Efficacy Evaluation of Clear Aligner Therapy Using a 3D Fusion Model: A Large-Scale Retrospective Analysis

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Abstract

Background: Investigating the safe range of orthodontic tooth movement is crucial for the stability of the oral and maxillofacial system following orthodontic treatment. Clear aligner orthodontic technology utilizes a goal-oriented pre-treatment model, yet its effects on periodontal hard tissues during orthodontic treatment remain uncertain. By combining the cervical and root portions obtained from Cone Beam Computed Tomography (CBCT) with the crown portions acquired from digital intraoral scanning (IOS) data, a fusion model can be constructed that meets the needs for precision and safety in tooth movement.

Objective: This study aims to construct a three-dimensional (3D) fusion model based on artificial intelligence (AI) software that matches CBCT and intraoral scanning data using the Andrews six element standard. The model will be utilized to assess the three-dimensional effects of clear aligners on tooth movement, to provide a reference for the design of pre-treatment target positions.

Methods: A total of 136 cases were analyzed, comparing pre-treatment models (simulation models) and post-treatment models (fusion models) to evaluate the effects of gender, age stage, and treatment method on tooth movement following clear aligner therapy.

Results: No statistically significant differences were observed in total scores across the gender, age stage, and treatment method groups. However, individual item scores revealed that adolescents exhibited smaller differences in Upper Core Discrepancy (UCD), Upper Anterior teeth Width discrepancy (UAW), Upper Canine Width discrepancy (UCW) and Upper Molar Width discrepancy (UMW) compared to adults, but greater differences in Upper incisors Antero-Posterior discrepancy (UAP) and Lower Spee curve Deep discrepancy (LSD) ($P<.001$). In extraction cases, smaller differences were noted in LSD, UAW, and UCW, while more significant differences were observed in UMW compared to non-extraction cases ($P<.001$).

Conclusions: The 3D fusion model provides a reliable clinical reference for target position design and treatment outcome evaluation in clear aligner systems. The construction and application of 3D fusion model in clear aligner orthodontics represent a significant leap forward, offering substantial clinical benefits while establishing a new standard for precision, personalization, and evidence-based treatment planning in the field. Clinical Trial: This clinical Trial approval from the Medical Ethics Committee (Approval number? KYKQ2022MEC0046)

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KEYWORDS

clear aligners; CBCT; intraoral scanning; fusion model; artificial intelligence; efficacy evaluation

Introduction

Background

Alveolar bone remodeling is closely linked to orthodontic treatment. Investigating the safe range of orthodontic tooth movement is crucial for the stability of the oral and maxillofacial system following such treatment.

Previous studies aimed at evaluating tooth alignment have primarily focused on clinical crown alignment, often neglecting root alignment, except when using panoramic X-rays to assess root parallelism. However, panoramic X-rays exhibit limited accuracy in evaluating the relationship between roots and the surrounding alveolar bone [1,2]. In contrast, Cone Beam Computed Tomography (CBCT) has emerged as the most widely used imaging technique capable of effectively distinguishing between soft and hard tissues, and it has been extensively applied in orthodontic treatment. Yosuke Tsukiboshi et al. utilized CBCT images from 28 patients, generating skull and mandible images through surface rendering, and established standard ranges for these surfaces, thereby allowing clinicians to reliably quantify and visualize patients' three-dimensional hard tissues of the face [3]. While complete tooth models can be reconstructed from CBCT images, the accuracy of this data ranges from 0.1 to 0.5 mm [13], and the precision—particularly for the crown portion—does not meet clinical requirements.

In recent years, digitally reconstructed three-dimensional dental models have demonstrated high accuracy when compared with traditional plaster models, along with the added benefit of reproducible measurements [4,12]. However, these models cannot capture data on the cervical and root portions of the teeth. Therefore, we speculate that fusing the CBCT-obtained data of the necks and roots of the teeth with intraoral scanning (IOS) data of the crowns may address this limitation.

Clear aligner orthodontic technology employs a goal-oriented pre-treatment target position model; however, its effects on periodontal hard tissues during orthodontic treatment remain uncertain. Existing research has proposed several methods for evaluating orthodontic treatment outcomes, including the American Board of Orthodontics Objective Grading System (ABO-OGS) and the Peer Assessment Rating (PAR) index [5,6]. Previous studies and some scholars have indicated that Andrews Six Elements possess advantages in assessing the effectiveness of orthodontic treatment, while the 3D positioning of treatment target positions has also proven effective [7,8,11].

In summary, this study aims to integrate CBCT and IOS data, referencing Andrews' Six Elements to construct target position models. The objective is to examine the clinical realization rate of clear aligner treatment cases, provide guidance for designing target positions in clear aligner treatment, and ensure fast, efficient, and safe tooth movement.

Methods

Sample Selection

The sample selection consisted of data from China involving individuals who had completed orthodontic treatment using clear aligners. The treatment plan was developed by one of the researchers, and the study protocol received approval from the Medical Ethics Committee (Approval No.: KYKQ2022MEC0046). Cone beam computed tomography (CBCT) data were obtained using NNT Viewer (NewTom VG; Aperio Services, Italy), while intraoral scanning (IOS) data were collected using iTero (iTero Element 2; Align Technology, USA).

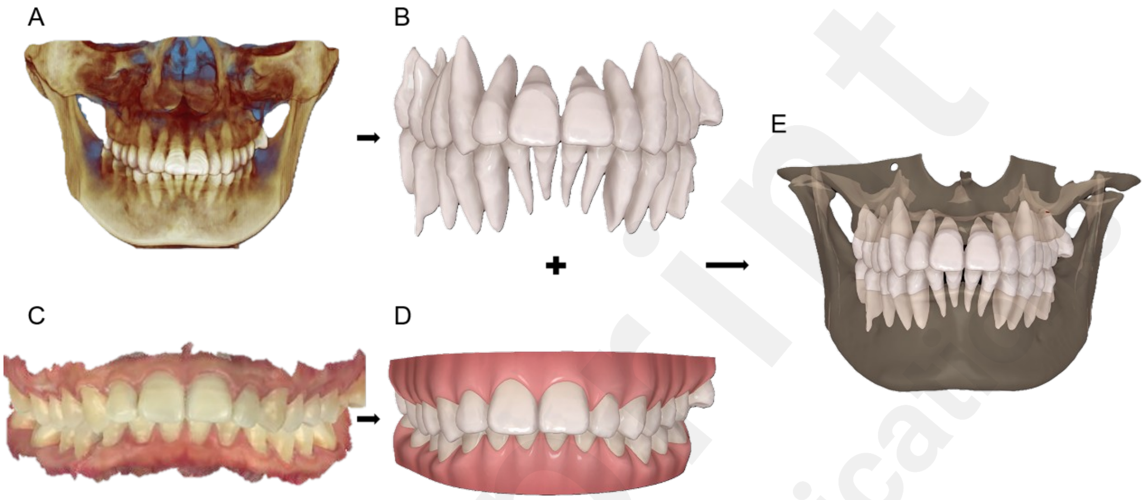
Inclusion criteria encompassed subjects aged 13 to 35 years with fully erupted teeth and a good periodontal condition (periodontal pocket depth < 3 mm). Exclusion criteria included individuals with lip and palate clefts, craniofacial deformities, or skeletal discrepancies that required orthognathic surgery. Based on these criteria, a total of 136 samples were selected.

Model Construction

The software Mimics (Mimics Innovation Suite; Materialise NV, Belgium) is utilized to import data, setting the threshold range from 1200 to 3045 based on the varying grayscale values that correspond to different tissues. A mask is generated, which is then refined through drawing, erasing, local threshold segmentation, hole filling, and Boolean operations. AI Edit Masks tool is employed to manually correct the segmentation results, removing non-dental tissues in order to reconstruct a 3D model of dental arches that contains only teeth [9]. AI Smooth tool is applied to enhance the model's surface, while the Split tool is used to separate the jaws, allowing for individual editing and optimization of each part. The output is in STL file format. The software Geomagic Wrap (Geomagic Wrap 2023; 3D Systems, America) is then used to fuse the data [10]. The N-point alignment tool selects at least three corresponding points for initial alignment, while the Best-fit alignment tool designates the CBCT as the fixed model and the IOS model as the floating model, setting the number of iterations and tolerance to execute the alignment operation. The Merge tool combines the root portion of the CBCT with the crown portion of the IOS model, resulting in a comprehensive dental arch model that includes root information (Figure 1). The Repair tool is employed to rectify minor defects, and the Smooth tool is again utilized to enhance the model's surface. Finally, a 3D tooth arrangement is performed on the pre-treatment 3D fusion model according to Andrews' Six Elements

Diagnostic System, resulting in the creation of a virtual fusion model.

Figure 1. Construction of 3D fusion model. The CBCT data (A) were imported into Mimics software using AI tools to reconstruct a 3D model containing crowns and roots (B); the intraoral scan data (C) were imported into Invisalign simulator software using AI deep learning tools to reconstruct a 3D model containing crowns and gingiva (D). Then the AI tool was used in Geomagic Wrap software to combine the two to form a 3D fusion model (E).



Measurement and Scoring

Based on Andrews' Six Elements Criteria [11], measurements encompass the following six indicators. Each indicator is scored individually, and the total score is the sum of these individual scores (Figure 2).

(1) Upper Core Discrepancy (UCD): This is measured from the distal of the last molar, along the central fossa of the molars and premolars, the canine cusp, and the incisor incisal edge, connecting to the opposite side.

(2) Upper incisors Antero-Posterior discrepancy (UAP): This refers to the antero-posterior distance between the target position and the post-treatment position of the clinical crown center point (FA point) of the maxillary central incisor.

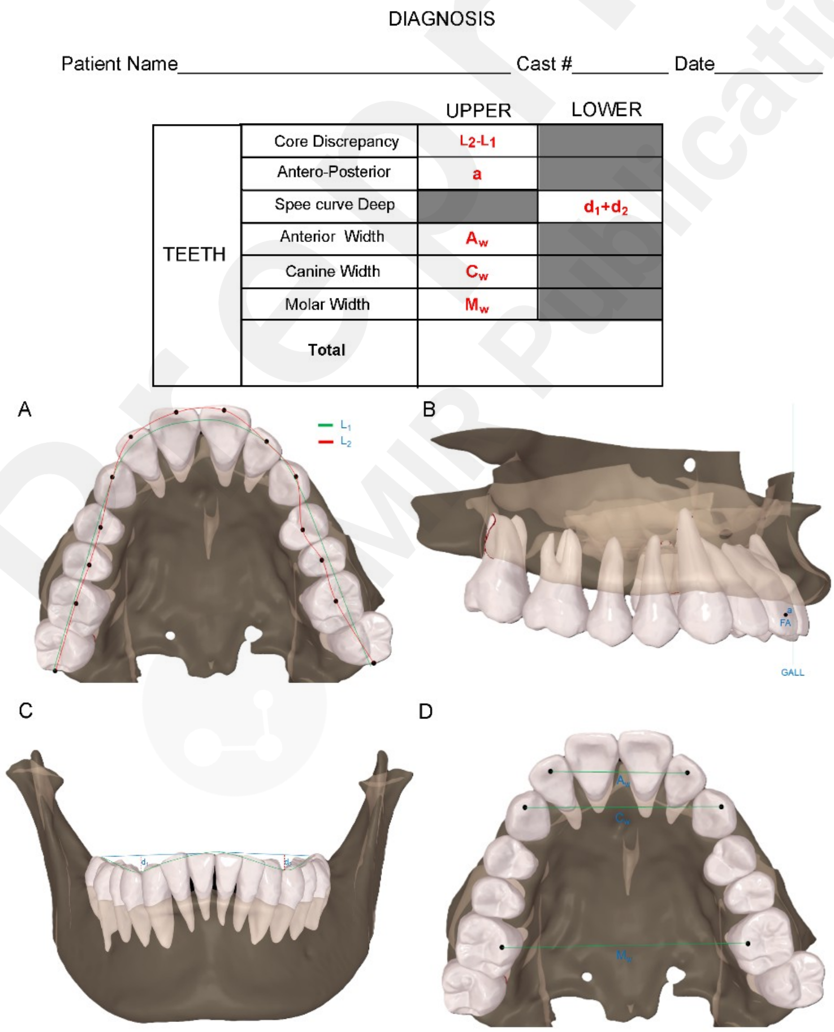
(3) Lower Spee curve Deep discrepancy (LSD): A curve is formed by connecting the incisor incisal edge, canine cusp, the buccal cusps of the molars and premolars, and the distobuccal cusp of the last molar. The depth of the lowest point of the curve is measured on both the left and right sides, and the two values are summed to obtain the Spee curve depth.

(4) Upper Anterior teeth Width discrepancy (UAW): This is defined as the distance between the midpoints of the incisal edges of the bilateral lateral incisors.

(5) Upper Canine Width discrepancy (UCW): This measures the distance between the midpoints of the cusps of the bilateral canines.

(6) Upper Molar Width discrepancy (UMW): This is the distance between the midpoints of the palatal cusps of the bilateral first molars.

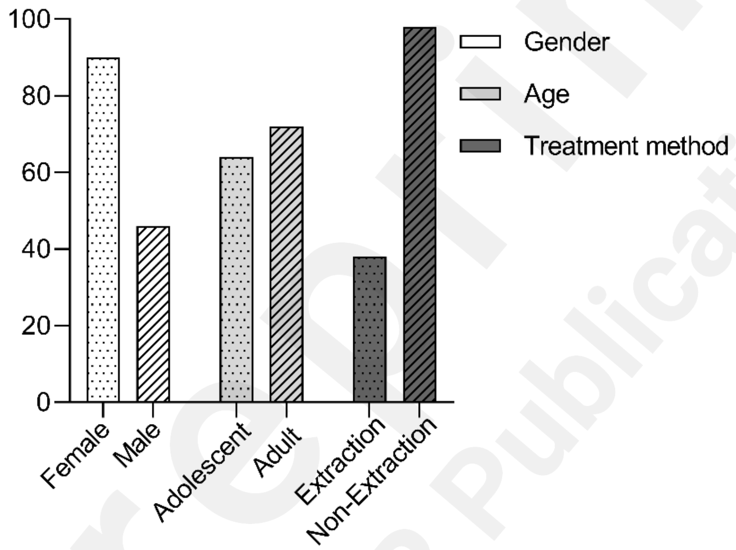
Figure 2. Measurement and scoring diagnostic sheet. The dental arch core line (A): L_1 is the desired length of the arch and L_2 is the existing length of the arch. The anteroposterior position of incisors (B): FA is the center point of the clinical crowns of the upper mesial incisors, GALL is an imaginary line passing through the interbrow point and perpendicular to the ground plane when in the natural cephalic position, and a is the perpendicular distance from the FA point to GALL. Mandibular Spee curve deep (C): d_1 and d_2 are the depths of the Spee curves on the left and right sides, respectively. The width of dental arch (D): A_w is the width of the anterior teeth, C_w is the width of the canine, and M_w is the width of the molar.



Group and statistical analysis

The Intraclass Correlation Coefficient (ICC) was employed to evaluate the consistency of sample scoring among the examiners, supplemented by Bland-Altman plots to illustrate the differences in scores between the examiners and assess potential systematic bias. Statistical analyses were performed using GraphPad Prism 9 (GraphPad Software, USA). Subjects were categorized by gender, age stage and treatment method, with 'Adolescent' defined as ages 13-17 and 'Adult' as ages 18-35 (Table S1 and Figure 3). Based on the scores, we calculated the mean and standard deviation for individual and total scores across various groupings, employing independent samples t-tests for comparison. The confidence level for all analyses was set at 95%.

Figure 3. The distribution for total samples. Subjects were categorized by gender (Female and Male), age stage (Adolescent and Adult) and treatment method (Extraction and Non-extraction).



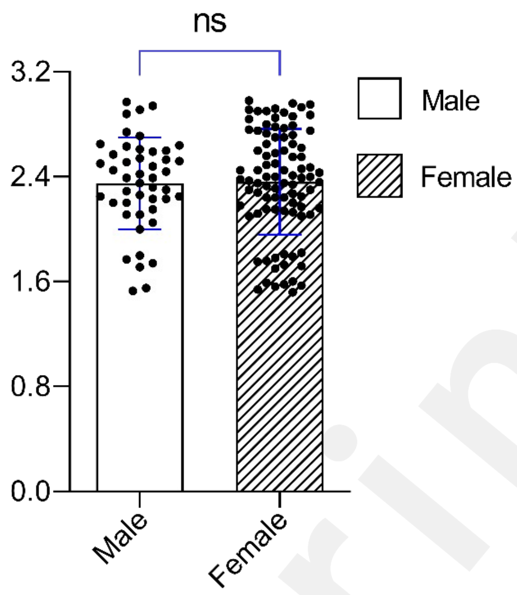
Results

To assess the difference between the scores of two inspectors, the Intraclass Correlation Coefficient (ICC) value was computed using GraphPad Prism 9. The result yielded an ICC of 0.98, indicating a very high level of consistency between the scores of the two inspectors (Figure S1).

Among the different gender groups (Figure 4). Male group comprised 46 cases aged 13-35 years (mean age: 21.30 years), with a total mean score of 2.35 ± 0.35, a minimum score of 1.53, and a maximum score of 2.97. Female group included 90 cases aged 13-35 years (mean age: 21.00 years), with a total mean score of 2.36 ± 0.40, a minimum score of 1.52, and a maximum score of 2.98. A comparison of total mean scores between the two groups revealed a t-value of 0.19 and a *P*-value of 0.85 (Table S2), indicating no statistically significant difference.

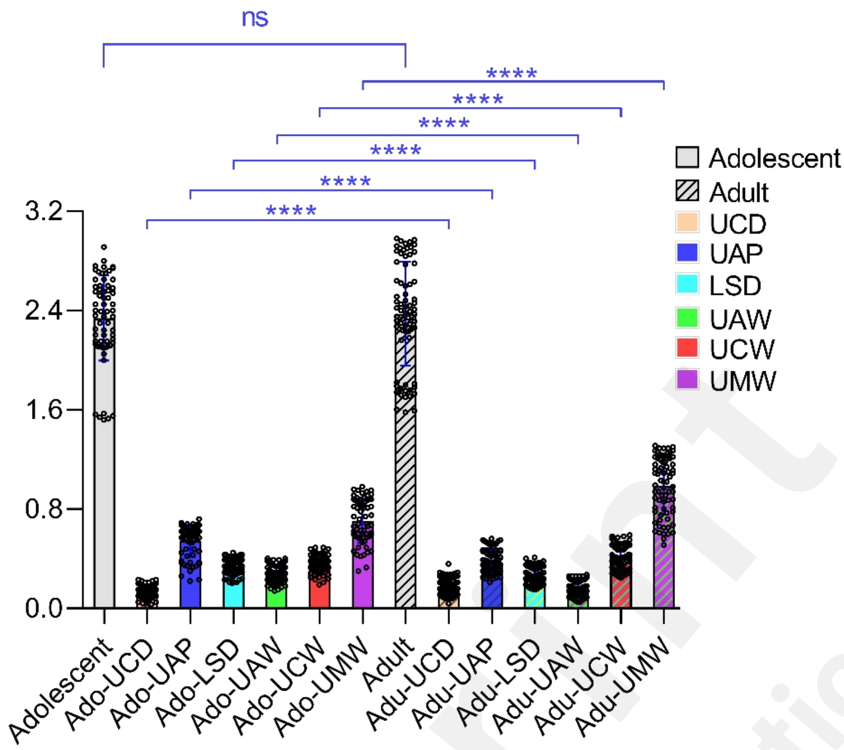
Figure 4. Total score distribution for gender groups. Male group total mean score of 2.35 ± 0.35,

Female group total mean score of 2.36 ± 0.40. Comparing the total mean scores between the two groups, *P*>.05, indicating no statistically significant difference.



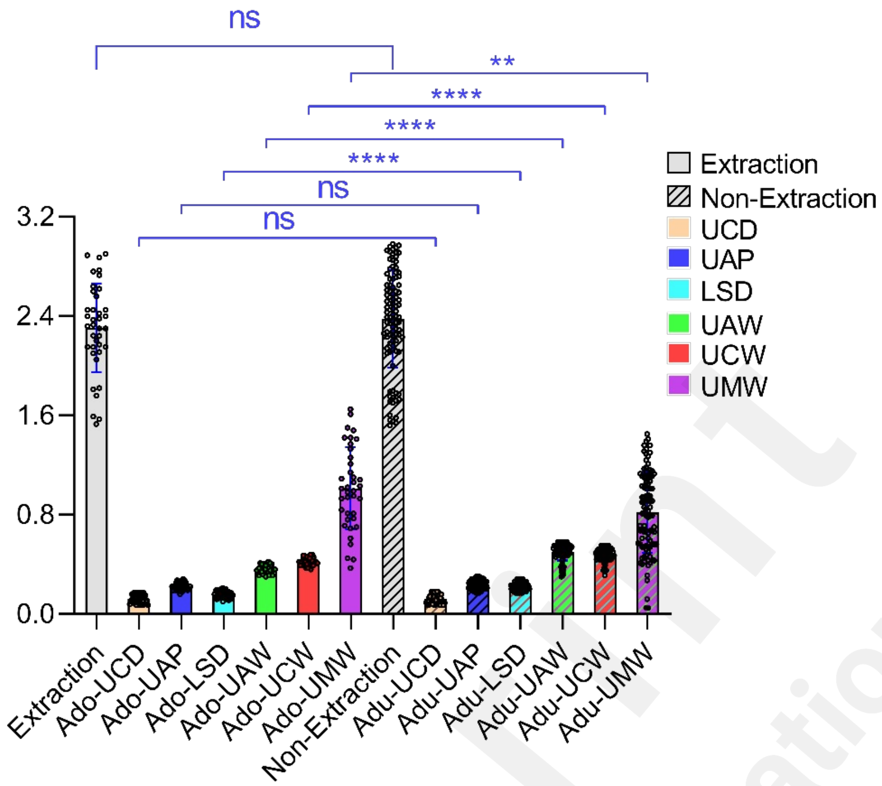
Among the different age stage groups (Figure 5). Adolescent group comprised 64 cases aged 13-17 years (average age: 13.58 years), with a total mean score of 2.34 ± 0.34, a minimum score of 1.52, and a maximum score of 2.91. Adult group included 72 cases aged 18-35 years (average age: 26.53 years), with a total mean score of 2.37 ± 0.42, a minimum score of 1.58, and a maximum score of 2.98. A comparison of total mean scores between the two groups showed a t-value of 0.52 and a *P*-value of 0.60, indicating no statistically significant difference. However, in the individual score items, significant statistical differences (*P*<.001) were observed in the following indicators: UCD, UAP, LSD, UAW, UCW and UMW (Table S3).

Figure 5. The score distribution for age stage groups. Adolescent group total mean score of 2.34 ± 0.34, Adult group total mean score of 2.37 ± 0.42. Comparing the total mean scores between the two groups (*P*>.05), indicating no statistically significant difference. In the individual score items, significant statistical differences (*P*<.001) were observed in the following indicators: UCD, UAP, LSD, UAW, UCW and UMW.



Among the different treatment method groups (Figure 6). Extraction group consisted of 38 cases, aged 13 to 35 years (average age: 19.74 years), with a total mean score of 2.30 ± 0.36, a minimum score of 1.53, and a maximum score of 2.90. Non-extraction group included 98 cases, aged 13 to 35 years (average age: 21.63 years), with a total mean score of 2.38 ± 0.40, a minimum score of 1.52, and a maximum score of 2.98. A comparison of the total mean scores between the two groups yielded a t-value of 0.99 and a P-value of 0.32 (*P*>.05), indicating no statistically significant difference. In the individual scoring items, there were no statistically significant differences (*P*>.05) in the comparisons of UCD and UAP. However, significant statistical differences were observed (*P*<.001) in the comparisons of LSD, UAW, UCW and UMW (Table S4).

Figure 6. The score distribution for different treatment method groups. Extraction group total mean score of 2.30 ± 0.36, Adult group total mean score of 2.38 ± 0.40. Comparing the total mean scores, UCD and UAP between the two groups (*P*>.05), indicating no statistically significant difference. In the individual score items, significant statistical differences (*P*<.001) were observed in the following indicators: LSD, UAW, UCW and UMW.



Discussion

3D Modeling

Based on pre-treatment cone beam computed tomography (CBCT) and intraoral scans, a digital full-arch dental model integrating intraoral scanning (IOS) and CBCT was constructed. Three-dimensional tooth arrangement was performed in accordance with Andrews' Six Keys diagnostic system, successfully establishing a pre-treatment three-dimensional integrated prediction model. This model encompasses three-dimensional images that include root and alveolar bone information. By comparing the differences between pre- and post-treatment three-dimensional integrated models, the actual three-dimensional tooth movement following clear aligner treatment can be examined. F Baan et al. conducted structured light scanning, CBCT scanning, and IOS on ten dry human skulls, achieving notable clinical accuracy in the integration of CBCT and IOS [12]. J. T. Deferm et al. registered intraoral scans with CBCT for eight dentate patients and fourteen edentulous patients, finding that the average error for dentate jaws was 0.49 ± 0.26 mm, for edentulous jaws was 0.16 ± 0.08 mm, and for alveolar ridges was 0.16 ± 0.05 mm, indicating high precision in the registration of intraoral scans with CBCT [13]. These studies provide a theoretical foundation for the modeling used in this research, The results of this study are consistent with the above studies.

Gender

Research indicates that the gender demographic variable does not influence treatment outcomes. JC Xie et al. assessed the clinical effectiveness of SmartTrack aligners and found that gender did not affect anterior tooth rotation movement [14]. PS Scott et al. discovered that Damon3 self-ligating brackets resulted in less discomfort during initial tooth alignment, regardless of gender [15]. M Tepedino et al. evaluated the predictability of the Nuvola® aligner system and concluded that gender did not influence the results [16]. M Palone et al. investigated the accuracy of the F22 Aligner system and found that gender did not play a significant role [17]. L Taner et al. evaluated pre-treatment dental models, lateral cephalometric measurements, and wrist X-rays, discovering that gender did not affect the outcomes of skeletal and dental cephalometric measurements [18]. Finally, NA Mandall et al. found that gender did not influence orthodontic patients' compliance and treatment motivation [19]. The above research is consistent with my findings.

Age Stage

In this research, adolescents scored lower than adults, suggesting that adolescents may have a higher bone remodeling capacity to meet tooth movement driven by orthodontic forces. Large amount clinical studies suggested that adolescents experience faster tooth movement and improved treatment outcomes compared to adults, as their bone tissue responds more readily to mechanical stress, allowing for quicker bone resorption and formation. K Kanou et al. discovered that younger individuals display accelerated rates of bone remodeling [20]. YY. Zheng et al. analyzed differences in alveolar bone support between adolescents and adults, noting that adults exhibited reduced alveolar bone support post-treatment [21]. E. Kalina et al. assessed changes in the lower incisor alveolar bone in both adolescent and adult patients, finding that while alveolar bone thickness decreased in both groups when lower anterior teeth were proclined or retracted, the reduction was less pronounced in adolescents [22]. Furthermore, E.K. Anna et al. evaluated maxillary morphological changes resulting from incisor movement and revealed that adolescents demonstrated significantly greater maxillary remodeling capacity than adults following such movement [23]. This results may be Adolescents more effective than adults in moving teeth, a phenomenon attributed to the biological adaptability of their dental arches, which enhances the efficacy of orthodontic treatment, particularly in adjusting the transverse width of the dental arch. During this phase of growth and development, adolescents exhibit higher skeletal plasticity, facilitating more efficient bone remodeling throughout orthodontic treatment.

In this research, found that adolescents exhibit better alignment of teeth, as well as sagittal and transverse width adjustments of the incisors and molars compared to adults. This phenomenon may be attributed to the intrusion of anterior teeth along the long axis during clinical treatment, which causes the entire periodontal tissue to move coronally, resulting in a higher rate of tooth movement. Adolescents possess a stronger capacity for bone remodeling. Some researchers [24-29] have longitudinally assessed changes in intercanine and intermolar widths from childhood to adulthood, discovering that both maxillary and mandibular arch intercanine and intermolar widths increase significantly between the ages of 3 and 13. Following the complete eruption of permanent dentition, arch widths experience a slight decrease, with intercanine width decreasing more than intermolar width. The mandibular intercanine width is generally established by age eight after the eruption of the four incisors. After the eruption of permanent dentition, clinicians should anticipate either no change or slight decreases in arch width. Although arch width changes from birth to adulthood, the magnitude and direction of these changes do not provide sufficient scientific evidence to support the expansion of dental arches beyond their established dimensions for typical patients. This is basically consistent with the results of this research.

Treatment Methods

In this research, the extraction group scored lower than the non-extraction group, suggesting that extraction may not significantly affect effective tooth movement. C Kirschneck et al. studied adolescents with borderline cases treated with tooth extraction and found no significant difference in the improvement of vertical relationships between extraction and non-extraction treatments in orthodontic patients [30]. TM Xu et al. compared Chinese borderline cases with and without extraction treatment and discovered that extraction treatment may lead to differences in facial profile at the end of treatment, but no differences were observed in tooth alignment, overbite, overjet, midline, or posterior occlusion [31]. Extraction treatment may have advantages over non-extraction treatment regarding the sagittal, vertical, and anteroposterior alignment of the anterior teeth; however, it is slightly inferior concerning the horizontal width adjustment of the posterior teeth. This may be due to extraction treatment resulting in the medial movement of molars and the distal movement of anterior teeth, which causes changes in the buccolingual width among molars, incisors, and canines. Extraction may provide additional space for adjusting the Spee curve. KG Elias et al. compared the effects of extracting premolars versus non-extraction treatment on dental arch width, contour, treatment duration, occlusal outcomes, smile aesthetics, and stability. They found that extraction led to decreased intermolar width in both arches and upper/lower lip retraction, while non-extraction treatment resulted in increased intercanine width in the lower jaw and a shorter treatment time [32]. HZ Shafique et al. recruited borderline cases and found that orthodontic treatment involving tooth extraction had a significant effect on the vertical dimension [33]. The above research results enrich this study.

Limitations and Prospects

The limitations of this study must be acknowledged. As a retrospective study, strict inclusion and exclusion criteria were established to minimize the selection bias inherent in all retrospective investigations, but they cannot completely eliminate bias in personalized prediction models. Future research could further integrate artificial intelligence technologies and employ big data analysis to enhance the predictive capabilities of personalized models.

Conclusions

The fusion model that integrates cervical and root sections from CBCT with crown data from IOS ensures highly accurate measurements and assessments of tooth positioning. This precision is crucial in orthodontics, where even minor deviations can significantly impact clinical outcomes. The utilization of a 3D model, facilitated by artificial intelligence, enables practitioners to tailor treatments more effectively to individual patients. By validating the safe range of orthodontic movement, these models help mitigate the risk of adverse effects on periodontal hard tissues. Such stability is essential for long-term success, reducing the likelihood of relapse or complications post-treatment. The study's findings, including the adaptive differences between adolescents and adults and the effects of extraction versus non-extraction methods, provide invaluable insights. Practitioners can rely on these data-driven insights to make informed decisions that optimize individual patient care. The integration of AI and 3D modeling technology introduces new methodologies that have the potential to transform traditional orthodontic practices. This technological advancement not only enhances diagnostic capabilities but also streamlines the treatment process, making it more efficient and patient-friendly. In conclusion, the construction and application of 3D fusion models in clear aligner orthodontics represent a significant leap forward, offering substantial clinical benefits while establishing a new standard for precision, personalization, and evidence-based treatment planning in the field.

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Authors' Contributions

LCF initialized the study, was involved in the study design as well as data generation, analysis and interpretation of the generated data and was a major contributor in writing the manuscript. XT, TJJ, DPP, LCY, SY and DHY were involved in data generation, analysis and interpretation. XYH was involved in study design and data interpretation as well as writing the manuscript. XYH was involved in study design and data interpretation as well as writing the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

The authors do not have any personal financial interests related to the subject matters discussed in this manuscript.

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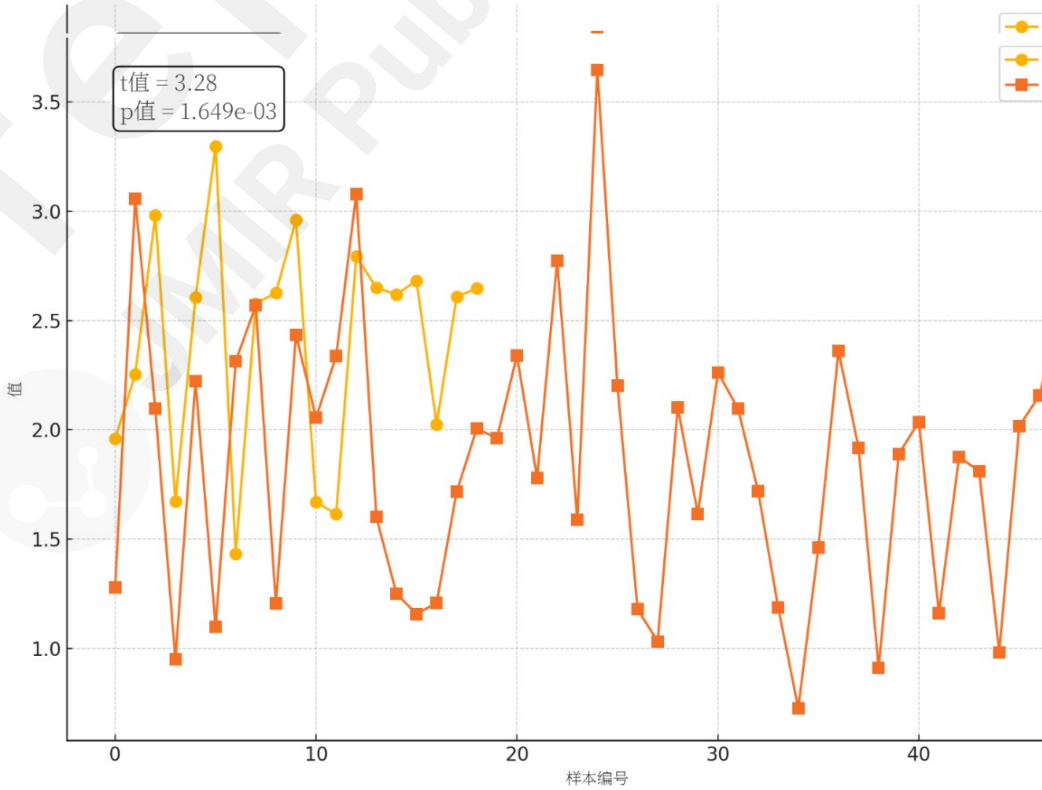
图表2 拔牙组与非拔牙组计分均值的比较

图表2 拔牙组与非拔牙组计分均值的比较

组别	例数	均值	标准差	t值	*P*值
拔牙组	19	2.46	0.64	3.28	0.0016
非拔牙组	49	1.77	0.69		



图表3 青少年组与成人组计分均值的比较（水平向差异

组别	例数	均值	标准差	t值	*P*值
青少年组	32	1.27	0.46	-13.14	0.001**
成人组	36	2.55	0.42		

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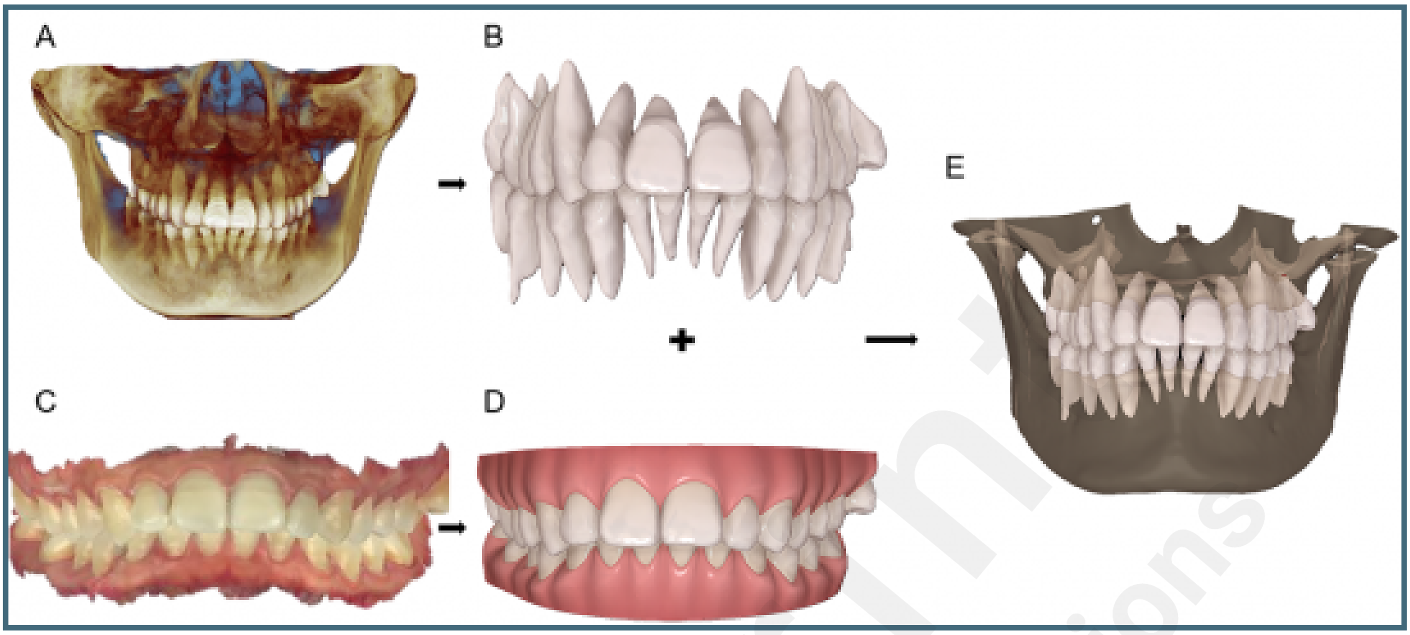
Abbreviations

CBCT: Cone Beam Computer Tomography
IOS: Intraoral Scanning
3D: Three-dimensional
AI: Artificial Intelligence
UCD: Upper Core Discrepancy
UAP: Upper incisors Antero-Posterior discrepancy
LSD: Lower Spee curve Deep discrepancy
UAW: Upper Anterior teeth Width discrepancy
UCW: Upper Canine Width discrepancy
UMW: Upper Molar Width discrepancy

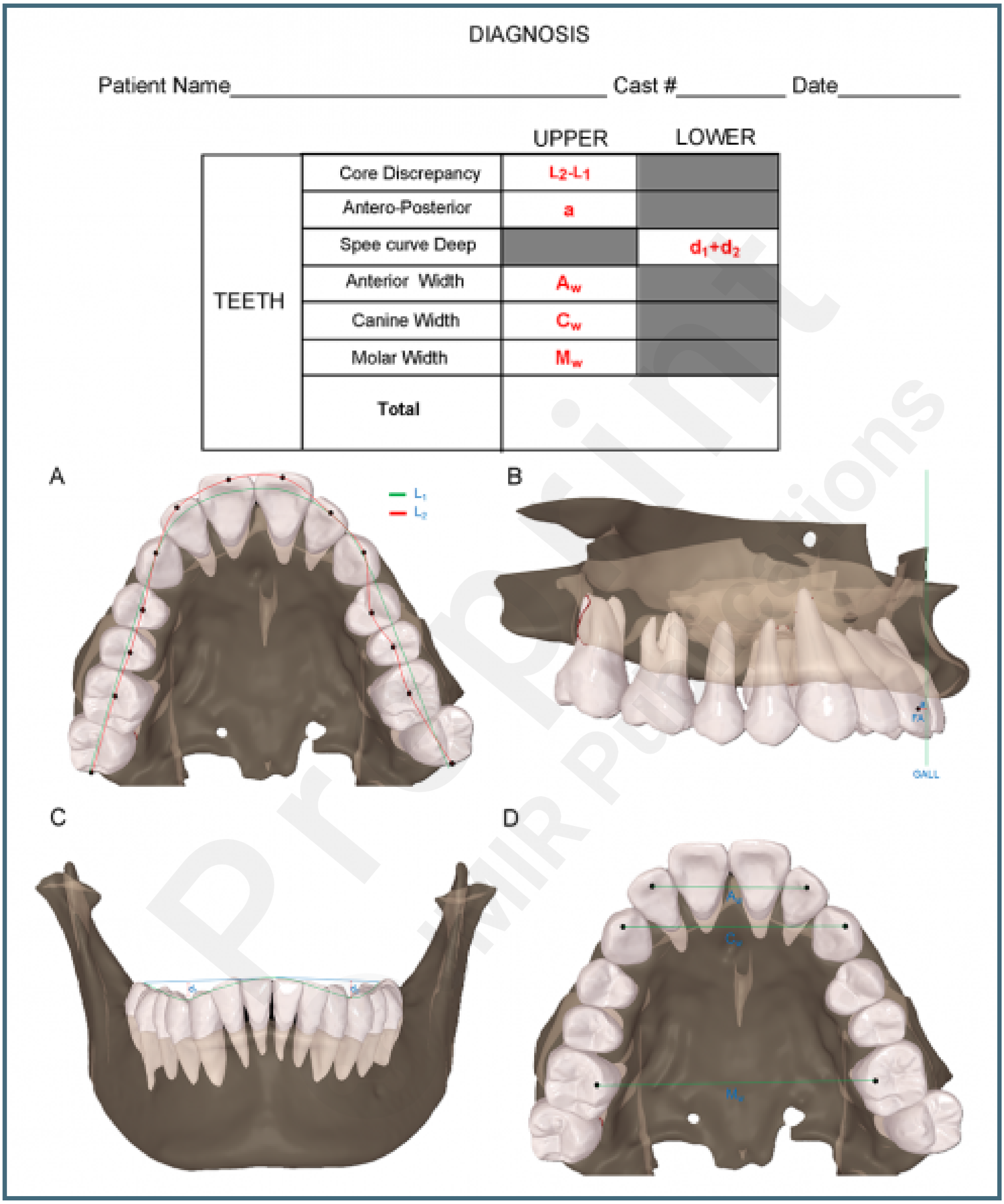
Supplementary Files

Figures

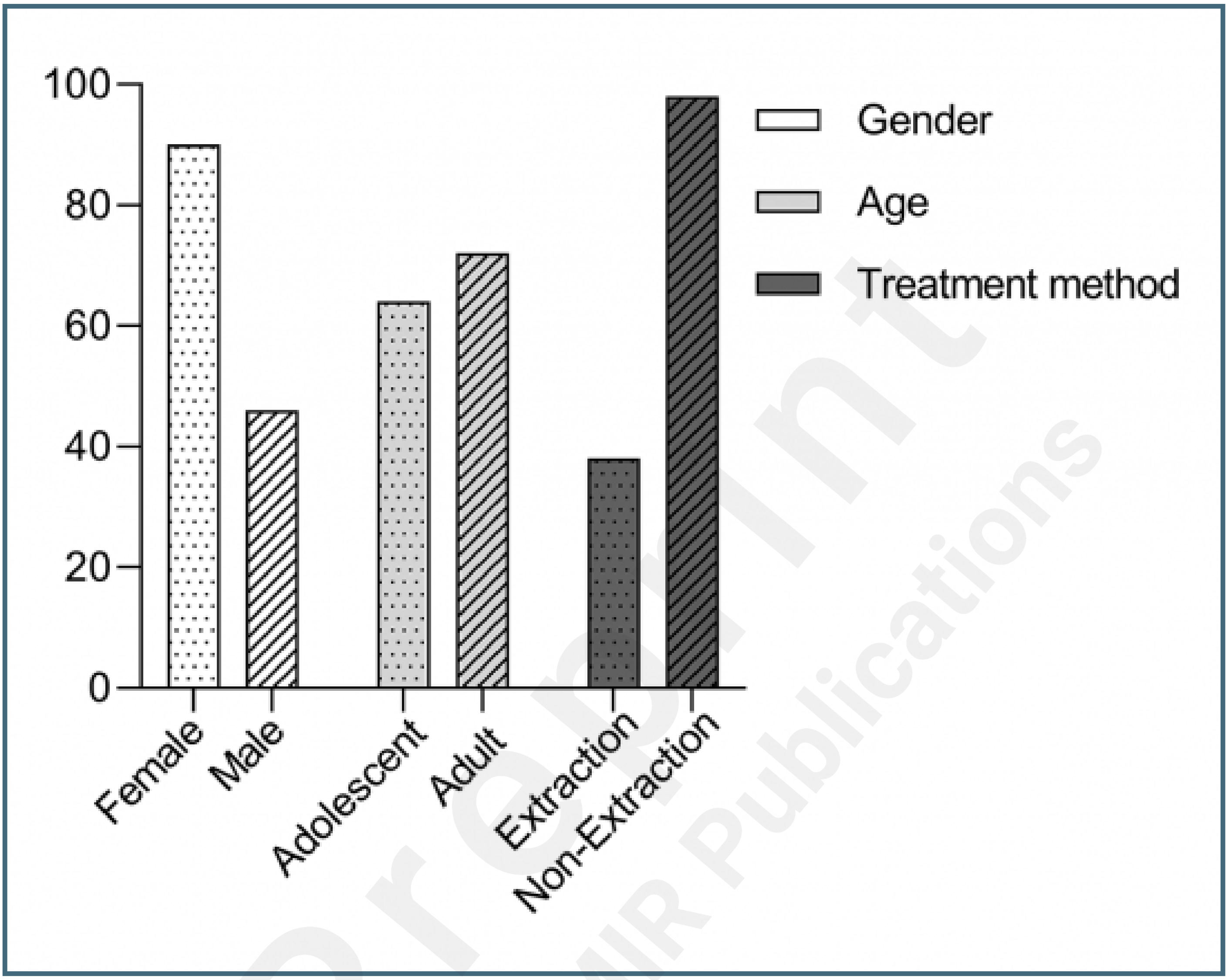
Construction of 3D Fusion Model.



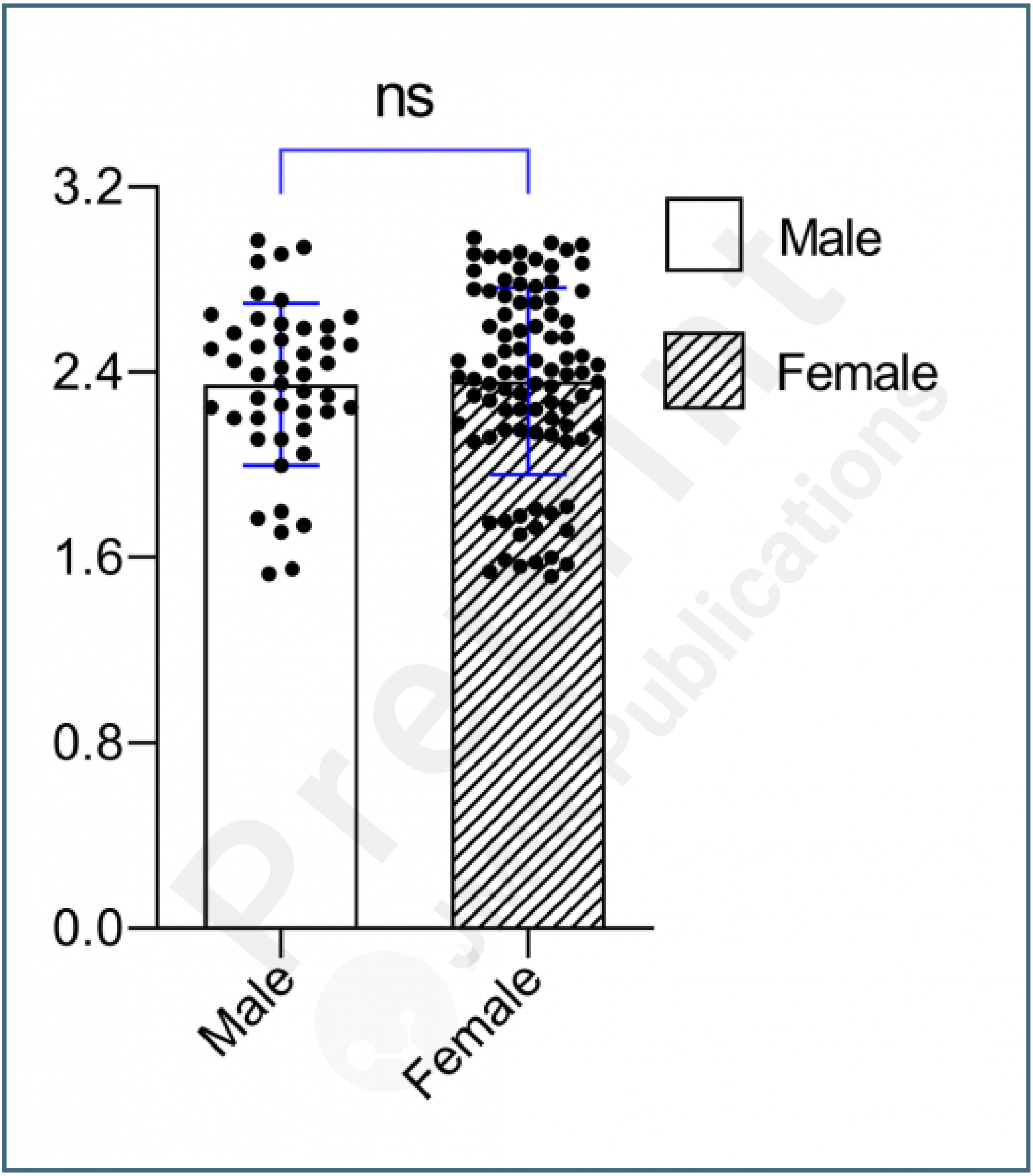
Measurement and Scoring Diagnostic Sheet.



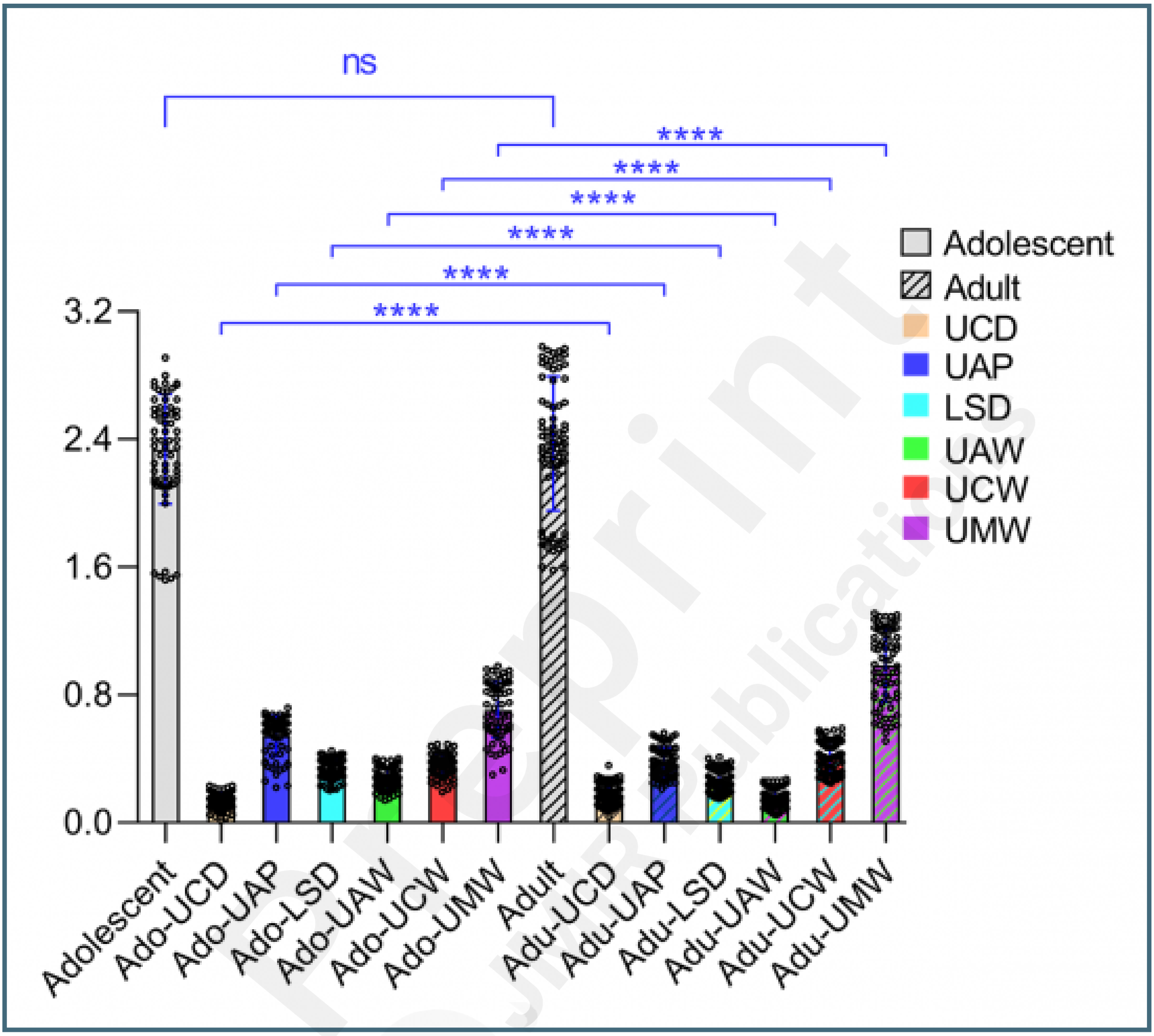
The Distribution for Total Samples.



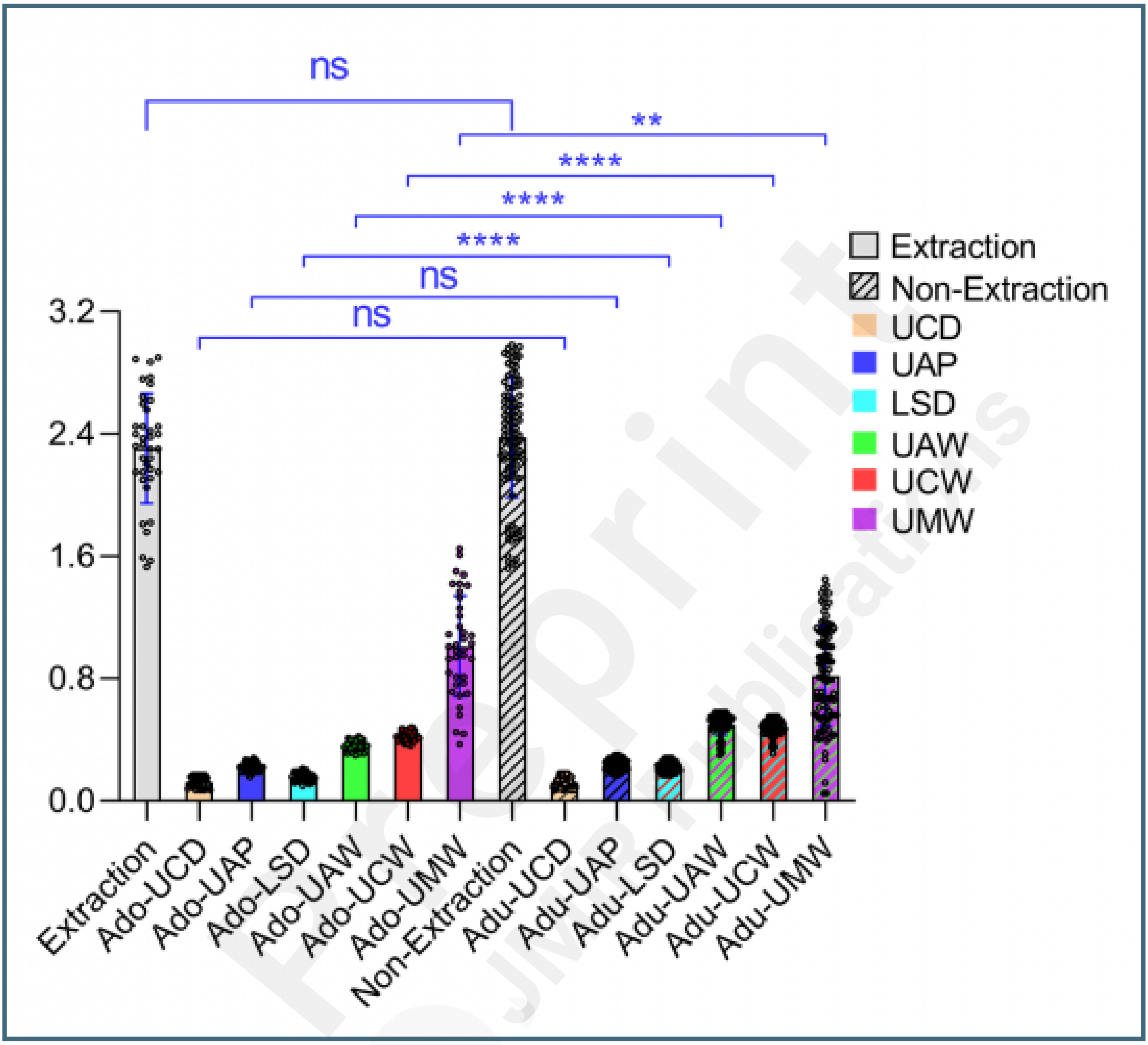
Total Score Distribution for Gender Groups.



The Score Distribution for Age Stage Groups.



The Score Distribution for Different Treatment Method Groups.



Multimedia Appendixes

The Intraclass Correlation Coefficient (ICC) Value.
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Difference vs. Average: Bland-Altman of ICC.
URL: http://asset.jmir.pub/assets/f030bb3ddd1a738fd4216337e33a520e.png

Supplementary Tables.
URL: http://asset.jmir.pub/assets/1609defc216e81032618ac79c7b05623.pdf

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