Infra-Zygomatic Mini Screws Compared to High Pull Headgear for Distalization And Intrusion of Maxillary Molars in Growing Patients with Class II Malocclusion: A Randomized Clinical Trial

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ABSTRACT

Objective: The aim of the present randomized clinical study was to evaluate the distalization and intrusion effect of an Infra-zygomatic mini-screws supported appliance and compare it with high pull headgear appliance in treatment of growing patients with class II malocclusion.

Methodology: 22 growing boys aged between (10 to 12 years) with class II div 1 malocclusion randomly divided to 2 equal groups. The first group treated with high pull headgear with acrylic splint and the second one treated with an Infra-zygomatic mini-screws supported appliance. The treatment duration was 8 months for both groups. Lateral cephalometric radiographs were taken before and after the treatment for each patient to be analyzed.

Results: The maxillary first molar distalization was 2.58±2.31 mm in head gear group and 1.53±2.83 mm in mini-screws group. There was no significant maxillary first molar intrusion in both groups. There were no significant differences between the two groups.

Conclusions: the mini-screws supported appliance can be used as the fixed replacement of the removable high pull headgear appliance with no need for patient cooperation.

Keywords: class II, distalization, headgear, infra-zygomatic, malocclusion, mini-screws.

I. INTRODUCTION

Class II malocclusion is the second most prevalent type of malocclusion which is seen in almost the third of the population and have many components which are usually expressed simultaneously, but to different extents [1]. The dental component is characterized as distal relationship of mandibular teeth relative to maxillary teeth. The skeletal component is either maxillary protrusion or mandibular retrusion and sometimes there is combination of both [2], [3]. Abnormal vertical facial heights are common in the class II malocclusion most probably exhibit excessive vertical development. Individuals with Class II malocclusion have functional deficits and impaired masticatory function [4].

Functional appliances can be used in case of mandibular retrusion to reposition the mandible in a forward direction in an attempt to stimulate condylar growth. The second option is the use of headgears in cases of maxillary protrusion to redirect the growth of the maxillary complex or drive the maxillary teeth distally with extra oral anchorage traction, while the mandible continues its forward growth.

High pull head gears are indicated in subjects with increased vertical growth pattern. Studies reported their effects to include restriction of the maxillary anterior growth, slight clockwise rotation of the palatal plane, distalization and maintenance of the vertical position of upper molars and reduction of the ANB angle [5], [6]. The problems with headgears include unaesthetic appearance and that they rely heavily on patient cooperation, as a lack of compliance may compromise the outcome [7]. Studies recommended a minimum of 12 hours daily to achieve the desired results [5]. An additional disadvantage to headgear treatment is the risk of facial injury [8].

The zygomatic buttress has been recommended by many working groups as a site for mini-plate placement referred to as zygomatic anchorage systems. With its thick cortical plate, the zygomatic process of the maxilla enables the anchorage device to be placed at a distance far from the developing teeth in a growing patient while maintaining better stability for anchor units under high forces [9]-[13]. Many authors used
III. MATERIALS & METHODS

A. Study Design

This study was designed as an interventional, parallel randomized, controlled trial with 1:1 allocation ratio.

B. Eligibility Criteria

All the recruited subjects followed the inclusion criteria of:

1. Gender: males.
2. Age: 10-12 years.
3. Skeletal maturation: cervical vertebrae maturation stage cs2-cs3.
4. Dentition: mixed or permanent (with erupted maxillary four incisors and maxillary first molars).
5. Skeletal classification: class II with maxillary excess
6. Vertical growth pattern: normal or increased vertical growth pattern (normal or increased maxillary-mandibular plane angle).
7. Incisors classification: Class II division 1.
8. Molar classification: class II.
9. Overjet: minimum 4 mm.
10. Incisal show: increased at rest and on smiling.

And exclusion criteria of:

1. Open bite.
2. Severe skeletal mandibular retrognathism (as measured by SNB angle).
3. Patients with any syndrome.
4. Patients with horizontal growth pattern (decreased maxillary-mandibular plane angle).
5. Congenitally missing teeth except third molars.
6. Previously extracted permanent teeth.
7. Previous orthodontic treatment.

C. Study Setting

It took place at the Department of Orthodontics outpatient clinic of the educational hospital of the Faculty of Dentistry, Cairo University. This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Cairo University. All patients and volunteers were informed about the study procedures and informed written consents were signed by their guardians.

Trial registration: www.clinicaltrial.gov with number: NCT03839303.

D. Interventions

- Initial records in both groups:
  - After clinical examination, panoramic and lateral cephalometric radiographs (T0) were taken to see all the dentition, the skeletal growth pattern and the cervical vertebrae maturation stage.
  - After patient’s selection according to the eligibility criteria, preoperative records were taken, including intra-oral and extra-oral photographs, and impressions.

- In the intervention group (Fig. 1, 2):
  - Bonding of 0.022-inch slot (Leone; Firenze, Italy) Roth brackets on upper four anteriors was done using gauge for accurate positioning, banding the upper first molars with bands of appropriate sizes and leveling of the four incisors upon reaching 0.019×0.025-inch stainless-steel arch wire, then a lateral cephalogram was taken (T1).
  - Two self-drilling mini screws (1.75×8 mm; Leone® with high head design) were placed in the infrazygomatic area [11, 16, 17].
  - A wire framework (made from 1.2 mm stainless-steel wire) with hooks placed incisally distal to upper lateral incisors was fabricated on the cast. The 0.019×0.025-inch stainless-steel arch wire was cut distal to upper laterals and curved by loop former plier on both ends to avoid sharp edge.
  - The appliance was inserted in the patient mouth inside the headgear tube of the bands and adjusted to be about 2 mm above the level of anterior brackets. The appliance was ligated to the 0.019×0.025-inch stainless-steel arch wire segment on the four anteriors by 2 ligature wires (0.012 inch stainless steel) distal to the upper laterals (one on each side). Two NiTi coil springs with proper length were used to apply the force from the screws to the hooks distal to the lateral incisors. The force was adjusted to 400 gm per side measured by force gauge by adjusting the length of the coil spring.

Fig. 1. Intraoral frontal view of the mini-screws appliance.

Fig. 2. Extra oral frontal view of the mini-screws appliance (smiling).
and flying tubes inserted in the premolars area for the headgear face bow.
- Acrylic resin was split palatal to the upper incisors.
- High pull headgear (Leone®) was used, and the level of the outer bow was adjusted so that the pull force of the elastic straps was directed through the center of resistance of maxilla as seen from profile view.
- The force was adjusted to 400 gm per side by force gauge.
- The participants were asked to wear it for at least 14 hours daily.

**In both groups:**
- Follow up and force adjustment were made every month.
- The treatment continued for 8 months, after which a lateral cephalogram (T2) was obtained.

- The distalization of the maxillary first molar was measured Cen U6 - S VRL difference between T2 and T1 lateral cephalograms.
- The intrusion of the maxillary first molar was measured by Cen U6 - HRL difference between T2 and T1 lateral cephalograms.

E. **Lateral Cephalogram Analysis**

A customized digital analysis was made by Facad (Version 3.11, ILEXIS AB, Sweden) software to analyze the data from T1 and T2 lateral cephalograms in both groups

F. **Methods of Measuring the Outcomes (Fig. 5)**

- The distalization of the maxillary first molar was measured Cen U6-S VRL difference between T2 and T1 lateral cephalograms.

G. **Sample Size Calculation**

Sample size was calculated by G power software. It was found that the group sample sizes of 10 and 10 can achieve 80% power to reject the null hypothesis of equal means when the effect size is 1.367 with a significance level (alpha) of 0.05 using a two-tailed two-sample equal-variance t-test.

H. **Randomization**

a) **Sequence generation**

The randomization was performed with a 1:1 ratio of allocation, the sequence was computer generated. The method of randomization was carried out through randomizer.org website.

b) **Allocation concealment**

The randomization numbers produced from the sequence generation were written on opaque papers and folded 4 times and sealed in opaque envelopes and kept in a sealed box. Each patient was then allowed to choose one of the sealed envelopes to be allocated to one of the two study groups.

I. **Blinding**

1. **To participant (subjects)**

Patients can detect the type of the intervention, so blinding is not possible.

2. **To operator**

The main operator is responsible for the intervention, so his blinding is not possible.

3. **To Assessor**

The 2 assessors (not involved in the study) carried out the measurements blindly on the pre and post treatment radiographs.
J. Statistical Analysis

- Quantitative variables are described by the Mean, Standard Deviation (SD), the Range (Maximum – Minimum).
- Kolmogorov-Smirnova and Shapiro-Wilk tests of normality were used to test normality hypothesis of all quantitative variables for further choice of appropriate parametric and non-parametric tests.
- Intra class correlation coefficient test was done for the measurements of the pre and post treatment cephalogram to detect inter and intra reliability
- Baseline characteristics were compared between the 2 groups using student t test.
- Paired sample t-test was used for testing relation between related samples (before and after treatment in each group), while independent sample t-test was used for comparing the non-related samples (mean difference of treatment between the 2 groups).
- The significance level was set at P ≤ 0.05. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows. Also, Microsoft office Excel was used for data handling and graphical presentation.

III. RESULTS

A. Baseline Analysis

Showed no statistically significance difference between the two groups where (p value > 0.05).

B. Inter and Intra Reliability Tests

Stated a statistically significance high inter class correlation coefficient (ICC) (>0.900) between different readings which states a strong reliability and agreement.

C. Normality Test

Kolmogorov-Smirnova and Shapiro-Wilk tests of normality showed parametric (normal) distribution of all quantitative variables.

D. Intervention (Mini-screws) Group (Table I)

Cen U6-S VRL showed a decrease (distalization) in mean post-treatment value by 1.53 mm.

U6-tipping showed an increase in mean post-treatment value by 4.72º.

Cen U6-HRL showed a decrease (intrusion) in mean post-treatment value by 0.74 mm.

E. Control (headgear) group (Table II):

Cen U6-S VRL showed a decrease (distalization) in mean post-treatment value by 2.58 mm.

U6-tipping showed an increase in mean post-treatment value by 3.62º.

Cen U6-HRL showed a decrease (intrusion) in mean post-treatment value by 0.2 mm.

There were no significant differences when the changes after treatment in the two groups were compared (Table III).

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TABLE 1: TABLE SHOWING RELATIONSHIP BETWEEN THE PRE AND POST READINGS IN DIFFERENT PARAMETERS IN MINI-SCREWS GROUP

| Measurement | Group    | Min. | Max. | Mean | S.D. | Mean diff. | p-value | 95% confidence interval of mean difference |
|-------------|----------|------|------|------|------|------------|---------|------------------------------------------|
| U6-tipping  | Pre      | -106.4 | -79.9 | -96.67 | 7.72 | -4.72     | 0.182  | -2.609 to 12.046                        |
|             | Post     | -117.6 | -89.3 | -101.39 | 8.38 | -1.53     | 0.103  | -0.371 to 3.426                        |
| Cen-U6-S VRL| Pre      | 33.4  | 51.8 | 39.72 | 5.28 | -4.66     | 0.074  | -0.276 to 2.161                        |
|             | Post     | 31.2  | 52.5 | 38.19 | 5.85 | -0.74     | 0.276  | -0.689 to 2.161                        |

S.D.= Standard deviation. Min.= Minimum value. Max.= Maximum value. *; significant (p≤ 0.05) ns; non-significant (p>0.05).

TABLE 2: TABLE SHOWING RELATIONSHIP BETWEEN THE PRE AND POST READINGS IN DIFFERENT PARAMETERS IN HEADGEAR GROUP

| Measurement | Group    | Min. | Max. | Mean | S.D. | Mean diff. | p-value | 95% confidence interval of mean difference |
|-------------|----------|------|------|------|------|------------|---------|------------------------------------------|
| U6-tipping  | Pre      | -110.4 | -93.1 | -101.97 | 5.74 | -3.63     | 0.02*  | 0.694 to 6.561                          |
|             | Post     | -124.2 | -96   | -105.6 | 7.7  | -2.58     | 0.004* | 1.03 to 4.134                           |
| Cen-U6-S VRL| Post     | 34.7  | 41.9 | 37.81 | 2.28 | -0.02     | 0.735  | -1.079 to 1.479                         |
|             | Pre      | 31    | 37.5 | 35.23 | 2.09 | -0.69     | 0.47   | -0.24 to 0.24                           |

S.D.= Standard deviation. Min.= Minimum value. Max.= Maximum value. *; significant (p≤ 0.05) ns; non-significant (p>0.05).

TABLE 3: TABLE SHOWING RELATIONSHIP BETWEEN THE HEADGEAR AND MINI-SCREWS READINGS IN DIFFERENT PARAMETERS

| Measurement | Change | Min. | Max. | Mean | S.D. | p-value | 95% confidence interval of mean difference |
|-------------|--------|------|------|------|------|---------|------------------------------------------|
| U6-tipping  | Headgear | -13.80 | 2.10 | -3.63 | 4.37 | 0.761  | -6.298 to 8.480                          |
|             | Mini-screw | -20.70 | 13.50 | -4.72 | 10.91 | 0.349  | -3.350 to 1.241                         |
| Cen-U6-S VRL| Headgear | -7.80  | 0.40  | -2.58 | 2.31 | 0.069  | -2.12 to 2.329                          |
|             | Mini-screw | -7.40  | 2.10  | -1.53 | 2.83 | 0.054  | -1.256 to 2.329                         |
| Cen-U6-HRL  | Headgear | -3.40  | 3.10  | -0.20 | 1.90 | 0.041  | -2.12 to 2.329                          |
|             | Mini-screw | -4.10  | 2.30  | -0.74 | 2.12 | 0.034  | -1.256 to 2.329                         |

S.D.= Standard deviation. Min.= Minimum value. Max.= Maximum value. *; significant (p≤ 0.05) ns; non-significant (p>0.05).
IV. DISCUSSION

Many orthodontic appliances were designed for treatment of class I 1 div 1 malocclusion. The choice of the appliance depend on the components of class I I in each case. Headgear appliance is one of the most used appliances especially in case of maxillary skeletal prognathism. The major problem with headgear is that it depends on patient cooperation as it should be worn for several hours daily for months to produce its effect [18].

The proposed appliance in the present study is considered a modification of the appliance designed by Nur et al. [14], [19] for distalization of maxillary molars. The differences between the two appliances are that in the present study infrrazygomatic mini-screws were used for anchorage, gabble bend was used as stopper for the wire, the direction of the anterior hooks for traction was incisally and the hooks were placed at the incisal edge level of the upper incisors and the four incisors were bonded and ligated as a one unit with the appliance, instead of infrrazygomatic mini-plates for anchorage (need surgical procedures for insertion and removal), bayonet bend as a stopper, the direction of anterior hooks was apically and the incisors were not bonded in the zygoma gear appliance.

Upper first molar distalization was the first main outcome in the study and the results showed that it was achieved by 2.58±2.31 mm with 3.63° of distal tipping in the headgear group and this comes in agreement with Firouz et al. [5] who showed 2.56 mm of molar distalization with also slight change in axial inclination. Watson [20] also found an average of 3.0 mm of distal maxillary molar movement over a period of 5 to 16 months but with higher forces and more hours of wearing the appliance.

In the mini-screws group the amount of distalization (Fig. 6) were 1.53±2.83 mm with 4.72° of distal tipping, although that this distalization amount was much less than shown by Nur et al. [14] and B. Kaya et al. [10] in their systematic review that when the appliances without screws group the amount of distalization (respectively with 3.30° and 5.43°) of distal tipping respectively but this can be explained by two things. First, the measurements of the distalization on lateral cephalogram was different in the studies. In the present study the distance between the centroid point of upper first molar to vertical reference plane was used while in the other studies the distance between mesial surface of the crown of upper first molar and vertical reference plane was used. So the tipping might have exaggerated the measurements in the other studies. The second explanation is that there were different line of action of force in the studies. In the present study the force had more intrusion and less distal component than the other studies. El Dawlatly et al. [21] showed distalization by 2.92±0.69 mm with 1.2° tipping.

In comparison with other non-compliance appliances for molar distalization, Antonarakis and Kiliaridis [22] showed distalization by 4.37 mm and 5.03 mm of distalization respectively [25] showed extrusion by 0.69 mm after treatment with headgear with bite plane. El Dawlatly et al. [21] showed extrusion by 1.57 mm.

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