Comparative evaluation of treatment effects between two fixed functional appliances for correction of class II malocclusion: A prospective clinical study

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Abstract---Objectives: to compare dental and skeletal effects produced by Forsus Fatigue Resistance Appliance and Advancesync II Appliance in patients with class II malocclusion. Patients and methods: The current study was conducted on 20 orthodontic patients with an age range from 14- to 16-year-old who were collected from the outpatient clinic at Orthodontic Department, Faculty of Dental Medicine, Al-Azhar University, Assiut, Egypt. They were separated at random into two equal groups; each consisted of 10 patients, Group 1: Patients treated with molar to canine fixed functional appliance. Group 2: Patients treated with molar to molar fixed functional appliances. Results: results showed non statistically significant difference between both groups. Conclusion: a statistically significant differences were found in dentoalveolar parameters with statistically non significance difference in skeletal parameters.

Keywords---Forsus, Advancesync 2, Class 2 malocclusion, fixed functional appliances.
Introduction

Class II malocclusions are one of the most common malocclusions observed in orthodontics. They are frequently caused by protruding maxilla, retruding mandible, or a combination of the two. In an effort to create a harmonic connection between the two jaws, growth modification is typically undertaken in developing patients. However, in adult patients with little growth potential, only orthognathic surgery or orthodontic concealment are viable solutions. (1, 2, 3, 4)

Fixed functional appliances (FFA) is one of the treatment modalities that were introduced by Emil Herbst due to a lack of patient cooperation in wearing removable functional appliances. To address these restrictions, the Functional appliances were developed. Class II angle-adjustment devices share some properties. The forces utilized to either advance the jaw or distalize the molars are generated by inter- or intramaxillary fixed auxiliaries. They require dental and/or palatal anchors, such as lingual or transpalatal arches, multibanded fixed appliances and modified palatal buttons, almost invariably. (5,6)

It is well known that patient compliance is essential for the successful completion of fixed functional appliance therapy. The patient’s most effective weapon against noncompliance is the fixed functional appliance (7,8). The method by which a permanent functional appliance adapts the mandible to forward posture is identical to that of a detachable functional appliance. The appliance is tooth-borne and exerts its effects on the underlying bone by passing the forces generated by the continual forward posture of the lower jaw via the teeth. (9,10)

Digital radiography offers various benefits above film-based systems superimposition. Superimposition is a technique used by dentists and researchers that involves overlaying cephalometric radiographs on certain anatomical structures to examine changes in growth and the impact of orthodontic therapy on the teeth and jaws. (11,12)

Patients and Methods

Study design:
Study design was a prospective clinical study done on 20 orthodontic patients who were split into two groups, group A (Forsus) and group B (Advancsync2).

Sample size calculation:
According to past research, the sample size for this study was calculated (7,13) depending on:

1. Acceptable level of significance p<0.05 (Type I or α error=5%). This means that we are ready to accept that the probability that the observed difference “false positive” due to chance is 5%.
2. Power of the study =0.80 The “power” of the study then is equal to (1 –β). This means that we are ready to accept a 10% failure to detect a difference when there is a difference “false negative”, i.e. Type II or β error=10%.
3. Expected effect size=1.195
4. Standard deviation is the measure of dispersion or variability in the data. The sample size=20 patients: 10 for each group.
Ethical consideration

An informed consent form that explains every step in the research was given and discussed carefully with the patients before participation in the study and should be signed freely. The objectives of the study will be discussed and explained with the patients and/or guardians as well.

Participants

This study was done on 20 orthodontic patient who were collected from outpatient clinic at the Orthodontic Department, Faculty of Dental Medicine, Al-Azhar University, Assiut, Egypt. They were randomly divided into two equal groups: 10 patients each as follows: The first group consisted of 10 patients, who received Forsus Fatigue Resistance Device fixed functional appliance therapy, the second group consisted of 10 patients, who received Advancsync2 fixed functional appliance therapy. The patients included in the study fulfilled the following criteria: Patients with skeletal class 2 due to mandibular retrognathism with cervical vertebrae index C3,4 and 5, patients with good oral hygiene and no previous orthodontic or orthopedic treatment, healthy female patients at post pubertal growth phase with no systemic nor genetic diseases that could interfere with orthodontic treatment. The patients were excluded from the study from the study if they had the following: Temporomandibular Joint disorder, patients with craniofacial anomalies, history of trauma or poor oral hygiene, patients with history of previous orthodontic treatment.

Intervention:

Before treatment, the following orthodontic information were collected for each patient in the study:

Preoperative:

Case history and clinical examination:
A complete diagnostic sheet was done for each patient, including a detailed case history, extra-oral and intra-oral examinations. Additionally, a thorough medical history was taken carefully from each patient to exclude any systemic disease that could interfere with orthodontic treatment and the patients were checked to meet the inclusion criteria previously mentioned.

Patients’ records:
For each patients a set of four extra-oral and five intra-oral photographs were taken, Panoramic radiograph, standardized lateral cephalometric radiograph, and orthodontic study cast model. For each patient, two standardized cephalometry were obtained; one before the appliance was installed and the other immediately after its removal.

Operative procedures:

Brackets: We bonded the maxillary and mandibular teeth using 0.022×0.028-inch slots Roth brackets***
**Arch wire**: After direct bonding of the brackets, installation of Nickel Titanium (Ni-Ti) arch wire for leveling and alignment of teeth starting from 0.012” up to stainless-steel (St.St.) arch wire 0.019” × 0.025” in diameter.

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**Fig (1) Group 1 FFRD**: (A): pre-operative lateral cephalometric radiograph, (B): Post-operative lateral cephalometric radiograph

**Fig (2) Group 2 Advancsync2**: (A): pre-operative lateral cephalometric radiograph, (B): Post-operative lateral cephalometric radiograph

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**Statistical analysis**

By examining the data distribution and performing the Kolmogorov-Smirnov and Shapiro-Wilk tests, numerical data were examined for normality. Except for the following measurements, all data indicated a normal (parametric) distribution: Measurements with a distribution that was not normal (parametric) included the following: U Lip to E-Line, L Lip to E-Line, Overbite, Glenoid fossa volume, Posterior joint space, AP Condylar position, Geo differences, and change in all measurements. The mean, standard deviation (SD), median, and range of the data
were shown. When dealing with parametric data, the changes over time within and between groups were investigated using the repeated measures ANOVA test. When the ANOVA test was significant, Bonferroni’s post-hoc test was employed for pair-wise comparisons. The Wilcoxon signed-rank test was employed to examine changes within each group when the data were non-parametric. Mann-Whitney In order to compare the two groups, we performed the U test. It was decided that the significance level should be set at 0.05. Data were analyzed using IBM SPSS Statistics for Windows Version 23.1. Armonk, New York: IBM Corp.

Results

Table (1): Mean, standard deviation values and results of repeated measures ANOVA test for the changes in sagittal angular measurements within each group

<table>
<thead>
<tr>
<th>Measurement (º)</th>
<th>Group</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>SNA</td>
<td>Forsus</td>
<td>85.22</td>
<td>6.21</td>
<td>84.36</td>
</tr>
<tr>
<td></td>
<td>Advanc sync2</td>
<td>83.16</td>
<td>4.03</td>
<td>82.33</td>
</tr>
<tr>
<td>SNB</td>
<td>Forsus</td>
<td>76.88</td>
<td>5.19</td>
<td>78.7</td>
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<tr>
<td></td>
<td>Advanc sync2</td>
<td>74.99</td>
<td>3.46</td>
<td>77.44</td>
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<tr>
<td>ANB</td>
<td>Forsus</td>
<td>8.02</td>
<td>2.16</td>
<td>6.75</td>
</tr>
<tr>
<td></td>
<td>Advanc sync2</td>
<td>7.98</td>
<td>1.85</td>
<td>5.03</td>
</tr>
<tr>
<td>Facial angle</td>
<td>Forsus</td>
<td>89.25</td>
<td>4.8</td>
<td>89.21</td>
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<tr>
<td></td>
<td>Advanc sync2</td>
<td>86.56</td>
<td>3.28</td>
<td>86.74</td>
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</table>

Table (2): Mean, standard deviation values and results of repeated measures ANOVA test for the changes in linear measurements within each group

<table>
<thead>
<tr>
<th>Measurement (mm)</th>
<th>Group</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
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<tr>
<td>LFH</td>
<td>Forsus</td>
<td>61.58</td>
<td>2.23</td>
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<td></td>
<td>Advanc sync2</td>
<td>61.42</td>
<td>3.27</td>
<td>63.12</td>
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</table>

Table (3): Mean, standard deviation values and results of repeated measures ANOVA test for the changes in angular dental measurements within each group

<table>
<thead>
<tr>
<th>Measurement (º)</th>
<th>Group</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>U1-SN</td>
<td>Forsus</td>
<td>109.29</td>
<td>10.38</td>
<td>106.31</td>
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<td></td>
<td>Advanc sync2</td>
<td>107.15</td>
<td>6.06</td>
<td>103.66</td>
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<td>IMPA</td>
<td>Forsus</td>
<td>97.05</td>
<td>8.25</td>
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<td>Advanc sync2</td>
<td>97.89</td>
<td>4.94</td>
<td>106.54</td>
</tr>
</tbody>
</table>
Discussion

Regarding skeletal measurements:

Change in SNA, SNB angles:
The present study recorded statistically non-significant value between pre and post measurements of both SNA and SNB angles in both groups which agreed with Arora et al (14) and Nishanth et al (7) who reported non significance value of both measurements after using Forsus appliance and in disagreement with Kaur et al (15) and O’Brien K et al (16) who reported significant decrease in SNA angle and significant increase in SNB after using Forsus appliance.

Change in ANB angle:
As for, it produced clinically and statistically significant decrease in ANB angle (-1.29°) in Advancsync 2 which agrees with the results of Kaur et al (15) and Shendy et al (16) who reported significant decrease in ANB angle (-3.2°) and (-3.8°) respectively after treating class 2 cases with age ranging from 11-16 year old of both genders using Advancsync 2, but it disagrees with Shetty et al (17) who recorded no significant difference between pre and post skeletal measurements after using Advancsync 2 in class 2 cases depending on lateral cephalometric radiographs for evaluation.
On the other hand, no statistically significant difference was found between the pre and post measurements in ANB angle in both groups which coincides with Shetty et al (17) who recorded that no significant difference was found between pre and post skeletal measurements after using Advancsync 2 in class 2 cases.

Change in Facial Angle:
This study reported no significant difference in facial angle between the pre and post measurements in both groups which disagrees with O’Brien K et al (16) who reported significant increase in facial angle after using Forsus for both genders with lateral cephalometric radiographic evaluation.

Change in Lower Facial Height (LFH):
The present study recorded statistically non significance difference between pre and post measurements of LFH which coincides with Nishanth et al (7), Kaur et al (15) and O’Brien K et al (16) who recorded the same.

Regarding dental measurements:

Change in U1-SN angle:
This present study reported statistically significant difference between pre and post measurement of U1-SN angle for both groups (-5.98°) and (-6.5°) respectively which coincides with O’Brien K et al (16) who reported a statistically significant decrease (-15.6°) in U1-SN angle. And vary from Kalra et al (18), Arora et al (14) and Kaur et al (15) who reported statistically not significant difference between pre and post measurements after using Advancsync 2 appliance.

Change in IMPA angle:
This study reported statistically significant increase between pre and post measurements of IMPA angle both groups (9.46°) and (8.65°) respectively which
agrees with Kaur et al (15) and Nishanth et al (7) and disagrees with Kalra et al (18) and Shetty et al (17).

Conclusions

1. In Class II correction, the Forsus Fatigue Resistance Appliance and the Advancesync II Appliance had skeletal and dentoalveolar effects in addition to their combined impact.
2. There was a significant difference in dentoalveolar effects between the Forsus Fatigue Resistance Appliance II and the Forsus Fatigue Resistance Appliance, with the latter having a greater impact on the Class II correction.
3. Except when eating, patients in the Advancesync II Appliance group reported higher discomfort than those in the other group.

Reference