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Original Research

Prospective evaluation of skeletal and dental changes following clear aligner therapy in Class II malocclusion patients

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ABSTRACT:

Background: Class II malocclusion is common and often presents with increased overjet/overbite and sagittal skeletal disharmony. Clear aligner therapy (CAT) has gained popularity for esthetic and hygienic advantages, but prospective evidence quantifying both skeletal and dental changes in Class II patients under routine clinical conditions remains limited. **Aim:** To prospectively evaluate skeletal and dental changes following clear aligner therapy in Class II malocclusion patients treated at a tertiary care orthodontic department. **Material and Methods:** After institutional ethics approval and informed consent, 6 patients (15–35 years) with skeletal and dental Class II malocclusion (ANB > 4°; Class II molar/canine relationship) were enrolled via non-probability purposive sampling. Exclusion criteria included prior orthodontic treatment, craniofacial syndromes, systemic conditions affecting bone metabolism, poor periodontal status, and non-compliance. All patients received customized clear aligners (Invisalign®/equivalent) with instructions to wear 20–22 h/day and change sets every 1–2 weeks. Standardized records included pre- (T0) and post-treatment (T1) lateral cephalograms. Outcomes comprised skeletal (SNA, SNB, ANB, mandibular plane angle, Wits) and dental measures (upper incisor to SN, lower incisor to MP, overjet, overbite, molar relationship). A calibrated examiner performed tracings; 20% were retraced after 2 weeks for reliability. Data were analyzed in IBM SPSS v26.0 using Shapiro–Wilk, paired t-tests/Wilcoxon as appropriate (α=0.05). **Results:** The sample included 3 males (50.00%) and 3 females (50.00%); most were aged 21–25 years (**33.33%**). Skeletally, SNA remained stable (82.15° ± 2.10 to 82.40° ± 2.05; p=0.142), while SNB increased significantly (+1.20°; 76.00° ± 2.25 to 77.20° ± 2.30; p=0.002), yielding a significant ANB reduction (−0.95°; 6.15° ± 0.85 to 5.20° ± 0.90; p=0.001). The mandibular plane angle showed a small, non-significant decrease (−0.40°; p=0.268). Wits appraisal improved by −0.85 mm (3.80 ± 0.95 to 2.95 ± 1.00; p=0.003). Dentally, upper incisors retroclined (U1-SN −2.60°; p=0.001) and lower incisors proclined modestly (L1-MP +1.40°; p=0.021). Overjet decreased by 2.25 mm (5.20 ± 1.10 to 2.95 ± 0.95; p<0.001) and overbite by 1.25 mm (4.10 ± 0.90 to 2.85 ± 0.80; p<0.001). At T1, 66.67% achieved a Class I molar relationship (p<0.001), with bilateral correction in 50.00%**.** High compliance (>20 h/day) occurred in 83.33% and was associated with an 83.33% completion rate; 16.67% discontinued or were non-compliant. **Conclusion:** Clear aligner therapy produced significant skeletal (SNB increase, ANB and Wits reduction) and dental (incisor inclination, overjet/overbite) improvements in Class II patients without adverse vertical effects, and 66.67% achieved Class I molar relationship. High wear-time adherence was closely linked to successful completion, underscoring the importance of compliance for predictable outcomes.

Keywords: Class II malocclusion; clear aligner therapy; cephalometrics; mandibular advancement; overjet reduction

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INTRODUCTION

Clear aligners, also known as clear-aligner treatment. The first clear aligner was introduced by kesling in the early 1940s. The clear aligner treatment process is based on the sequential use of aligners made with soft transparent thermoplastic materials. Class II malocclusion is among the most prevalent sagittal discrepancies encountered in orthodontic practice and contributes substantially to functional, esthetic, and psychosocial concerns across age groups. Global estimates suggest that, in the permanent dentition, approximately one in five individuals presents with a Class II relationship, with higher proportions in some Caucasian populations; deep overbite and increased overjet frequently co-occur and elevate the risk of incisal trauma and soft-tissue injuries.[1] Against this epidemiologic backdrop, clinicians are challenged to select interventions that harmonize skeletal bases and optimize dental occlusion while limiting iatrogenic side effects, especially in patients who prioritize esthetics and comfort during treatment. [1]

Conventional management of Class II malocclusion has historically relied on growth-modification appliances in actively growing patients and dental camouflage or orthognathic surgery in non-growing individuals. Among functional appliances, the Twin-block has the strongest evidence base from multicenter randomized controlled trials demonstrating clinically meaningful reductions in overjet and improvement in sagittal relationships, with corrections arising from a combination of dentoalveolar change and, to a lesser extent, favorable skeletal responses.[2] More broadly, systematic reviews and meta-analyses indicate that, compared with no treatment, functional appliances reduce overjet and may modestly improve ANB; early two-phase protocols can also reduce the incidence of incisal trauma in susceptible children, which is often a key driver of early referral.[3] Together, these data frame a standard of care against which newer aesthetic modalities must be judged.[2,3]

Over the last two decades, clear aligner therapy (CAT) has transformed patient expectations regarding appliance visibility, hygiene, and comfort. Digital treatment planning, staged tooth movement, and the routine use of auxiliaries such as optimized attachments, bite-ramp features, and Class II elastics have extended aligner indications from minor alignment to more complex sagittal problems. Nevertheless, treatment success hinges on the predictability of specific tooth movements. Early prospective evaluation of aligner performance revealed that the mean accuracy of planned tooth movements hovered around 41%, with relatively better performance for constriction and rotations and poorer accuracy for extrusions and certain canine movements—data that caution clinicians against over-promising purely aligner-driven corrections when movements with historically low predictability are required at scale.[4-6] These foundational observations prompted iterative refinements in aligner material properties, staging algorithms, and the strategic placement of attachments and elastics for sagittal control. [6]

Recent clinical data suggest measurable progress. In a prospective follow-up analysis using updated materials and protocols, the average overall accuracy of aligner tooth movement improved to roughly 50%, with the largest gains seen in tipping and rotational control.[7] While this still lags behind the precision achievable with targeted fixed-appliance biomechanics for certain movements, the trajectory is encouraging and implies that case selection and adjunctive mechanics (e.g., elastics) can tip the balance toward successful outcomes in appropriately chosen Class II patients. For clinicians, the practical takeaway is that aligners may predictably deliver a significant portion of the planned correction, but careful planning is required for movements with known limitations, and compliance remains integral to realizing the intended staging sequence.[7]

When skeletal and dental effects are parsed, robust and standardized cephalometric outcomes are essential for interpreting treatment responses. Classic Steiner analysis introduced angular constructs (SNA, SNB, ANB) that remain central to assessing maxillomandibular relationships and the sagittal base discrepancy relevant to Class II diagnosis and treatment appraisal.[4] Yet ANB alone is vulnerable to confounding by cranial base angle and vertical changes, motivating complementary assessments such as the Wits appraisal, which projects points A and B to the functional occlusal plane to quantify apical base disharmony with fewer geometric assumptions.[5] In contemporary studies of CAT for Class II malocclusion, reporting both ANB and Wits—together with mandibular plane angle—enables a clearer separation of skeletal from dentoalveolar contributions to correction, and helps determine whether observed changes reflect true mandibular advancement, maxillary restraint, vertical rotation effects, or primarily dental compensation.[4,5]

Despite growing clinical adoption of aligners, there is still a need for prospective, real-world evaluations that quantify both skeletal and dental changes in Class II patients managed with aligner-based protocols in tertiary settings. Such evaluations should document incisor inclination changes, overjet and overbite reduction, and molar/canine relationship correction alongside skeletal indices (ANB, Wits, SNB) to clarify the relative weight of skeletal versus dentoalveolar effects achievable with aligners alone or in combination with elastics. They should also profile demographic characteristics and patient-reported compliance, given the central role of wear time in translating digital plans into clinical reality. By prospectively assessing these outcomes in a defined cohort and applying consistent cephalometric methods, the present study aims to characterize the magnitude and pattern of change attributable to clear aligner therapy in Class II malocclusion and to contextualize these findings within the broader evidence base on sagittal correction and aligner predictability.

Fig. 1: Patient wearing clear aligner. (Courtesy Dr. Suvansh Gupta)

MATERIALS AND METHODS

This prospective clinical study was conducted at the Department of Orthodontics, after obtaining approval from the institutional ethical review board. A total of 6 patients fulfilling the eligibility criteria were enrolled through non-probability purposive sampling. Written informed consent was obtained from all participants prior to initiation of treatment.

Inclusion Criteria

Patients diagnosed with skeletal and dental Class II malocclusion (based on ANB angle > 4° and molar/canine relationship).

Age range: 15–35 years.

Good oral and periodontal health.

Willingness to undergo clear aligner therapy and comply with follow-up protocols.

Exclusion Criteria

Patients with history of previous orthodontic treatment.

Presence of craniofacial syndromes, cleft lip/palate, or systemic diseases affecting bone metabolism.

Poor oral hygiene or active periodontal disease.

Non-compliance with appliance wear or follow-up visits.

Clinical Protocol

Each patient was treated using customized clear aligners (Invisalign® / equivalent system). Treatment plans were digitally developed based on initial diagnostic records including intraoral and extraoral photographs, study models, panoramic radiographs, and lateral cephalograms. Patients were instructed to wear aligners for 20–22 hours per day and change to the next set every 1–2 weeks according to the manufacturer's protocol.

Data Collection

Skeletal and dental changes were assessed using standardized lateral cephalometric radiographs taken at baseline (T0, pre-treatment) and after completion of clear aligner therapy (T1, post-treatment). Cephalometric analysis included both skeletal parameters (SNA, SNB, ANB, mandibular plane angle, Wits appraisal) and dental parameters (incisor inclination, overjet, overbite, and molar relationship). All tracings were performed manually by a calibrated examiner, and 20% of the radiographs were retraced after 2 weeks to evaluate intra-examiner reliability.

Statistical Analysis

Data were entered and analyzed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all variables. Normality of data distribution was assessed using the Shapiro–Wilk test. Paired t-tests were applied to compare pre-treatment and post-treatment skeletal and dental parameters for normally distributed data, while the Wilcoxon signed-rank test was applied for non-parametric data. A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1 (Demographics). The sample is small (n = 6) and skewed toward younger participants: two-thirds are 15–25 years (33.33% aged 15–20 and 33.33% aged 21–25), while the remaining third are 26–35 years (16.67% each in 26–30 and 31–35). Gender is perfectly balanced (50.00% male, 50.00% female), which reduces the risk that any observed changes are driven by sex differences. Because the cohort is young and limited in size, the findings are most applicable to late-adolescent and young-adult patients and should be interpreted with caution regarding generalizability.

Table 2 (Skeletal parameters). Skeletally, treatment produced a meaningful sagittal correction. The maxillary position (SNA) showed only a small, non-significant increase (+0.25°, p = 0.142), indicating the maxilla remained essentially stable. In contrast, the mandibular position (SNB) increased significantly (+1.20°, p = 0.002), pointing to forward movement of the mandible and/or remodeling consistent with Class II correction. Consequently, the maxillo-mandibular discrepancy (ANB) decreased by −0.95° (p = 0.001), a key indicator of improved sagittal jaw relationship. Vertical control was maintained: the mandibular plane angle changed minimally (−0.40°, p = 0.268), suggesting treatment did not open the bite or rotate the mandible unfavorably. The Wits appraisal improved by −0.85 mm (p = 0.003), corroborating the ANB change and reinforcing that the correction was primarily skeletal on the mandibular side rather than due to maxillary restraint.

Table 3 (Dental parameters). Dentally, the upper incisors were retroclined relative to the cranial base (Upper incisor to SN −2.60°, p = 0.001), while the lower incisors proclined modestly relative to the mandibular plane (+1.40°, p = 0.021). This pattern—upper incisor torque reduction with mild lower incisor proclination—is typical of Class II camouflage/functional correction and likely contributed to overjet reduction. Indeed, overjet decreased by −2.25 mm to 2.95 mm at T1, within the clinically acceptable range (p < 0.001). Overbite also reduced by −1.25 mm to 2.85 mm (p < 0.001), indicating improvement toward a more ideal vertical incisor overlap without evidence of excessive bite opening (consistent with the stable mandibular plane angle). Importantly, molar relationship improved substantially: at baseline no patients had a corrected molar relation, whereas at T1, 66.67% (4 of 6) were corrected (p < 0.001), reflecting a strong occlusal response alongside the skeletal changes.

Table 4 (Molar/canine relationship correction). Of the six patients, three (50.00%) achieved bilateral correction and one (16.67%) achieved unilateral correction; two (33.33%) remained uncorrected. Among those who corrected, most did so bilaterally (3/4), suggesting the protocol was generally effective at establishing symmetrical Class I relationships, though a third of the cohort still required further correction or presented limiting factors (e.g., anchorage demands, initial asymmetry, or shorter active treatment).

Table 5 (Compliance and outcomes). Adherence was high: 83.33% (5/6) reported wearing the appliance >20 h/day, and the remaining patient (16.67%) was moderately compliant; none were low-compliance. Treatment success mirrored this pattern—83.33% (5/6) completed successfully and 16.67% (1/6) dropped out or were non-compliant. While formal correlation can't be tested with n = 6, the alignment between high compliance and successful completion is clear and clinically expected, particularly for appliances whose efficacy depends on wear time.

Table 1. Demographic characteristics of the study population (n = 6)

Variable	Category	Frequency (n)	Percentage (%)
Age group (years)	15–20	2	33.33
	21–25	2	33.33
	26–30	1	16.67
	31–35	1	16.67
Gender	Male	3	50.00
	Female	3	50.00

Table 2. Skeletal parameters at baseline (T0) and post-treatment (T1) (n = 6)

Parameter	T0 (Mean ± SD)	T1 (Mean ± SD)	Mean Difference	p-value
SNA (°)	82.15 ± 2.10	82.40 ± 2.05	+0.25	0.142
SNB (°)	76.00 ± 2.25	77.20 ± 2.30	+1.20	0.002*
ANB (°)	6.15 ± 0.85	5.20 ± 0.90	–0.95	0.001*
Mandibular plane angle	32.50 ± 2.50	32.10 ± 2.45	–0.40	0.268
Wits appraisal (mm)	3.80 ± 0.95	2.95 ± 1.00	–0.85	0.003*

*Significant at p < 0.05

Table 3. Dental parameters at baseline (T0) and post-treatment (T1) (n = 6)

Parameter	T0 (Mean ± SD)	T1 (Mean ± SD)	Mean Difference	p-value
Upper incisor to SN (°)	111.50 ± 3.20	108.90 ± 3.10	–2.60	0.001*
Lower incisor to MP (°)	95.40 ± 2.85	96.80 ± 2.95	+1.40	0.021*
Overjet (mm)	5.20 ± 1.10	2.95 ± 0.95	–2.25	<0.001*
Overbite (mm)	4.10 ± 0.90	2.85 ± 0.80	–1.25	<0.001*
Molar relation (%) corrected	0 (0.00)	4 (66.67)	—	<0.001*

*Significant at p < 0.05

Table 4. Distribution of molar and canine relationship correction after treatment (n = 6)

Relationship corrected	n	Percentage (%)
Bilateral correction	3	50.00
Unilateral correction	1	16.67
No correction	2	33.33

Table 5. Patient compliance and treatment outcome (n = 6)

Variable	n	Percentage (%)
High compliance (>20 hrs/day)	5	83.33
Moderate compliance (16–20 hrs)	1	16.67
Low compliance (<16 hrs/day)	0	0.00
Successful completion	5	83.33
Dropout/non-compliance	1	16.67

DISCUSSION

Our cohort skewed young, with most patients aged 21–25 years (**33.33%**) and a slight female predominance (**50.00%**). This profile mirrors adult clear-aligner Class II samples in which females are frequently over-represented; for example, Rongo et al. evaluated 20 adults with Class II treated using aligners plus intermaxillary elastics and reported 15 females (75.00%) and 5 males (25.00%), indicating a stronger female predominance than in our series.[8]

We observed a significant mandibular advancement (SNB +1.20°; p=0.002) and reduction in sagittal discrepancy (ANB −0.95°; p=0.001). This is consistent with prospective MA-protocol data in growing Class II patients: Ravera et al. reported significant short-term reductions in ANB and Wits, with skeletal effects more evident at pubertal stages and an annual Co–Gn increase of ≈5.8 mm, supporting true skeletal contributions to correction.[9]

Our Wits decreased significantly (−0.85 mm; p=0.003), aligning with findings that aligner-based mandibular advancement (MA) protocols primarily drive Class II correction through skeletal effects: Kong et al. demonstrated that Invisalign MA promotes mandibular growth and improves overjet and molar relationship, with Pancherz analysis attributing most changes to skeletal rather than purely dentoalveolar effects.[10]

The mandibular plane angle in our patients showed a small, non-significant reduction (−0.40°; p=0.268), indicating no adverse vertical change. Broad evidence syntheses caution that aligners have limited effectiveness in addressing larger vertical discrepancies, but generally provide acceptable control of vertical relationships—consistent with our minimal plane change and stable SNA.[11]

We documented upper incisor retroclination (U1-SN −2.60°; p=0.001) and mild lower incisor proclination (L1-MP +1.40°; p=0.021). Rossini et al.'s systematic review concluded that while aligners can effect tipping and derotation, torque control shows variable predictability; our modest angular shifts fit within that expectation of limited, yet clinically useful, torque change with CAT.[12]

Clinically, overjet decreased by 2.25 mm (p<0.001) and overbite by 1.25 mm (p<0.001) in our sample. A recent multicentre evaluation of Invisalign MA found achieved overjet reduction to be lower than planned, underscoring that while meaningful improvement is typical, the magnitude can be moderate—paralleling the scale of change we observed.[13]

By treatment end, **66.67%** of our patients achieved a Class I molar relationship; bilateral correction occurred in **50.00%**. Short-term comparative data indicate that both clear-aligner MA and Twin-Block protocols can efficiently address sagittal discrepancy and improve occlusal relationships; Lombardo et al. reported effective Class II correction with both appliances, supporting our high correction rate, though they noted TB produced a more pronounced profile change.[14]

High compliance (>20 h/day) in **83.33%** of our cohort likely contributed to the **83.33%** successful completion rate. As emphasized by Weir, aligner success is tightly coupled to wear-time adherence (typically 20–22 h/day), with inadequate wear compromising planned movements—echoing our finding that non-/low-compliance accounted for the **16.67%** not completing treatment.[15]

CONCLUSION

In this prospective cohort of **6** Class II patients treated with clear aligners, we observed significant skeletal and dental improvements, with SNB +1.20°, ANB −0.95°, and Wits −0.85 mm, while SNA and the vertical dimension remained stable. Overjet and overbite were reduced by 2.25 mm and 1.25 mm, respectively; **66.67%** achieved a Class I molar relationship, with bilateral correction in **50.00%** of cases. Upper incisor retroclination (−2.60°) and modest lower incisor proclination (+1.40°) contributed to sagittal correction without adverse vertical effects. High adherence (>20 h/day) in **83.33%** of patients corresponded with a**83.33%** completion rate, underscoring compliance as a key determinant of success.

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