Cover page

Official Title of the Study

Dento-skeletal effects of clear twin block treatment at specific period in growing patients: A CBCT based controlled clinical trial

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Introduction

Class II malocclusion is a common dentofacial discrepancy in orthodontic practice and a frequent reason for seeking treatment during childhood and adolescence. Its prevalence varies according to population, dentition, ethnicity, and diagnostic criteria. Pooled global evidence indicates that Class II relationships affect a substantial proportion of individuals with mixed or permanent dentitions. This condition may arise from skeletal, dentoalveolar, or combined discrepancies involving the maxilla, mandible, dentition, and surrounding soft tissues. Mandibular retrusion is a frequent skeletal component; however, maxillary protrusion, altered vertical development, dental compensation, or combinations of these factors may also contribute. Identifying the underlying components is essential because treatment objectives and appliance selection differ between predominantly skeletal and dentoalveolar forms of Class II malocclusion.

Growth modification is commonly considered for growing patients with skeletal Class II malocclusion primarily associated with mandibular retrognathism. Functional appliances position the mandible anteriorly and may induce adaptive changes throughout the craniofacial complex. Among these appliances, the Twin Block, introduced by Clark, is one of the most widely used removable functional systems. Cephalometric studies have shown that Twin Block therapy produces both skeletal and dentoalveolar effects, including reduced overjet, improved molar relationships, increased mandibular dimensions, and reduced facial convexity.

Despite its effectiveness, the conventional Twin Block appliance has limitations related to its bulk, visible wire components, speech adaptation, and patient acceptance. Clear Twin Block appliances have therefore been developed using transparent thermoplastic materials to maintain mandibular advancement while potentially improving esthetics and comfort. Recent randomized clinical trials have reported favorable dentoskeletal outcomes, together with improvements in patient satisfaction, speech adaptation, and esthetics.

Nevertheless, evidence concerning clear Twin Block treatment remains more limited than that for conventional Twin Block therapy. Existing studies vary in appliance design, treatment duration, skeletal maturity, and outcome assessment. Previous evidence suggests that functional jaw orthopedics is most effective when treatment begins during the pubertal growth period. Therefore, evaluating clear Twin Block treatment during a defined stage of skeletal maturation may provide a more reliable estimate of its dentoskeletal effects.

Accordingly, this controlled clinical trial aims to evaluate the dentoskeletal effects of clear Twin Block treatment initiated during a specific stage of skeletal maturation in growing patients with skeletal Class II malocclusion associated with mandibular retrognathism.

Subjects and Methods

A total of 40 patients, irrespective of sex, aged 9–12 years and presenting with Class II Division 1 malocclusion and a skeletal Class II pattern will be included in the study.

The study will be conducted under ethical approval No. ISU.26.1.25, granted by the Institutional Review Board (IRB)/Ethics Committee of Ibn Sina University of Medical and Pharmaceutical Sciences.
The following primary diagnostic records will be obtained for each patient:

1- Pretreatment and post-treatment photographs.
2- Pretreatment and post-treatment lateral cephalometric radiographs.
3- Pretreatment and post-treatment digital dental models.

Additional diagnostic records will include:

1- A pretreatment hand–wrist radiograph.
2- Pretreatment and post-treatment cone-beam computed tomography (CBCT) scans.

Each patient will be instructed to wear the appliance for 20 hours per day over a treatment period of 3 months.
Written informed consent describing the treatment protocol will be obtained from the parent or legal guardian of each patient.
The following parameters will be assessed:

1- Overbite, overjet, intercanine width, and intermolar width, measured on digital dental models.
2- SNA, SNB, and ANB angles; AO–BO distance (Wits appraisal); and the A–B difference (Chang measurement), assessed on lateral cephalometric radiographs.
3- The interincisal angle, the angle between the upper incisor axis and the SN plane, and the angle between the lower incisor axis and the mandibular plane, assessed on lateral cephalometric radiographs.

4- Changes in condylar morphology and permanent first molar root length, assessed using CBCT, as detailed in Table 1.

Table 1. CBCT parameters measured.

No.	Parameter	Abbr.	Unit
1	Anterior joint space	AJS	mm
2	Superior joint space	SJS	mm
3	Depth of the glenoid fossa	DGF	mm
4	Sagittal condylar angle	SCA	°
5	Height of the condyle	HC	mm
6	Length of mandibular rami	LMR	mm

7	Length of mandibular body	LMB	mm
8	Width of mandibular rami	WMR	mm
9	Mandibular length	ML	mm
10	Medial joint space	MJS	mm
11	Lateral joint space	LJS	mm
12	Mandibular molar root length	HCA	°
13	Mand. molar root length	MRL	mm
14	Volume of the condyle	VC	mm^3

Statistical Analysis:

Statistical analyses will be performed using IBM SPSS Statistics. Continuous variables will be summarized as means and standard deviations (SDs). The normality of paired pretreatment–post-treatment differences will be assessed using the Shapiro–Wilk test. For normally distributed differences, paired-samples t-tests will be used to compare pretreatment and post-treatment measurements within the same patients, including digital model, cephalometric, and quantitative CBCT parameters. Mean differences, 95% confidence intervals, and corresponding p-values will be reported. Statistical significance will be set at a two-sided p-value of less than 0.05. If paired differences do not meet the normality assumption, the Wilcoxon signed-rank test will be considered. Any between-group comparisons required by the controlled trial design will be analyzed separately.

References

1. Alhammadi MS, Halboub E, Fayed MS, Labib A, El-Saaidi C. Global distribution of malocclusion traits: a systematic review. Dental Press J Orthod. 2018;23(6):40.e1–40.e10. doi:10.1590/2177-6709.23.6.40.e1-10.onl.

2. McNamara JA Jr. Components of Class II malocclusion in children 8–10 years of age. Angle Orthod. 1981;51(3):177–202.

3. Rédua RB. Different approaches to the treatment of skeletal Class II malocclusion during growth: Bionator versus extraoral appliance. Dental Press J Orthod. 2020;25(2):69–85. doi:10.1590/2177-6709.25.2.069-085.bbo.

4. Proffit WR, Fields HW, Larson BE, Sarver DM. Contemporary Orthodontics. 6th ed. Philadelphia: Elsevier; 2019.

5. O'Brien K, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw I. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. Am J Orthod Dentofacial Orthop. 2003;124(3):234–243. doi:10.1016/S0889-5406(03)00352-4.

6. O'Brien K, Wright J, Conboy F, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw I, Berk NW. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 2: Psychosocial effects. Am J Orthod Dentofacial Orthop. 2003;124(5):488–494. doi:10.1016/S0889-5406(03)00642-5.

7. Clark WJ. The Twin Block technique: a functional orthopedic appliance system. Am J Orthod Dentofacial Orthop. 1988;93(1):1–18. doi:10.1016/0889-5406(88)90188-6.

8. Mills CM, McCulloch KJ. Treatment effects of the Twin Block appliance: a cephalometric study. Am J Orthod Dentofacial Orthop. 1998;114(1):15–24. doi:10.1016/S0889-5406(98)70232-X.

9. Toth LR, McNamara JA Jr. Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. Am J Orthod Dentofacial Orthop. 1999;116(6):597–609. doi:10.1016/S0889-5406(99)70193-9.

10. Baccetti T, Franchi L, Toth LR, McNamara JA Jr. Treatment timing for Twin-block therapy. Am J Orthod Dentofacial Orthop. 2000;118(2):159–170. doi:10.1067/mod.2000.105571.

11. Franchi L, Baccetti T, McNamara JA Jr. Mandibular growth as related to cervical vertebral maturation and body height. Am J Orthod Dentofacial Orthop. 2000;118(3):335–340. doi:10.1067/mod.2000.107009.

12. Baccetti T, Franchi L, McNamara JA Jr. The cervical vertebral maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopedics. Semin Orthod. 2005;11(3):119–129. doi:10.1053/j.sodo.2005.04.005.

13. McNamara JA Jr, Franchi L. The cervical vertebral maturation method: a user's guide. Angle Orthod. 2018;88(2):133–143. doi:10.2319/111517-787.1.

14. O'Brien K, Wright J, Conboy F, Appelbe P, Davies L, Connolly I, Mitchell L, Littlewood S, Mandall N, Lewis D, Sandler J, Hammond M, Chadwick S, O'Neill J, McDade C, Oskouei M, Thiruvenkatachari B, Read M, Robinson S, Birnie D, Murray A, Shaw I, Harradine N, Worthington H. Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: a multi-center, randomized, controlled trial. Am J Orthod Dentofacial Orthop. 2009;135(5):573–579. doi:10.1016/j.ajodo.2007.10.042.

15. O'Brien K, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw I. Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. Am J Orthod Dentofacial Orthop. 2003;124(2):128–137. doi:10.1016/S0889-5406(03)00345-7.

16. Ehsani S, Nebbe B, Normando D, Lagravère MO, Flores-Mir C. Short-term treatment effects produced by the Twin-block appliance: a systematic review and meta-analysis. Eur J Orthod. 2015;37(2):170–176. doi:10.1093/ejo/cju030.

17. Koretsi V, Zymperdikas VF, Papageorgiou SN, Papadopoulos MA. Treatment effects of removable functional appliances in patients with Class II malocclusion: a systematic review and meta-analysis. Eur J Orthod. 2015;37(4):418–434. doi:10.1093/ejo/cju071.

18. D'Antò V, Bucci R, Franchi L, Rongo R, Michelotti A, Martina R. Class II functional orthopaedic treatment: a systematic review of systematic reviews. J Oral Rehabil. 2015;42(8):624–642. doi:10.1111/joor.12295.

19. Chen JY, Will LA, Niederman R. Analysis of efficacy of functional appliances on mandibular growth. Am J Orthod Dentofacial Orthop. 2002;122(5):470–476. doi:10.1067/mod.2002.126730.

20. Antonarakis GS, Kiliaridis S. Short-term anteroposterior treatment effects of functional appliances and extraoral traction on Class II malocclusion. Angle Orthod. 2007;77(5):907–914. doi:10.2319/061706-244.

21. Baysal A, Uysal T. Dentoskeletal effects of Twin Block and Herbst appliances in patients with Class II division 1 mandibular retrognathy. Eur J Orthod. 2014;36(2):164–172. doi:10.1093/ejo/cjt013.

22. Pacha MM, Fleming PS, Shagmani M, Johal A. The skeletal and dental effects of Hanks Herbst versus twin block appliances for class II correction in growing patients: a randomized clinical trial. Eur J Orthod. 2024;46(1):cjad065. doi:10.1093/ejo/cjad065.

23. Xu F, Fang Y, Sui X, Yao Y. Comparison of Twin Block appliance and Herbst appliance in the treatment of Class II malocclusion among children: a meta-analysis. BMC Oral Health. 2024;24:278. doi:10.1186/s12903-024-04027-w.

24. Shahbodaghi MR, Zali M, Behroozian A, Dadgar H. Comparison of the effect of clear twin block and traditional twin block on speech: a randomized clinical trial. Angle Orthod. 2024;94(6):608–614. doi:10.2319/030323-149.1.

25. Lombardo EC, Lione R, Franchi L, Gaffuri F, Maspero C, Cozza P, Pavoni C. Dentoskeletal effects of clear aligner vs twin block—a short-term study of functional appliances. J Orofac Orthop. 2024;85(5):317–326. doi:10.1007/s00056-022-00443-1.

26. Alsilq MN, Youssef M. Dentoskeletal effects of aesthetic and conventional twin block appliances in the treatment of skeletal class II malocclusion: a randomized controlled trial. Sci Rep. 2025;15:1879. doi:10.1038/s41598-025-86219-0.

27. Behroozian A, Pourahmad A, Zali M, Zandesh A. Comparison of dental effects of traditional and clear twin block: a randomized clinical trial. J Dent Res Dent Clin Dent Prospects. 2025;19(1):57–60. doi:10.34172/joddd.025.41445.

28. Alsilq MN, Youssef M. Soft tissue effects of aesthetic and conventional twin block appliances in the treatment of skeletal class II malocclusion: a randomized controlled trial. Sci Rep. 2025;15:37627. doi:10.1038/s41598-025-21538-w.

29. Haik AA, Yassir YA. A modified clear twin block appliance for treatment of class II malocclusion: a randomized clinical trial. Eur J Orthod. 2026;48(1):cjaf103. doi:10.1093/ejo/cjaf103.

30. Baccetti T. Malocclusions de classe II : bien choisir le moment du traitement pour optimiser l'effet orthopédique des appareils fonctionnels. Orthod Fr. 2010;81(4):279–286. doi:10.1051/orthodfr/2010026