II patients. The present study shows versatile changes in the upper incisive angulation, which could be explained with the braces mode of action. Braces tend to align teeth in their optimal proper position in three dimensions.

Functional appliances treatment lead to vestibular inclination of the lower incisors. In the present study there is no significant changes in lower incisors’ inclination, which could be explained by the tooth controlled movement with braces.

Conclusion:
The applied treatment approach was effective for growing skeletal and dental Class II patients. While braces were more effective in achieving great improvement in the tooth position, myofunctional appliances improve occlusion by producing adequate occlusal contacts and sagittal skeletal relationship. Therefore, clinicians should consider the combination of braces and Trainer as treatment option for Class II growing patients with permanent dentition.

Acknowledgements:
This research was supported by the National Program “Young scientists and Post-Doctoral Students”. The author receives funding from the Medical university of Sofia.

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