

The effects of removable vs fixed twin block appliances on the oral and gingival health. A randomized clinical trial

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ABSTRACT

Introduction: Twin block appliance (TB) has been used for decades as a gold standard treatment for class 2 skeletal malocclusion in growing patients. Different designs of fixed twin block appliances have been introduced recently.

The aim of this study is to investigate the oral side effects associated with fixed or removable twin block appliance.

methodology: a group of 24 skeletal class 2 patients with deficient mandible were randomly received either fixed twin block or removable twin block appliance and followed up for 9 months to investigate the oral and gingival effects.

The results: showed that speech and eating difficulties was evident in the fixed twin block group for only one week. Redness of palatal mucosa was evident in some cases of the removable appliance but without pain or signs of candida infection. This was healed after appliance discontinuation. The oral hygiene was the main factor influencing the oral and gingival health. The cephalometric measurements showed significant proclination of the lower incisors in both groups with insignificant decrease in the thickness of the labial bone.

Conclusion: both fixed and removable appliance cause lower incisor proclination but with no significant decrease in the labial alveolar bone thickness, the gingival health is mainly affected by the oral hygiene not the type of the appliance, The gingival and mucosal redness, swelling, speech or eating difficulties associated with twin block was temporary and not significant.

Keywords: Biopesticides, Management, Potato, Viruses,

1. INTRODUCTION

Class 2 skeletal malocclusion is one of the most common skeletal malocclusions in the growing children ¹ the main etiological factor is deficient mandibular growth.² Twin block appliance (TB) introduced by Clark ³ has been used for decades as a gold standard treatment for class 2 skeletal

malocclusion in growing patients. Conventionally removable twin block is used but it depends on the child co-operation to wear the appliance full time in order to achieve good results. Recently fixed twin block was introduced by Clark^{4,5}, and some other researcher also published different designs of fixed twin

block to overcome the problem of patient co-operation. Fixed twin block is supposed to be less bulky and can be cemented to the patient mouth 24 hours for the whole treatment duration which is in average 9 months.

The effect of the twin block treatment is mainly dentoalveolar as skeletal effects is minimum.⁶ After twin block treatment, the lower incisors are found to be proclined and this affect the labial alveolar bone⁷

The risks and side effects associated with fixed vs removable twin block have not been thoroughly investigated. Speech and eating difficulties in addition to possible gingival or periodontal damage and the labial alveolar bone thickness and lower incisors anteroposterior movement need to be investigated.

The aim of this study is to investigate the oral, gingival, and periodontal health hazards associated with fixed or removable twin block appliance.

2. MATERIAL AND METHODS

The design of the study is randomized clinical trial. two Parallel groups equivalent trial with 1:1 allocation ratio.

The study was performed in the outpatient clinic of the Orthodontic Department at the Faculty of Dentistry, Cairo University.

Eligibility criteria: inclusion criteria include growing patients less than 14 years old with skeletal Class 2 malocclusion cases ($ANB \geq 5$ degrees), overjet ≥ 5 mm.

The exclusion criteria include any patients with normal mandible and only protruded upper incisors, Syndromic, cleft patients and patients with dental anomalies or patients that had previous orthopedic or orthodontic treatment.

Research ethics approval: This study was approved by the Research Ethics Committee of the Faculty of Dentistry- Cairo University after the protocol was reviewed and approved by Centre of Evidence Based Dentistry, Cairo University. All patients and volunteers were acquainted with all the study procedures and radiation exposure then informed written consents were signed.

Conflict of Interest: Non-financial competing interests: the study was a part of a PhD degree in Orthodontics, Faculty of Dentistry, Cairo University. No financial conflict of interests was to be declared. The study was self-funded by the principal investigator.

Declaration of interests: no financial competing interests: the study was a part of a PhD degree in Orthodontics, Faculty of Dentistry, Cairo University. No financial conflict of interests was to be declared. The study was self-funded by the principal investigator.

Sample size Calculation: Sample size calculation was done using sample size calculation software of the faculty of dentistry biostatistics committee – Cairo university (figure 1) based on data from previous study⁸ which compared the dentoalveolar and skeletal effects of Bite-Jumping Appliance versus the Twin-Block Appliance in the treatment of skeletal Class II malocclusion in a randomized controlled trial. The following assumptions were used: a paired t test with a power of 80%, a significance level of 0.05, and an effect size of 2. Consequently, the required sample size was 10 patients for each group. However, with an assumed withdrawal rate of 20%, the required sample size was increased to 12 patients for each group.

Power and Sample Size Program: Main Window

File Edit Log Help

Survival Hest Regression 1 Regression 2 Dichotomous Mantel-Haenszel Log

Output

What do you want to know? Sample size

Sample Size 10

Design

Paired or independent? Independent

Input

α 0.05 δ 2

power 0.8 σ 1.47

Calculate Graphs

Description

We are planning a study of a continuous response variable from independent control and experimental subjects with 1 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 1.47. If the true difference in the experimental and control means is 2, we will need to study 10 experimental subjects and 10 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this

Figure 1: Sample size calculation using the software.

Patient recruitment, Randomization, allocation and blinding:

The patients were recruited from the Outpatient Clinic of Department of Orthodontics, Faculty of Dentistry- Cairo University. A computer random sequence table was generated using the random number generator at random.org website by a person (H.K) who was not involved in the study at all. 1:1 allocation ratio. The patients were randomly assigned either to the fixed twin block group (Group A) or the control removable twin block group (Group B) according to the randomly generated table. Due to the

nature of this study, neither the treating clinician nor the participants could be blinded. The statistician was totally blinded from the nature of the clinical trial.

Diagnosis and Pre-treatment records at (T0): before the application of the appliance complete orthodontic diagnosis was done for both groups include history, extraoral and intraoral examination. Diagnostic records include extra-oral and intra-oral photographs. (Figure 2), Standardized lateral Cephalogram, Panoramic radiograph and dental digital casts were obtained indirectly through impression taking followed by scanning of the poured cast to be transformed to digital 3D models. (Figure 3-5)



Figure 2: extra oral and intra oral photos for the patient



Figure 2: panoramic x ray for the patient



Figure 4: lateral cephalogram x ray for the patient



Figure 5: digital cast for the patient

Intervention: For each patient, upper and lower alginate impressions were taken and then poured into hard stone after 15 minutes to ensure dimensional accuracy. Followed by functional bite registration was done using softened pink wax while the patient having incisal edge-to-edge bite with at least 2 mm inter-incisal separation. To fabricate the twin block according to the allocated group. All patients received oral hygiene instructions and an emergency telephone number to contact in case of emergency or any inquiry.

Application of the appliances:

Group A received modified fixed twin-block appliance. (Figure 6). The appliance is cemented with glass ionomer cement.



Figure 6: fixed twin block appliance

Group B received the conventional removable twin block appliance (figure 7) and instructed to wear the appliance full time (22 hours/day) and only remove appliance for teeth brushing or for the main meals if there is difficulty in eating.



Figure 7: removable twin block appliance

Follow up: All patients are instructed to attend for follow-up after one week to make sure the appliance was well fitted and the patient maintaining good oral hygiene and to ask the patient about any functional difficulties in the beginning of the appliance regarding, eating, speaking, pain or discomfort then instructed to attend for follow up every four weeks in the orthodontic department out-patient clinic for 9 months. At each follow up visit, the clinician check the appliance retention and status, patient oral hygiene and retention of plaque or foods around the appliance, the gingival and periodontal health. Functional difficulties were evaluated subjectively by asking the patient about speech and eating problems.

Post-treatment records at (T1): extraoral and intraoral photos, digital casts and lateral cephalogram were taken for every patient after 9 months of functional treatment. These measurements were measured on both groups before and after the treatment (T0 and T1): The lower incisor anteroposterior movement and inclination:

- 1- the angle between lower incisor long axis and nasion – B point line (L1/NB)
- 2- the distance between the lower incisor edge to the nasion – B point line (L1-NB)
- 3- The thickness of the labial alveolar bone in the lower incisor area

Participants timeline shown in (figure 8) according to CONSORT 2010⁹ flow diagram

Participant timeline

Reported using CONSORT 2010 flow-chart.

CONSORT 2010 Flow Diagram

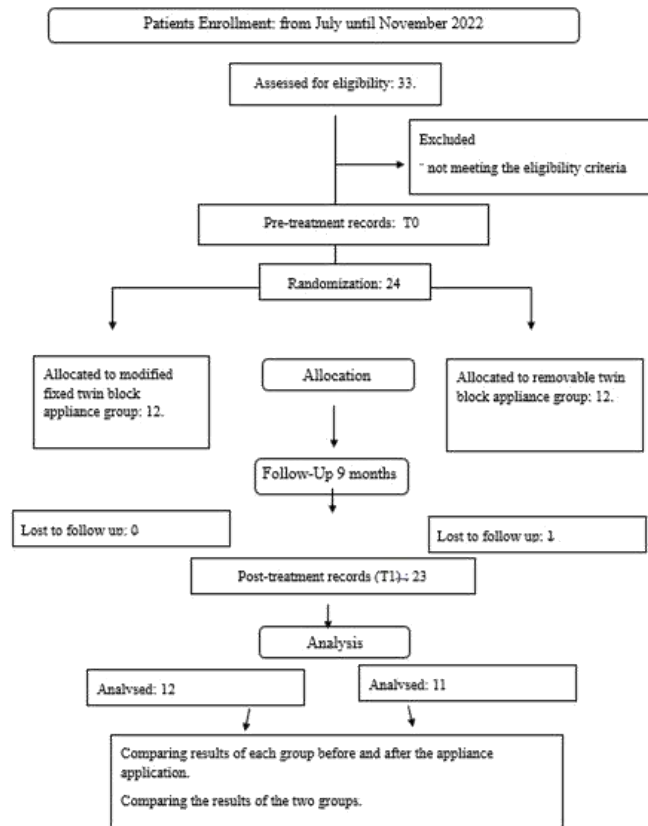


Figure 8: Participant timeline reported using CONSORT 2010 flow chart.

3. RESULTS

Clinically: the speech and eating difficulties was evident in the fixed twin block group for only one week, from the second week the patients reported almost normal speech and accepted eating ability.

Redness of palatal mucosa was evident in 6 cases of the removable appliance (figure 9). But without pain or signs of candida infection. This was healed after appliance discontinuation.

The oral hygiene was the main factor influencing the oral and gingival health. It was a little bit more challenging in the fixed twin block group: some cases showed good oral hygiene and good gingival health (figure 10) while others showed gingival inflammation associated with bad oral hygiene and plaque accumulation either with fixed twin block (figure 11) or with removable twin block (figure 12)

In two fixed twin block cases where the lingual arch was very near the lower incisors gingival some gingival inflammation and swelling was observed (figure13) which then healed spontaneously after appliance removed.



Figure 9: redness and sign of inflammation at the palatal mucosa below the removable twin block appliance



Figure 10: fixed twin block appliance patient showing good gingival health and good oral hygiene



Figure 11: fixed twin block appliance patient showing mild gingival inflammation and bad oral hygiene.



Figure 12: removable twin block appliance patient showing mild gingival inflammation and bad oral hygiene and calculus accumulation at the clasp areas.



Figure 13: gingival inflammation and swelling at the lingual gingival of the lower incisors when no sufficient relief is present between the gingiva and the lingual arch.

Lateral cephalometric analysis:

L1 to NB (°)

In both groups, there was a statistically significant increase in L1 to NB after removal of appliance. There was no statistically significant difference between the amounts of change in L1 to NB in the two groups.

L1 to NB (mm)

In both groups, there was no statistically significant change in L1 to NB after removal of appliance. There was no statistically significant difference between the amounts of change in L1 to NB in the two groups

Labial bone thickness at L1 area (mm):

In both groups, there was no statistically significant change in labial bone thickness after removal of appliance. There was no statistically significant difference between the amounts of change in labial bone thickness in the two groups

Table 1: statistical analysis of the lateral cephalometric measurement in the fixed and removable twin block groups

Measurement	Fixed TB mean (SD)				Removable TB mean (SD)				P – value (between groups)
	Before	after	Change	P – value	Before	after	change	P -value	
L1/NB (°)	29.6 (6.56)	32.47 (5.53)	2.87 (4.1)	0.011*	29.86 (6.88)	34.14 (8.23)	4.28 (3.6)	<0.001*	0.389
L1–NB (mm)	7.18 (2.4)	7.34 (2.23)	0.16 (1.28)	0.583	7.36 (2.98)	7.84 (2.98)	0.48 (1.79)	0.286	0.295
Labial bone thickness (mm)	2.73 (1.04)	2.11 (1.8)	0.62 (1.02)	0.235	3.03 (1.04)	2.83 (1.8)	0.2 (1.56)	0.371	0.312

*Statistically significant

4. DISCUSSION

The redness of the palatal mucosa was suspected to be candida infection or allergic reaction to the acrylic, but the absence of whitish pseudo membrane and the absence of any discomfort symptoms rule out those possibilities.

Regarding the lower incisor proclination during twin block treatment this was evident during this study in both groups, and this was similar to other studies such as ¹⁰⁻¹³

Regarding the thickness of the labial bone there was no significant difference between the before and after measurements and also between the two groups. This result is different from the results of previous study of Zhang in 2020 ¹⁴

The change in L1-NB line was insignificant, this may be due to advancement of B point along with advancement of the lower incisors due to combined skeletal and dental effects of the twin block treatment.

5. LIMITATIONS

The labial alveolar bone thickness was done in 2D lateral cephalogram. It can be better evaluated using CBCT three-dimensional x-ray however CBCT will subject the patient to high dose of radiation which is unnecessary.

The standardization of oral hygiene could help in rolling out the effect of the appliance, but this was not achievable in real clinical situation as there's individual variations between the participant children.

6. CONCLUSION

- 1- Both fixed and removable appliance cause lower incisor proclination but with no significant decrease in the labial alveolar bone thickness.
- 2- The gingival health is mainly affected by the oral hygiene not the type of the appliance.
- 3- The gingival and mucosal redness or swelling are temporary and spontaneously relief after appliance discontinuation.
- 4- Speech and eating difficulties associated with fixed twin block last only for the first week of treatment.

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