College of Dentistry

Effect of AI-Enhanced Visual Simulations and Explanations on Patient Understanding and Acceptance of Orthodontic Treatment: A Randomized Controlled Trial

A Research Proposal Submitted to the Scientific Committee and Ethical Committee of College of Dentistry, University of Sulaimani for Registration and Obtaining Ethical Approval

22 Sep 2025

1- Project details

1.1 Investigators details

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1.2 Sponsor details

- College of Dentistry/ University of Sulaimani.

1.3 Project title

Effect of AI-Enhanced Visual Simulations and Explanations on Patient Understanding and Acceptance of Orthodontic Treatment: A Randomized Controlled Trial

1.4 Contain

A. Introduction:

Orthodontic treatment success depends not only on accurate diagnosis and effective biomechanics but also on clear communication between orthodontist and patient. Patients often struggle to fully understand malocclusion severity, treatment options, and potential risks due to the technical complexity of orthodontic information [1,2]. This knowledge gap may reduce satisfaction, increase decisional conflict, and delay treatment acceptance [3].

Artificial intelligence (AI) is rapidly transforming the field of orthodontics. Applications now include cephalometric landmark detection, automated diagnosis, treatment planning, growth prediction, and monitoring of treatment outcomes [4,5]. AI tools can also support clinicians in improving patient communication by providing personalized 2D or 3D visual simulations, which allow patients to better visualize treatment progress and final outcomes [6,7]. Early clinical studies indicate that such simulations can enhance patient comprehension, trust, and engagement during consultations [7].

Beyond visual tools, AI-powered conversational systems, such as chatbots, have demonstrated promise in orthodontics. They provide real-time, simplified explanations of procedures, oral hygiene instructions, and reminders, which improve patient compliance and overall satisfaction [9,10]. Moreover, AI systems trained to deliver information at an appropriate reading level can overcome literacy barriers, particularly in regions where health literacy levels vary [11].

Despite these advancements, high-quality randomized controlled trials are still lacking to assess the true impact of AI-enhanced communication strategies on key patient outcomes such as comprehension, satisfaction, and acceptance of orthodontic treatment. Addressing this gap is particularly relevant in Middle Eastern contexts, including Iraq, where cultural, linguistic, and educational differences may influence patient decision-making. Therefore, this study aims to evaluate whether AI-generated visual simulations and plain-language explanations improve patient comprehension and treatment acceptance compared with standard consultations.

B. Originality of the research

The originality of this research lies in five aspects:

1. Focuses on AI in patient–clinician communication, not just diagnosis or treatment planning.
2. First randomized controlled trial (RCT) to test whether AI simulations and plain-language explanations improve treatment acceptance and decision quality in orthodontics.
3. Combines multiple AI tools (visual simulations, digital take-home materials) in a single standardized clinical workflow.
4. Conducted in Sulaimani, Iraq – the first trial of its kind in the Middle East, addressing cultural and health literacy diversity.
5. Provides patient-centered evidence on comprehension, satisfaction, and decisional conflict, outcomes rarely studied in AI orthodontics.

3. Research questions, Aim(s) and Objectives

3.1 Research question(s)

1. Does the use of AI-generated visual simulations and plain-language explanations during orthodontic consultations improve patient comprehension compared with standard consultations?
2. Does AI-enhanced communication reduce decisional conflict and increase satisfaction with the consultation?
3. Does AI-assisted communication increase treatment acceptance within 14 days of consultation?
4. Are the effects of AI-enhanced communication influenced by patient age, sex, education, eHealth literacy, or malocclusion severity?

3.2 Aim(s)

To evaluate the impact of AI-enhanced patient communication tools (visual simulations and plain-language explanations) on treatment acceptance and decision quality in orthodontic consultations.

3.3 Objectives

The objectives of this study will be to:

1. To determine whether AI-enhanced communication increases treatment acceptance within 14 days of consultation compared with standard consultation.
2. To assess differences in patient comprehension scores between AI-enhanced and standard consultations.
3. To compare decisional conflict, decisional regret, satisfaction, and trust in the clinician between groups.
4. To measure differences in consultation duration and clinician workload.
5. To explore whether demographic or clinical variables (age, sex, education, electronic health literacy (eHealth literacy), malocclusion severity, treatment type) modify the effect of AI-enhanced communication.

3.4 Hypotheses

Null Hypotheses (H_0):

The treatment acceptance rate is the same in AI-enhanced and standard consultations.

4. Material and methods

4.1 Method

This study will be conducted following ethical approval from the Scientific and Ethical Committee of the College of Dentistry, University of Sulaimani.

Participants and Recruitment

Consecutive new patients attending orthodontic consultations at the Asia International hospital will be invited to participate. Written informed consent will be obtained before enrollment.

Sample Size Calculation

The required sample size was estimated using *G*Power software version 3.1.9.4. The calculation was based on the *t*-test family, employing the point-biserial correlation model for a two-tailed test. An anticipated effect size of $|\rho| = 0.30$, an alpha level of 0.05, and a desired statistical power of 0.95 were specified. Under these parameters, the analysis indicated that a minimum total of 134 participants would be required (degrees of freedom = 132, noncentrality parameter = 3.64, critical $t = 1.98$), achieving an actual power of approximately 95%.

Randomization and Allocation

Participants will be randomized in a 1:1 ratio into either the control group (standard consultation) or the intervention group (AI-enhanced consultation) using a concealed allocation process. Outcome assessors will remain blinded.

Diagnostic Records

All patients in both groups will receive the same standard diagnostic records, including:

- Extraoral and intraoral photographs
- Orthopantomogram (OPG) and lateral cephalogram (if indicated)
- Study models or intraoral scans (where available)

These records form the basis of the consultation in both arms.

Interventions

- **Control group (Standard consultation):** The orthodontist explains the patient's condition and treatment options using the diagnostic records (photos, radiographs, tracings, and models) together with a generic printed brochure about orthodontic treatment and appliance care.
- **Intervention group (AI-enhanced consultation):** Patients receive all elements of the control consultation plus AI-generated visual simulations, plain-language explanations (Kurdish) and a digital take-home summary via QR code**.** Consultation duration is kept similar between groups.
- **AI-Generated Visual Simulations**

  Individualized treatment simulations will be generated using 3Shape OrthoAnalyzer™ software, version 2025.1 (3Shape A/S, Copenhagen, Denmark). The software integrates AI-based algorithms trained on extensive orthodontic datasets to simulate predicted outcomes of malocclusion correction.

  Baseline diagnostic records, including intraoral and extraoral photographs, lateral cephalograms, and digital study models obtained via intraoral scanning, will serve as input data. The system produces:

- **2D before–after overlays** superimposed on facial and intraoral photographs,
- **3D interactive digital models** illustrating predicted tooth alignment and occlusal changes, and
- **Animated treatment progression sequences** that demonstrate key transitional stages and the anticipated final result.

To ensure consistency and reliability, all simulations will be generated following standardized parameters embedded in the software (e.g., correction of crowding, overjet reduction, arch coordination). Each simulation will be reviewed by the investigator for clinical plausibility prior to presentation. During the consultation, patients will view the simulation on a tablet, and a secure QR code will be provided to access the same materials at home.

The simulations are intended exclusively as decision-support and communication tools to enhance patient comprehension and confidence; they do not replace the orthodontist's diagnostic judgment or definitive treatment planning.

Data Collection

Baseline demographic and clinical data will be recorded before consultation. Post-consultation surveys will assess comprehension, satisfaction, and decisional conflict. At 14 days, follow-up will measure acceptance, decisional regret, and knowledge retention.

Data Management

Data will be anonymized, coded using study IDs, and securely stored on hospital servers accessible only to the researcher.

4.2 Design

single-center, parallel-group randomized controlled trial (RCT).

4.3 Inclusion and exclusion criteria:

Inclusion criteria

1. New patients attending for an initial comprehensive orthodontic consultation.
2. Age 18–40 years (representing the core orthodontic patient population who are legally capable of providing informed consent and making independent treatment decisions.)
3. Index of Orthodontic Treatment Need (IOTN-DHC ≥ 3, indicating moderate to severe need).
4. Ability to read and understand Kurdish (Sorani)**.**
5. Able to provide informed consent.

Exclusion criteria

1. Previous comprehensive orthodontic treatment within the last 5 years.
2. Emergency cases requiring urgent pain or trauma management.
3. Patients with cognitive, hearing, or visual impairments that preclude participation in surveys or comprehension tests.
4. Patients who cannot complete follow-up (e.g., no phone or digital access for the 14-day follow-up survey).

4.4. Data analysis including statistical methods

All analyses will follow the intention-to-treat principle, with per-protocol as sensitivity. Categorical outcomes (e.g., treatment acceptance) will be compared between groups using chi-square tests and logistic regression to adjust for covariates. Continuous outcomes (e.g., comprehension, decisional conflict, satisfaction) will be analyzed using ANCOVA with adjustment for baseline and demographic variables. Non-parametric methods will be applied if assumptions are violated. Subgroup analyses will explore effect modification by age, sex, education, eHealth literacy, malocclusion severity, and treatment type. Missing data will be addressed using multiple imputation if >5%. Results will be reported as effect sizes with 95% confidence intervals, and significance set at $p < 0.05$.

Outcome measure(s)

- **Primary outcome:** Treatment acceptance within 14 days of consultation (yes/no).
- **Secondary outcomes:** Patient comprehension, decisional conflict, decisional regret, satisfaction, trust in the clinician, consultation duration, clinician workload, and knowledge retention at 14 days.

Setting

The study will be conducted at the Dental Center of Asia International Hospital.

4.5.Ethical Considerations

This study will be conducted in accordance with the Declaration of Helsinki and relevant national research ethics guidelines. The protocol will be reviewed and approved by the Ethics Committee of the College of Dentistry, University of Sulaimani prior to initiation.

All participants will provide written informed consent before enrollment. Participation is voluntary, and patients may withdraw at any stage without any effect on their access to standard care.

The study involves minimal risk**:** both groups will receive standard orthodontic records and consultation. The intervention group will receive additional AI-generated visual simulations and plain-language explanations, which pose no physical risk but are intended to improve understanding. No invasive procedures are introduced by the research.

Confidentiality will be strictly maintained. All data will be coded with study IDs and stored securely on password-protected servers accessible only to the researcher. Identifiable information will not appear in publications or presentations.

4.6. Intervention and quality control

Intervention

All participants will undergo standard orthodontic diagnostic procedures, including extraoral and intraoral photographs, panoramic radiographs (OPG), lateral cephalograms, and study models or intraoral scans, as clinically indicated.

Quality Control

To ensure fidelity of the intervention:

- **Standardized scripts** will be used for both control and intervention consultations.
- **Clinician training sessions** will be conducted before trial initiation to calibrate communication approaches and proper use of AI tools. Hands-on training with the AI software (3Shape OrthoAnalyzer™) will be done to ensure accurate input of diagnostic records, generation of visual simulations, and presentation of outputs to patients.
- **Fidelity monitoring:** Every 10th consultation will be observed or reviewed using a 10-item checklist. A ≥90% adherence threshold will be required; retraining will be provided if adherence falls below this level.
- **Data quality checks:** Study coordinators will review case report forms and digital entries weekly to identify missing or inconsistent data.
- **Technical control:** AI tools will be validated before use, hosted on secure local systems, and tested to ensure accurate generation of simulations without compromising patient confidentiality.

5. Project plan

The estimated duration of the project is 6 months**.**

Submission date: 21 Sep 2025
Starting date: 21 Oct 2025
Accomplishment date: 1 Apr 2026

6. Project management and expertise

This project will be led and managed entirely by the Zhwan Jamal Rashid Hama, at the Dental Center of Asia International Hospital. The investigator will be responsible for all stages of the study.

Dissemination

The findings of this study will be disseminated through:

1. **Peer-reviewed publications** in international orthodontic and dental journals.
2. **Conference presentations** at national and international meetings.

7. Intellectual Property:

The University of Sulaimani will hold all rights for intellectual property.

8. Funding, costing schedule and funding arrangements

The study is self-funded by the investigator.
No external sponsorship or commercial funding is involved.

10. Conflict of interest:

The author declares no conflict of interest related to this study.

11. Author contribution:

Zhwan Jamal Rashid Hama is the sole author of this work and was responsible for:

- Conception and design of the study protocol
- Preparation of ethical approval documents
- Recruitment of participants and obtaining informed consent
- Delivery of both standard and AI-enhanced consultations
- Data collection, entry, and management
- Monitoring intervention fidelity and ensuring quality control
- Data analysis and interpretation
- Drafting, revising, and final approval of the manuscript

No other individuals meet the criteria for authorship.

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