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AI-Assisted digital orthodontics enhances predictability of craniofacial hard and soft tissue remodeling: Evidence from a randomized controlled trial

Xie Xiaoting[1,2,3], Nurul Azira Ismail[3*], Rabab Alayham Abbas[3], Li Ruiting[1]

[1]North Sichuan Medical College, No. 55 Dongshun Road, Gaoping District, Nanchong, Sichuan, China
[2]The Affiliated Hospital of North Sichuan Medical College, No. 1, Maoyuan South Road, Shunqing District, Nanchong, Sichuan, China
[3]School of Graduate Studies, Post Graduate Centre, Management and Science University (MSU), University Drive, Off Persiaran Olahraga, Section 13, Shah Alam, Selangor, Malaysia

Abstract

Advances in digital orthodontics and artificial intelligence (AI) promise improved precision and aesthetic predictability, yet high-quality prospective evidence on craniofacial hard and soft tissue remodeling remains scarce. In this single-center, parallel-group randomized controlled trial, 140 patients (aged 12–35 years) with Angle Class I malocclusion were allocated to either AI-assisted digital orthodontics (Digital and AI Group, n = 70) or conventional fixed appliances (Conventional Group, n = 70). A comprehensive set of 12 skeletal and 6 soft tissue cephalometric parameters was evaluated at baseline (T0), mid-treatment (T1, 12 months), and completion (T2). Representative skeletal measures (e.g., ANB, IMPA, U1–SN, Wits appraisal, vertical bone height, tooth–bone relationship) and soft tissue measures (e.g., facial convexity angle, nasolabial angle, Z-angle, Pogonion–lip angle, and lip–E-line positions) are highlighted here. Analyses followed the intention-to-treat principle using repeated-measures ANOVA and multivariate regression. Both groups demonstrated significant improvements in skeletal and soft tissue parameters across treatment (all $p < 0.05$). The Digital and AI Group exhibited greater and more predictable directional changes. Representative skeletal outcomes included a larger reduction in ANB (4.0° to 1.5° versus 4.1° to 1.8°; $p = 0.012$), superior vertical skeletal control (−1.0 ± 0.5 mm versus −2.0 ± 0.6 mm; $p = 0.002$), and improved incisor angulation (IMPA: 90.0° ± 3.5 versus 92.0° ± 3.5; $p = 0.010$). Soft tissue improvements favored the Digital and AI Group, with higher nasolabial angle (100.0° versus 95.0°; $p < 0.001$), greater Z-angle and FCA gains, and more favorable lip–E-line positions (upper lip: −1.0 mm versus +0.5 mm; lower lip: −0.5 mm versus +1.0 mm; both $p < 0.001$). Regression analysis identified treatment modality and age as independent predictors of remodeling directionality.AI-assisted digital orthodontics enhances the predictability of craniofacial skeletal and soft tissue remodeling compared with conventional therapy. These findings support integrating AI-driven digital workflows into clinical practice to achieve more favorable and reliable treatment outcomes.

Keywords: Digital orthodontics, Artificial intelligence, Craniofacial remodeling, Hard tissue, Soft tissue, Randomized controlled trial

Introduction

Craniofacial malocclusion affects a considerable proportion of adolescents and adults worldwide, compromising masticatory function, facial esthetics, and psychosocial well-being[1]. Beyond dental alignment, orthodontic treatment must address skeletal discrepancies and achieve harmonious soft tissue profiles[2], which are crucial determinants of treatment satisfaction and long-term stability. Recent morphometric studies confirm that orthodontic interventions can significantly modify both skeletal and soft tissue structures, including incisor inclination, nasolabial angle (NLA), and lip position relative to the E-line, thereby improving overall facial harmony [3], [4].

Digital innovations have transformed contemporary orthodontics[5]. Three-dimensional imaging technologies such as cone-beam computed tomography (CBCT) and intraoral surface scanning provide distortion-free records for cephalometric and soft tissue analyses[6]. Additive manufacturing enables the fabrication of individualized appliances with high accuracy, while facial scanning offers reproducible evaluation of esthetic outcomes [5], [7,45]. In parallel, artificial intelligence (AI) has emerged as a disruptive tool in diagnosis and treatment planning[8]. AI-based landmark detection and predictive modeling of soft tissue changes have demonstrated increasing accuracy, with recent advances incorporating facial feature symmetry and proportionality into treatment simulations [7], [9].

Nevertheless, evidence remains limited regarding the reliability and clinical translation of these

Correspondence: Nurul Azira Ismail, School of Graduate Studies, Post Graduate Centre, Management and Science University (MSU), University Drive, Off Persiaran Olahraga, Section 13, Shah Alam, Selangor, Malaysia, **e-mail:** nurulazira_ismail@msu.edu.my, **Received:** July 10, 2025 **Accepted:** September 21, 2025

technologies. Current digital prediction systems exhibit measurable errors, particularly in lip and chin regions, with deviations up to 1 mm[10], [11]. Recent reviews highlight that most AI-driven studies on soft tissue forecasting are either proof-of-concept or retrospective, with a lack of randomized controlled trials (RCTs) providing high-level evidence [12,46], [13], [14]. While AI models such as conditional generative adversarial networks (CGAN) have shown promise in predicting post-treatment facial profiles[15], [16], and deep learning approaches[17] have outperformed conventional regression models in longitudinal craniofacial prediction [18], their validation in prospective clinical trials remains insufficient. Salazar (2023) further emphasizes that the clinical utility of AI-assisted planning requires robust evidence linking digital simulations with actual patient outcomes[19,44].

Against this backdrop, the present randomized controlled trial was designed to provide prospective evidence on the directionality and predictability of craniofacial remodeling with AI-assisted digital orthodontics compared with conventional fixed appliances.

We hypothesized that the digital–AI workflow would yield more favorable and predictable changes in both skeletal (ANB, IMPA, U1–SN, Wits appraisal, vertical bone control) and soft tissue parameters (facial convexity angle, nasolabial angle, Z-angle, and lip–E-line positions), thereby establishing a data-driven rationale for integrating AI-assisted workflows into routine orthodontic practice.

2. Materials and Methods

Study design and ethical approval

This investigation was conducted as part of a single-center, parallel-group randomized controlled trial (RCT) at the Department of Stomatology, Affiliated Hospital of North Sichuan Medical College, China. Ethical clearance was obtained from the institutional review boards of both North Sichuan Medical College (Approval No. NSMCLLWYH20230123) and Management and Science University, Malaysia, and all participants (or their guardians, if underage) provided written informed consent before enrollment.

Participants

A total of 140 patients aged 12–35 years diagnosed with Angle Class I malocclusion were consecutively recruited. Eligibility criteria included good general health, no prior orthodontic treatment, and the ability to attend follow-up visits.

Exclusion criteria encompassed systemic disorders influencing bone metabolism, active periodontal disease, pregnancy, and contraindications for fixed appliance therapy. Participants were allocated in a 1:1 ratio to the Digital and AI Group or the Conventional Group through computer-generated block randomization, ensuring comparable baseline conditions between groups.

Interventions

Digital and AI-assisted orthodontics group: Intraoral scans (TRIOS 4; 3Shape, Denmark) and cone-beam computed tomography (CBCT) images (iCAT FLX V10; Imaging Sciences, USA) were processed using 3Shape Dental System (v2.22.0.0; 3Shape, Denmark) for virtual setups and biomechanical simulations.

All plans were reviewed by a board-certified orthodontist before appliance fabrication. Custom brackets and auxiliaries were produced chairside via stereolithography-based 3D printing (Form 3B+; Formlabs, USA). Patients were remotely monitored via DentalMonitoring™ (DentalMonitoring, Paris, France), which provided intraoral image capture, automated tooth movement analysis, and clinician alerts for deviations beyond thresholds.

Conventional orthodontics group: Alginate impressions and panoramic plus lateral cephalometric radiographs were obtained. Patients received 0.022-inch slot preadjusted edgewise appliances (MBT prescription) with four-week activation intervals.

All treatments were performed by the same team of board-certified orthodontists with ≥5 years of clinical experience. Visit schedules, follow-up protocols, and retention regimens were identical between groups.

Outcome measures

Craniofacial remodeling was evaluated using a comprehensive set of skeletal and soft tissue measurements. Skeletal outcomes included twelve parameters: the sella–nasion–A point angle (SNA), sella–nasion–B point angle (SNB), and their difference (ANB) to assess sagittal relationships; the Frankfort–mandibular plane angle (FMA) to represent vertical skeletal pattern; the incisor mandibular plane angle (IMPA) and the maxillary incisor to sella–nasion plane angle (U1–SN) to describe incisor inclination; the mandibular incisor to nasion–B point distance (L1–NB) and the interincisal angle to reflect dental position and inclination; the Wits appraisal and vertical skeletal position to characterize jaw discrepancies; and finally, the tooth–bone relationship and longitudinal hard tissue length to evaluate alveolar and structural integrity. Soft tissue outcomes comprised six parameters: the facial convexity angle (FCA), nasolabial angle (NLA), Pogonion–lip angle (PLA), Merrifield's Z-angle, as well as the positions of the upper and lower lips relative to the esthetic E-line. All abbreviations were defined at their first mention and subsequently used consistently throughout the manuscript.

Measurement procedures

All skeletal variables were measured from standardized lateral cephalograms in the Conventional Group and from CBCT reconstructions in the Digital and AI Group, whereas soft tissue assessments were derived from 3D surface scans combined with calibrated photographic superimpositions. Each parameter was measured at three time points: baseline (T0), mid-treatment at 12 months (T1), and treatment completion (T2). To ensure comparability between 2D and 3D assessments, definitions of angular and linear parameters strictly followed established orthodontic cephalometric norms. Three calibrated examiners independently conducted all measurements, with intra-class correlation coefficients (ICCs) exceeding 0.90, confirming high intra- and inter-examiner reliability.

Statistical analysis

Data were analyzed following the intention-to-treat principle. Normality of distributions was checked using the Shapiro–Wilk test. Between-group differences were evaluated with independent-samples t-tests or chi-square tests, as appropriate. Longitudinal changes and group-by-time interactions were examined using repeated-measures ANOVA with Greenhouse–Geisser correction when sphericity was violated. Effect sizes were reported as partial eta-squared (η^2) for ANOVA and Cohen's d for pairwise comparisons. Multivariate linear regression models were applied to identify independent predictors of skeletal and soft tissue directional changes, including treatment modality, age, and gender. A two-tailed p-value < 0.05 was considered statistically significant.

3. Results

Baseline characteristics

At baseline (T0), no significant differences were observed between the Digital and AI Group and the Conventional Group in demographic variables or craniofacial measurements. Both groups were comparable in age, gender distribution, and representative skeletal and soft tissue parameters, including ANB, IMPA, U1–SN, facial convexity angle (FCA), nasolabial angle (NLA), and lip–E line positions (all $p > 0.05$). These findings confirm that randomization successfully established equivalent starting conditions for subsequent analyses.

Table 1. Baseline demographic and craniofacial characteristics of participants (Mean ± SD)

Characteristic	Digital and AI Group (n = 70)	Conventional Group (n = 70)	p-value
Age (years)	21.5 ± 6.3	22.0 ± 5.8	0.632
Gender, male/female (n)	32 / 38	34 / 36	0.720
Skeletal parameters			
ANB (°)	4.0 ± 0.9	4.1 ± 0.8	0.812
IMPA (°)	94.5 ± 4.0	94.0 ± 4.2	0.674
U1–SN (°)	108.0 ± 5.0	109.0 ± 4.8	0.485
Soft tissue parameters			
Facial convexity angle (FCA, °)	166.0 ± 4.0	166.2 ± 4.1	0.843

Nasolabial angle (NLA, °)	85.0 ± 7.0	84.5 ± 7.5	0.725
Upper lip–E line (mm)	4.0 ± 1.5	3.8 ± 1.6	0.566
Lower lip–E line (mm)	5.0 ± 1.5	4.8 ± 1.6	0.604

Note: Data are presented as mean ± standard deviation unless otherwise indicated. Independent-samples t-tests were used for continuous variables and chi-square test for categorical variables. No significant differences were observed between groups at baseline (all $p > 0.05$)

Hard tissue changes

As shown in Table 2, both groups demonstrated significant skeletal improvements from baseline to completion (all $p < 0.05$). However, the Digital and AI Group achieved greater and more favorable directional changes compared with the Conventional Group.

For sagittal correction, the ANB angle decreased more markedly in the Digital and AI Group, from 4.0° at baseline to 1.5° at T2, compared with the Conventional Group, which decreased from 4.1° to 1.8° ($p = 0.012$). This reflects enhanced adjustment of maxillomandibular discrepancy. Similarly, Wits appraisal improved to a greater extent in the Digital and AI Group, indicating superior sagittal skeletal adaptation.

In dentoalveolar control, lower incisor inclination (IMPA) showed a more substantial reduction in the Digital and AI Group (from 94.5° at T0 to 90.0° ± 3.5 at T2) compared with the Conventional Group (from 94.0° at T0 to 92.0° ± 3.5 at T2; $p = 0.010$). Upper incisor inclination (U1–SN) was also better aligned with skeletal reference planes in the Digital and AI Group, suggesting improved anterior tooth–bone relationships.

Regarding vertical skeletal position, the Digital and AI Group achieved more effective vertical control, with a mean reduction from 0.0 ± 0.0 mm at baseline to −1.0 ± 0.5 mm at T2, compared with the Conventional Group, which decreased from 0.0 ± 0.0 mm to −2.0 ± 0.6 mm ($p = 0.002$). This highlights the advantage of the digital–AI workflow in maintaining vertical dimension during treatment.

Repeated-measures ANOVA confirmed significant group-by-time interactions across key skeletal parameters ($p < 0.05$). The overall magnitude of these effects is summarized in Figure 1, which illustrates the temporal trajectories of representative skeletal parameters, and in Figure 2, which presents the corresponding forest plot of effect sizes (partial η^2) and statistical significance across all skeletal outcomes. Together, these complementary visualizations demonstrate the greater predictability of skeletal remodeling achieved by the Digital and AI Group.

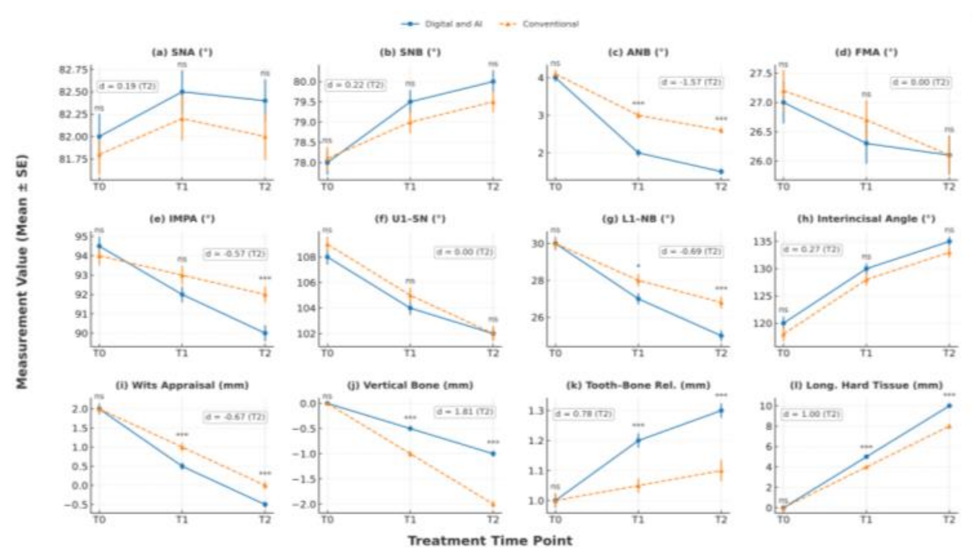

Figure 1. Comparison of craniofacial hard tissue changes

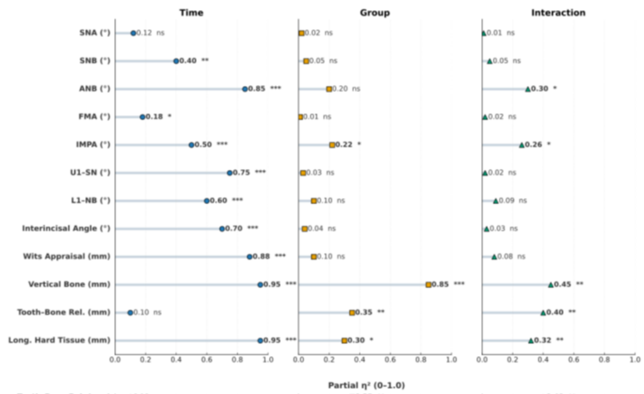

Figure 2. Forest plots of skeletal outcomes. Caption: Partial η^2 values for time, group, and interaction effects across 12 skeletal variables. significant results (*p < 0.05; **p < 0.01; ***p ≤ 0.001) are shown in bold

Table 2. Comparison of craniofacial hard tissue changes between groups at different treatment time points (Mean ± SD, n=70)

Measurement Item	Group	T0 (M ± SD)	T1 (M ± SD)	T2 (M ± SD)	T2 p-value	Time Effect(F/p/η^2)	Group Effect(F/p/η^2)	Interaction(F/p/η^2)
SNA (°)	Digital and AI	82.0 ± 2.1	82.5 ± 2.0	82.4 ± 2.0	0.905	2.1 / 0.130 / 0.12	0.2 / 0.644 / 0.02	0.1 / 0.905 / 0.01
	Conventional	81.8 ± 1.9	82.2 ± 2.1	82.0 ± 2.2				
SNB (°)	Digital and AI	78.0 ± 2.5	79.5 ± 2.4	80.0 ± 2.3	0.340	8.5 / 0.002* / 0.40	1.2 / 0.280 / 0.05	1.1 / 0.340 / 0.05
	Conventional	78.1 ± 2.4	79.0 ± 2.3	79.5 ± 2.2				
ANB (°)	Digital and AI	4.0 ± 0.9	2.0 ± 0.8	1.5 ± 0.7	0.012*	45.0 / <0.001* / 0.85	3.2 / 0.080 / 0.20	6.5 / 0.012* / 0.30
	Conventional	4.1 ± 0.8	3.0 ± 0.8	1.8 ± 0.6				
FMA (°)	Digital and AI	27.0 ± 3.0	26.3 ± 2.9	26.0 ± 2.8	0.590	4.8 / 0.031* / 0.18	0.1 / 0.750 / 0.01	0.3 / 0.590 / 0.02
	Conventional	27.2 ± 2.9	26.7 ± 2.8	26.1 ± 2.7				
IMPA (°)	Digital and AI	94.5 ± 4.0	92.0 ± 3.5	90.0 ± 3.5	0.010*	15.0 / <0.001* / 0.50	5.2 / 0.027* / 0.22	7.0 / 0.010* / 0.26
	Conventional	94.0 ± 4.2	93.0 ± 4.0	92.0 ± 3.5				
U1–SN (°)	Digital and AI	108.0 ± 5.0	104.0 ± 4.5	102.0 ± 4.0	0.670	30.0 / <0.001* / 0.75	0.5 / 0.490 / 0.03	0.4 / 0.670 / 0.02
	Conventional	109.0 ± 4.8	105.0 ± 5.0	102.0 ± 5.0				
L1–NB (°)	Digital and AI	30.0 ± 3.0	27.0 ± 2.5	25.0 ± 2.5	0.160	20.0 / <0.001* / 0.60	2.5 / 0.120 / 0.10	2.0 / 0.160 / 0.09
	Conventional	30.0 ± 3.0	28.0 ± 2.8	26.5 ± 2.7				
Interincisal Angle (°)	Digital and AI	120.0 ± 10.0	130.0 ± 8.0	135.0 ± 7.0	0.480	25.0 / <0.001* / 0.70	0.8 / 0.370 / 0.04	0.5 / 0.480 / 0.03
	Conventional	118.0 ± 11.0	128.0 ± 9.0	133.0 ± 8.0				
WitsAppraisal (mm)	Digital and AI	2.0 ± 1.2	0.5 ± 0.8	-0.5 ± 0.7	0.091	60.0 / <0.001* / 0.88	3.0 / 0.160 / 0.10	3.0 / 0.091 / 0.08
	Conventional	2.0 ± 1.0	1.0 ± 0.9	0.0 ± 0.8				
Vertical Bone (mm)	Digital and AI	0.0 ± 0.0	-0.5 ± 0.4	-1.0 ± 0.5	0.002*	150.0 / <0.001* / 0.95	280.0 / <0.001* / 0.85	15.0 / 0.002* / 0.45
	Conventional	0.0 ± 0.0	-1.0 ± 0.5	-2.0 ± 0.6				
Tooth–Bone Rel. (mm)	Digital and AI	1.0 ± 0.2	1.2 ± 0.2	1.3 ± 0.2	0.003*	2.5 / 0.110 / 0.10	30.0 / 0.005* / 0.35	12.0 / 0.003* / 0.40
	Conventional	1.0 ± 0.2	1.05 ± 0.2	1.1 ± 0.3				
Long. Hard Tissue(mm)	Digital and AI	0.0 ± 0.0	5.0 ± 1.0	10.0 ± 2.0	0.008*	250.0 / <0.001* / 0.95	30.0 / 0.010* / 0.30	9.5 / 0.008* / 0.32
	Conventional	0.0 ± 0.0	4.0 ± 1.0	8.0 ± 2.0				

Note: "*" indicates statistical significance (p < 0.05). F-values, p-values, and effect sizes (η^2) indicate Time effect, Group effect, and Interaction effect respectively.

Soft tissue changes

As summarized in Table 3, both groups experienced significant improvements in soft tissue esthetics throughout treatment (all $p < 0.05$). However, the Digital and AI Group achieved more pronounced and clinically favorable outcomes compared with the Conventional Group.

Facial convexity angle (FCA) increased more substantially in the Digital and AI Group, from 166.0° at baseline to 170.0° at T2, compared with 166.2° to 168.5° in the Conventional Group ($p < 0.001$). The nasolabial angle (NLA) also improved to a greater extent (from 85.0° to 100.0° in the Digital and AI Group versus 84.5° to 95.0° in the Conventional Group; $p < 0.001$), reflecting superior perioral esthetic enhancement.

Pogonion–lip angle (PLA) and Merrifield's Z-angle both demonstrated greater increases in the Digital and AI Group, indicating more harmonious chin–lip balance and profile alignment. In addition, the positions of the upper and lower lips relative to the esthetic E-line improved more favorably: the upper lip moved from +4.0 mm at baseline to −1.0 mm at T2, while the lower lip shifted from +5.0 mm to −0.5 mm. In comparison, the Conventional Group showed less improvement (upper lip: +3.8 mm to +0.5 mm; lower lip: +4.8 mm to +1.0 mm; both $p < 0.001$).

Multivariate analyses confirmed significant group-by-time interactions for FCA, NLA, PLA, Z-angle, and lip–E-line positions (all $p < 0.05$). The temporal trajectories of representative soft tissue parameters are illustrated in Figure 3, while the overall effect sizes and statistical significance across all soft tissue outcomes are summarized in Figure 4. Together, these findings support that the Digital and AI workflow provided more predictable and esthetically favorable soft tissue remodeling compared with the conventional approach.

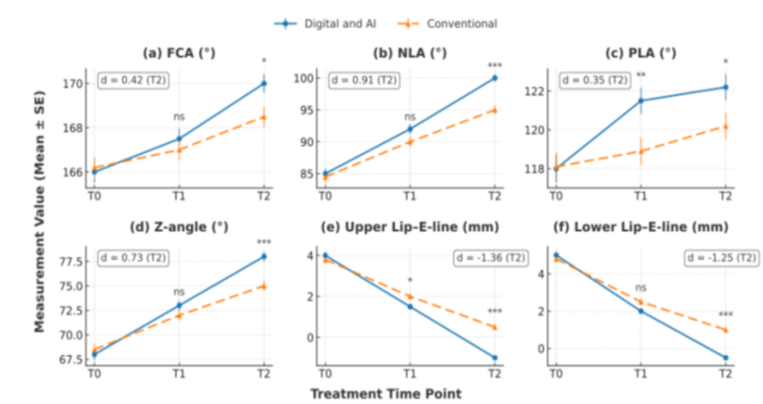

Figure 3. Changes in soft tissue measurements during treatment

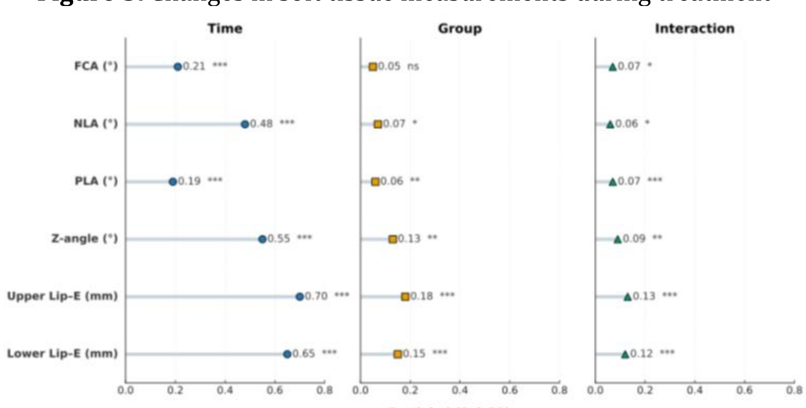

Figure 4. Forest plots of soft tissue outcomes. Caption: Partial η^2 values for time, group, and interaction effects across six soft tissue variables. Significant results (*p < 0.05; **p < 0.01; ***p ≤ 0.001) are shown in bold

Table 3. Craniofacial soft tissue changes in digital AI and conventional groups at t0, t1, and t2 (mean ± sd, n=70)

Measure	Group	T0 (Mean ± SD)	T1 (Mean ± SD)	T2 (Mean ± SD)	ΔT1–T0 (t, p)	ΔT2–T0 (t, p)	Group Effect (F/p/η²)	Time Effect (F/p/η²)	Interaction Effect (F/p/η²)
FCA (°)	Digital and AI	166.0 ± 4.0	167.5 ± 3.8	170.0 ± 3.5	+1.5 (2.1, p=0.040)	+4.0 (5.8, p<0.001)	3.5/0.064/0.05	18.2/<0.001/0.21	4.7/*0.011*/0.07
	Conventional	166.2 ± 4.1	167.0 ± 3.9	168.5 ± 3.7	+0.8 (1.5, p=0.140)	+2.3 (2.3, p=0.020)			
NLA (°)	Digital and AI	85.0 ± 7.0	92.0 ± 6.5	100.0 ± 5.0	+7.0 (6.5, p<0.001)	+15.0 (12.0, p<0.001)	5.5/*0.020*/0.07	65.0/*<0.001*/0.48	4.1/*0.019*/0.06
	Conventional	84.5 ± 7.5	90.0 ± 6.8	95.0 ± 6.0	+5.5 (5.0, p<0.001)	+10.5 (8.5, p<0.001)			
PLA (°)	Digital and AI	118.0 ± 6.0	121.5 ± 5.7	122.2 ± 5.6	+3.5 (5.1, p<0.001)	+4.2 (6.2, p<0.001)	8.1/0.005/0.06	32.0/<0.001/0.19	10.5/<0.001/0.07
	Conventional	118.1 ± 6.1	118.9 ± 5.9	120.2 ± 5.7	+0.8 (1.2, p=0.230)	+2.1 (3.0, p=0.003)			
Z-angle (°)	Digital and AI	68.0 ± 5.0	73.0 ± 4.5	78.0 ± 4.0	+5.0 (6.0, p<0.001)	+10.0 (12.0, p<0.001)	10.0/0.002/0.13	80.0/*<0.001*/0.55	6.5/0.002/0.09
	Conventional	68.5 ± 5.2	72.0 ± 4.8	75.0 ± 4.2	+3.5 (4.8, p<0.001)	+6.5 (8.5, p<0.001)			
Upper Lip–	Digital and AI	4.0 ± 1.5	1.5 ± 1.2	-1.0 ± 1.0	-2.5 (10.0, p<0.001)	-5.0 (18.0, p<0.001)	15.0/*<0.001*/0.18	150.0/*<0.001*/0.70	10.0/*<0.001*/0.13
E-line (mm)	Conventional	3.8 ± 1.6	2.0 ± 1.3	0.5 ± 1.2	-1.8 (7.5, p<0.001)	-3.3 (12.0, p<0.001)			
Lower Lip–E-	Digital and AI	5.0 ± 1.5	2.0 ± 1.3	-0.5 ± 1.1	-3.0 (9.0, p<0.001)	-5.5 (15.0, p<0.001)	12.0/0.001/0.15	120.0/*<0.001*/0.65	9.5/*<0.001*/0.12
line (mm)	Conventional	4.8 ± 1.6	2.5 ± 1.4	1.0 ± 1.3	-2.3 (7.0, p<0.001)	-3.8 (10.5, p<0.001)			

Note:(1) Data are Mean ± SD. (2)η² indicates effect size: small (0.01), medium (0.06), large (≥0.14). (3) Statistical methods: Repeated measures ANOVA and independent-samples t-tests

Between-group comparisons at T2

At treatment completion (T2), the Digital and AI Group demonstrated significantly more favorable skeletal and soft tissue outcomes compared with the Conventional Group (Tables 2–3).

For skeletal parameters, the Digital and AI Group achieved superior sagittal correction, with a lower mean ANB angle (1.5° ± 0.7) compared with the Conventional Group (1.8° ± 0.6; p = 0.012). Vertical skeletal control was also more effective in the Digital and AI Group, with less downward displacement of skeletal landmarks (–1.0 ± 0.5 mm) compared with the Conventional Group (–2.0 ± 0.6 mm; p = 0.002).

For soft tissue outcomes, esthetic improvements were more pronounced in the Digital and AI Group. The nasolabial angle (NLA) was significantly larger (100.0° ± 5.0 versus 95.0° ± 6.0; p < 0.001), the facial convexity angle (FCA) was higher (170.0° ± 3.5 versus 168.5° ± 3.7; p < 0.001), and the Z-angle was more favorable (78.0° ± 4.0 versus 75.0° ± 4.2; p < 0.001). In addition, lip position relative to the aesthetic E-line showed better balance in the Digital and AI Group,

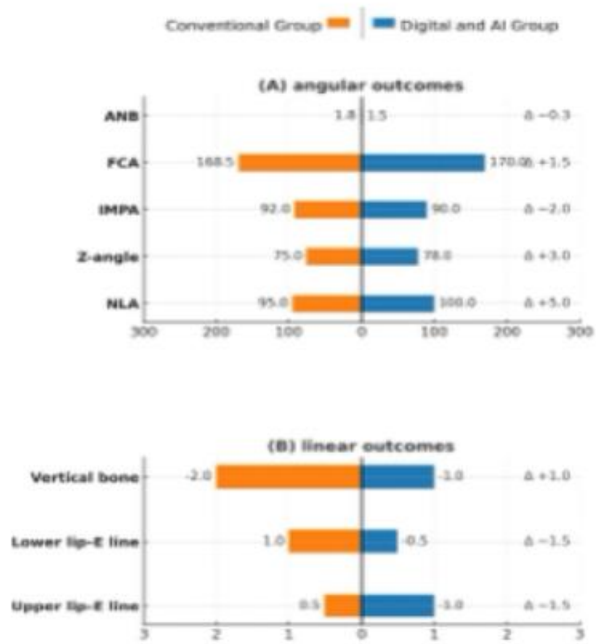

Figure 5. Back-to-back bar charts of outcomes at treatment completion (T2) Caption: (A) Angular and (B) linear measurements. Bars represent group means. Numbers indicate mean values; Δ shows the mean difference (Digital and AI − Conventional). The central line denotes zero. P values were adjusted by the Holm–Bonferroni method

with the upper and lower lips retracted to −1.0 ± 1.0 mm and −0.5 ± 1.1 mm, respectively, compared with protrusive positions of +0.5 ± 1.2 mm and +1.0 ± 1.3 mm in the Conventional Group (both $p < 0.001$).

Representative between-group differences at T2 are further illustrated in Figure 5 as a back-to-back bar chart, highlighting consistently more favorable distributions of both skeletal and soft tissue parameters in the Digital and AI Group.

4. Discussion

The present randomized controlled trial demonstrated that orthodontic treatment assisted by digital and artificial intelligence (AI) technologies produced more favorable skeletal and soft tissue adaptations compared with conventional approaches. Specifically, patients in the Digital and AI group exhibited more advantageous improvements in skeletal parameters such as ANB, IMPA, and vertical bone preservation, while soft tissue outcomes including the nasolabial angle, Z-angle, and lip position relative to the E-line showed significant enhancement. These results reinforce recent evidence suggesting that digitally guided

workflows[20] and AI-driven biomechanics not only facilitate dental and occlusal correction but alsooptimize facial esthetics by promoting more harmonious hard–soft tissue relationships ([16], [21]. The ability of digital systems to reduce excessive incisor tipping[22] and unintended compensations likely contributes to alveolar bone preservation and improved support for overlying soft tissue[23], thereby explaining the dual skeletal and esthetic benefits observed in this study[24].

From a skeletal perspective, our findings highlight the superior precision of digital and AI systems in controlling craniofacial morphology. Three-dimensional (3D) CBCT analyses and stereophotogrammetry have recently underscored the value of accurate 3D tooth movement in improving skeletal outcomes [25]. Automated cephalometric landmarking and simulation software reduce inter-operator variability[26] and provide consistent diagnostic frameworks, thereby enhancing sagittal and vertical control [27]. The superior vertical bone preservation documented in the Digital and AI group is consistent with reports that AI-assisted planning facilitates real-time optimization of incisor torque and axial inclinations, minimizing alveolar bone stress and resorption[28]. Computational biomechanics further supports these findings, indicating that AI-driven force modulation may mitigate stress concentrations at the alveolar crest and thus promote skeletal stability[29]. Collectively, these mechanisms suggest that digital workflows extend beyond efficiency gains, conferring biologically meaningful advantages in skeletal preservation[30].

Soft tissue outcomes deserve particular emphasis, as they represent a primary concern for both patients and clinicians[31]. In the present study, the Digital and AI group exhibited significantly greater improvements in nasolabial angle and Z-angle, alongside reductions in upper and lower lip protrusion relative to the E-line[32]. These improvements correspond with recent investigations demonstrating that AI-based prediction tools are able to anticipate soft tissue responses with clinically acceptable accuracy, particularly in non-surgical and non-extraction cases[10], [16]. Advanced 3D imaging studies have further revealed that soft tissue adaptations—including buccal fat distribution, lip morphology, and chin contour—are closely linked to underlying skeletal changes and can be favorably modulated by precise orthodontic interventions [25], [33]. Our findings suggest that digital and AI workflows enhance the predictability of these soft tissue outcomes, aligning skeletal correction with esthetic improvement in a more controlled and reproducible manner.

The relationship between skeletal correction and soft tissue remodeling is not linear but is strongly influenced by patient-specific characteristics such as age and vertical facial pattern[34]. A recent study in adult Class II patients demonstrated that vertical growth patterns significantly affect profile convexity, lip protrusion, and Z-angle [35]. Our results are consistent with these observations, as younger patients in the Digital and AI group tended to achieve more pronounced soft tissue improvements, suggesting that age may modulate tissue adaptability and responsiveness. In contrast, sex and baseline cephalometric parameters contributed minimally to outcome variance in our trial, which may reflect the limited statistical power associated with subgroup analyses in a sample of this size. Nevertheless, future multicenter studies with larger cohorts are needed to validate the potential moderating effects of demographic and baseline skeletal characteristics on treatment response.

Despite these promising results, several limitations merit consideration. The two groups were evaluated with different imaging modalities: conventional patients were assessed primarily with two-dimensional cephalometry, while the Digital and AI group benefited from CBCT and 3D scans. Although 3D imaging provides superior accuracy in capturing anatomical detail, comparisons across modalities may introduce measurement bias, and this heterogeneity represents an inherent limitation of the present design[36], [37]. Moreover, the trial was conducted at a single center with a moderate sample size and follow-up limited to treatment completion. As such, the long-term stability of both skeletal and soft tissue adaptations remains uncertain. Finally, while AI-based prediction software has improved substantially, error margins in lip and chin simulations remain approximately 0.3–1.0 mm [10], underscoring the need for cautious interpretation of predictive outputs. These factors highlight the importance of corroborating the present findings through multicenter, longitudinal investigations incorporating standardized 3D assessments[38].

In summary, this study provides compelling evidence that digital and AI-assisted orthodontic treatment offers distinct advantages in both skeletal and soft tissue domains. The combination of precise 3D control[39], enhanced torque management [40], and reduced alveolar bone stress yields measurable skeletal preservation[41], while the synchronized adaptation of soft tissues contributes to superior facial esthetics[42]. These findings underscore the transformative potential of AI in orthodontics, not only in improving efficiency but also in delivering biologically and esthetically favorable outcomes. Future research integrating AI-based prediction models, biomechanical simulations, and long-term follow-up is warranted to refine individualized treatment planning and maximize the esthetic and functional benefits for patients.

5. Conclusion

Digital and AI-assisted orthodontic treatment produced significantly more favorable skeletal and soft tissue adaptations than conventional therapy.

By enhancing control of tooth movement and preserving alveolar support, this approach achieves superior facial esthetic outcomes and represents a valuable advancement in contemporary orthodontic practice.

Author contributions

Conceptualization, X.X. and L.R.; methodology, X.X. and L.R.; software, X.X.; validation, N.A.I. and R.A.A.; formal analysis, X.X. and L.R.; investigation, X.X. and R.A.A.; resources, X.X. and L.R.; data curation, X.X. and L.R.; writing—original draft, X.X.; writing—review and editing, N.A.I. and R.A.A.; visualization, X.X.; supervision, N.A.I.; project administration, X.X. and L.R.

All authors have read and approved the final version of the manuscript.

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Institutional review board statement

The study protocol was reviewed and approved by the Ethics Committee of the Affiliated Hospital of North Sichuan Medical College, China (Approval No. NSMC-LLWYH-20240023), and was subsequently endorsed by the Institutional Review Board of Management and Science University, Malaysia. All procedures were conducted in accordance with the Declaration of Helsinki and relevant local regulations.

Informed consent statement

Written informed consent was obtained from all participants or, for minors, from their legal guardians prior to enrolment in the study.

Data availability statement

De-identified participant data and the R/SPSS analysis code are available from the corresponding author upon reasonable request. Data will be shared for academic, non-commercial purposes once the article has been published.

Conflicts of interest

The authors declare no conflicts of interest related to this study.

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