

Validation of a Patient-Reported Questionnaire on Adjunctive Methods to Accelerate Orthodontic Tooth Movement

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Abstract

Objective

This study aimed to develop and validate a patient-reported questionnaire to comprehensively assess perceptions during adjunctive orthodontic therapy, ensuring methodological rigor and cross-cultural applicability.

Material and Methods

A structured questionnaire was developed, consisting of 21 items investigating the emotional, physical, and functional domains. A multi-phase validation process was then implemented. Orthodontic experts (n = 12) evaluated the content validity using Lynn's criteria. In addition, both the orthodontic experts and 30 patients assessed face validity to ensure clarity, readability, and relevance. Based on expert consensus, the questionnaire was refined, expanded to 22 items, and subjected to a second round of validation. To guarantee cross-cultural applicability, the instrument was translated into Arabic by a certified bureau, using forward and back-translation. Reliability was examined using Cronbach's alpha to measure internal consistency across domains.

Results

The questionnaire demonstrated exceptional content validity (S-CVI = 1.00), perfect face validity (100% agreement), and acceptable internal consistency reliability (Cronbach's alpha 0.722 for pain/discomfort items; 0.708 for pain/function items; 0.750 for psychosocial items). The instrument successfully captured multidimensional aspects of patient perception, including pain intensity, analgesic use, functional difficulties, and psychosocial consequences. The translation ensured linguistic accuracy and cultural adaptability in English and Arabic.

Conclusion

This validated bilingual questionnaire provides a reliable tool for assessing patient perceptions of adjunctive orthodontic acceleration techniques. It offers a practical framework for integrating patient perspectives into orthodontic research/clinical protocols. Its methodological strength and cross-cultural adaptability establish a valuable reference for future patient-centered investigations. Importantly, it represents the first questionnaire dedicated to adjunctive orthodontic methods.

Introduction

The questionnaire plays an essential role in research by featuring a set list of questions designed to collect vital information from respondents. Generally, it is used in conjunction with surveys to gather both quantitative and qualitative data. The primary purpose of questionnaires is to extract specific information, which can subsequently be analyzed to identify patterns, viewpoints, behaviors, or insights related to a particular subject.^{1,2}

Validating a questionnaire is a fundamental aspect of the research process, ensuring that the instrument accurately and reliably measures the intended constructs or variables.^{2,3} Validation serves to confirm that the questionnaire effectively captures the underlying concepts it is designed to assess, thereby improving the credibility and integrity of the gathered data.^{4,5} This process is critical because it addresses various uncontrollable factors that can influence data quality, such as respondent misunderstanding, bias, or environmental distractions during data collection.⁶⁻⁸ Validation procedures for questionnaires encompass a range of categories and subcategories, each tailored to specific types of instruments and research objectives.^{2,3} Rather than applying a one-size-fits-all approach, each questionnaire undergoes a particular validation method that best suits its unique design and intended use.^{8,9} This ensures that the instrument accurately measures the constructs it aims to assess while maintaining reliability and validity across different contexts.^{4,10}

Content validity involves a systematic and quantitative evaluation to ensure that a questionnaire comprehensively covers the construct it aims to measure.^{11,12} This process entails assessing the suitability of each item and discarding those that are not relevant by utilizing the Content Validity Index (CVI).^{11,13} Typically, this evaluation is conducted by a panel of experts, with a minimum of three specialists recommended to provide diverse perspectives, although involving more experts can enhance the robustness of the validation process.⁸ The essence of the expert panel work is to estimate the relevance and clarity of each questionnaire item.¹⁴ In general, validation is a qualitative process by which the adequacy of a questionnaire or measurement instrument is determined by using two different rounds with a minimum of a 10-day interval between them, during which the

feedback and required adjustments should be considered to enhance the accuracy and comprehension of the questionnaire.⁸⁻¹² Face validity, on the other hand, is the process that determines the appropriateness of the content of questionnaire or measurement instrument, where the two rounds are used. The elements that are investigated by this type of validation include readability, language clarity, feasibility, and formatting consistency. Even though face validation is usually regarded as a most basic and the weakest type of validation, it is essential in the initial phase of the instrument development since it helps to determine whether the items are comprehensible and applicable to the target audience.^{15,16} To secure the measurement of the intended constructs, content and face validation must be used. This method, called "validation by assumption".¹⁷⁻¹⁹ To effectively use the questionnaire for cross-cultural research, it may need translation for cultural adaptation and universal understanding. Translating presents challenges as the original content meaning and intent must be preserved. Translation approaches include using an unqualified individual, a qualified team, or the back-translation method.²⁰⁻²²

Most research in orthodontics predominantly focuses on the orthodontist's perspective, emphasizing factors such as patient compliance and adaptability to treatment. However, more attention needs to be given to understanding patients' experiences of discomfort during orthodontic treatment. Moreover, an in-depth review of the current literature reveals that the majority of research on patient discomfort during orthodontic treatment focuses predominantly on pain-related aspects, while overlooking a multitude of other factors linked to the patient's physical and psychological health.²³ In orthodontics, for adjunctive interventions like osteoperforation, accelerated tooth movement injections, and laser applications to be effective, they need to meet two criteria: technically, they should be beneficial and applicable, and practically, they should be easy to administer and comfortable for patients.²⁴⁻²⁷ Including patients' perspectives on new orthodontic treatments combined with adjunctive therapies will allow researchers to evaluate the treatments advantages and disadvantages by examining various aspects of oral health-related quality of life (OHRQoL).

Existing instruments for assessing orthodontic perception often rely on limited measures and lack cultural adaptation, leaving patient experiences with adjunctive orthodontic modalities underexplored. Therefore, this study aims to develop and validate a bilingual questionnaire to address that gap, offering a reliable and culturally adapted tool that enables systematic evaluation of patient perceptions and supports evidence-based optimization of adjunctive orthodontic care. To the best of our knowledge, this will be the first culturally adapted instrument specifically targeting patient experiences with adjunctive orthodontic modalities in our region.

Subjects and methods

Study design

This study is a cross-sectional research design which is a part of a randomized clinical trial structure. The Ethics Committee of the College of Dentistry at the University of Baghdad approved the study under reference number 1014 in January 21, 2025 and registered in ClinicalTrials.gov on February 26th, 2025, with a registration ID: NCT06847880.

The Design of the questionnaire

The initial draft of this questionnaire was developed by gathering relevant questions from multiple questionnaires which studied patient discomfort experiences in orthodontic treatment.²⁸⁻⁴⁰

The Sample

The research validation process involves the following participant groups:

- Specialist orthodontists: comprised of a quota sample of 12 participants to assess both the content and face validity of the questionnaire. They were belonged to the education and healthcare sectors and had between 2 to 20 years of experience.
- Orthodontic patients: a sample of patients undergoing fixed appliance orthodontic treatment was randomly selected as part of the broader clinical trial, based on predefined inclusion and exclusion criteria. These participants represented typical orthodontic cases recruited from routine clinical settings, including specialized governmental dental centers, private clinics, and the Department of Orthodontics at the College of Dentistry, University of Baghdad. Their role was to assess the face validity of the questionnaire by evaluating its clarity, relevance, and comprehensibility.

All participants provided written informed consent to confirm their voluntary involvement. For patients younger than 18 years, parental consent was obtained. The study procedures adhered to the ethical standards of the institutional research committee and complied with the principles of the Declaration of Helsinki.

Inclusion Criteria:

1. Patients aged 12 years and above, who are indicated for fixed appliance orthodontic treatment.
2. Patients with moderate to severe crowding (4–9 mm) of the mandibular anterior teeth as per the Little's Irregularity Index (LII).
3. Treatment with or without two mandibular first premolars extraction.
4. Presence of all the mandibular permanent teeth, except the third molars.
5. The overbite and overjet should not impede bracket placement on the mandibular anterior teeth.

Exclusion Criteria:

1. History of previous orthodontic intervention.
2. History of trauma or root resorption in the mandibular anterior teeth.
3. Presence of mandibular anterior teeth crowding of less than 4 mm or greater than 9 mm (LII).
4. Existence of blocked-out teeth precluding engagement with the aligning archwire.
5. History of systemic diseases, especially diabetes and bone diseases.
6. Patients with periodontitis and obvious loss of tooth attachment according to Plaque and Bleeding on Probing indices.
7. Pregnant and lactating mothers.
8. Mouth breathing patients and smokers.
9. Healthy patients who used any medications (such as anti-inflammatory or antimicrobial drugs) or supplements (such as vitamins).

Validation Process

To formulate questions that are validated, relevant, and easily comprehensible for patients who speak Arabic, the initially selected questions were subjected to a series of structured steps:

Step 0: Initial Questionnaire Construction

The preliminary version of the questionnaire was developed following an exhaustive review of validated instruments assessing patient discomfort and perception during orthodontic treatment.^{28–40} Items were selected for their relevance to adjunctive orthodontic procedures. There were 21 items that were collected so as to be inclusive of physical, functional, and emotional domains, while maintaining respondent manageability.

The pool of items was collected and narrowed down by the principal investigator under the guidance of a senior orthodontic specialist and both clinical and linguistic validity were maintained by the authors before the item pool was reviewed by an expert panel.

Step 1: First Round of Content and Face validation by Experts

All professionals were invited to participate in a content validity panel in the form of an invitation letter. All the questions of the questionnaire were rated through 4-point Likert scale; 1 (not relevant), 2 (somewhat relevant), 3 (relevant), and 4 (very relevant). The professionals made their evaluations on their own. The assessment process classified items rated 1 or 2 as irrelevant and items rated 3 or 4 as relevant. The Content Validity Index (CVI) was used for measuring questionnaire validity. Using Lynn's approach, the Item-Level Content Validity Index (I-CVI) was calculated by dividing expert ratings of 3 or 4 to the total expert count. An item qualified as valid when the I-CVI rating reached or exceeded 0.78. Since the questionnaire included 12 experts, 10 of them should rate 3 or 4 for the items to remain in the study, otherwise it would be removed. On the other hand, the Scale-Level CVI (S-CVI) was used to measure the questionnaire validity through averaging the I-CVI values. The questionnaire overall needed to attain a minimum S-CVI value of 0.9 to qualify as valid.^{11, 41,42}

The experts who validated the content also assessed the face validity of the questionnaire. They examined the clarity, readability, and the general suitability of the questionnaire. The evaluation was conducted through a 4-point Likert scale that ranged from 1 for strongly disagree to 4 for strongly agree.

Step 2: Questionnaire modification

Based on the first round results, the questionnaire underwent several changes. Some items were modified or merged, new items were added, and items deemed non-valid (I-CVI < 0.78) were excluded.

Step 3: Second round of content validation by experts

A group of 12 experts from the initial content validation were asked again to assess the modified version of the questionnaire.

Step 4: Translation process

A certified professional translation bureau translated the questionnaire from English to Arabic language. Three qualified translators were participated in this translation process. Two independent translators worked on the translation of the English questionnaire to Arabic. The team leader reviewed and merged both versions to create one accurate Arabic version. A back-translation method was used to verify the accuracy and maintain consistency of the Arabic version.

Step 5: Face Validation by Patients

A total of 30 orthodontic patients (under fixed appliance orthodontic treatment) were invited to validate the face validity of the questionnaire. The participants received the translated and validated questionnaires to evaluate the readability and clarity of questionnaire items with a specific face validation form.

Step 6: Reliability

The internal consistency reliability of the translated and validated questionnaire was used to assess the inter-item correlation. On the other hand, the long-term stability of the questionnaire cannot be assessed using a test-retest reliability method, as it captures an evolving experience of orthodontic patients undergoing adjunctive treatment.

Statistical Analysis

The I-CVI, S-CVI, and the percentages of face validity agreement were calculated using an Excel spreadsheet (Excel, Microsoft Office Professional Plus 2019, Washington, USA). The Statistical Package for Social Sciences (SPSS) version 26.0 released by SPSS Inc. (Chicago, IL, USA) was used for statistical analysis. The internal consistency reliability was tested using the Cronbach's alpha analysis.

Results

Step 1: First Round of Content and Face validation by Experts

In this round of content validation, each of the 21 items was found to be relevant to the core concept ($I-CVI \geq 0.78$). As a result, all questionnaire items were retained. Similarly, the average S-CVI for the entire questionnaire was 0.94 (valid) (Table 1). In the face validation, the questionnaire had a total agreement of 91.7 which shows that it is adequate. Nonetheless, certain specialists suggested changes to some of the items in order to make them more suitable

Table 1
First round of content validation by 12 orthodontic experts

No.	Items	Responses					I- CVI	Validity
1	Do you have Pain/discomfort/soreness in:	Teeth	Not at all	A little	A lot		1.00	Valid
2		Jaws	Not at all	A little	A lot		1.00	Valid
3		Gingiva	Not at all	A little	A lot		1.00	Valid
4		Muscles	Not at all	A little	A lot		0.92	Valid
5		Headache	Not at all	A little	A lot		0.83	Valid
6	Did you have pain during the intervention?		Yes	No			1.00	Valid
7	How would you describe the intensity of pain during the intervention?		None	Mild	Moderate	Severe	1.00	Valid
8	Have you taken analgesics for pain?		Yes	No			1.00	Valid
9	Do you have pain in your teeth when they are in contact?		Yes	No			0.92	Valid
10	Did you stay at home from school or work specifically due to discomfort following the intervention?		Yes	No			0.83	Valid
11	Where did you feel the pain		Anterior teeth	Posterior teeth	All the dentition	Cannot locate	0.92	Valid
12	Do you have difficulty in:	Speech	Not at all	A little	A lot		0.92	Valid
13		Sleeping	Not at all	A little	A lot		0.92	Valid
14		Eating/Chewing/Biting	Not at all	A little	A lot		0.92	Valid
15		Tooth brushing	Not at all	A little	A lot		0.92	Valid
16	Has the following been affected due to treatment?	Physical activity	Not at all	A little	A lot		0.83	Valid
17		Social activity					1.00	Valid
18		School/work					1.00	Valid
19		Emotional Status					1.00	Valid
20	How would you describe the duration of the intervention visit		Normal	Lengthy			1.00	Valid
21	How would you describe the intervention visit		Normal	Annoying			0.92	Valid

Step 2: Questionnaire Modification

Following the first round of expert review, the research team reviewed all comments and recommendations. Modifications to the questionnaire were made following collective expert consensus and statistical criteria of validity ($I-CVI \geq 0.78$). While individual suggestions were taken into account, changes were only implemented when supported by more than one reviewer or were in line with the study methodological framework. All revisions were completed by the authors following synthesis from expert consultation of 12 orthodontic specialists.

Based on the recommendations made by the experts, the questionnaire underwent the following modifications:

- The phrase **“After the intervention”** was added to items 1, 2, 3, 4, 5, 8, 9, 12, 13, 14, 15, 16, 17, and 19.
- The phrase **“Temporomandibular Joints”** was added to item 2.

- The responses to items 1, 2, 3, 4, and 5 were changed to **“Yes/No”** instead of **“Not at all, A little, A lot”**. The format of the response to items 1–5 was altered to binary (Yes/No) to indicate their diagnostic quality, and items 14–20 were kept in the form of a graded scale since they measured the subjective impact.
- The phrase **“If you have pain in your teeth after the intervention”** was added to item 11.
- The word **“Biting”** was deleted from the item 14 **“Eating/Chewing/Biting”**.
- The sequence of some items was changed.
- The phrase **“e.g., sport”** was added to item 16.
- Item 18 was deleted.
- The phrase **“Happiness/Depression”** was added to item 19.
- The phrase **“due to treatment addition”** was deleted, and the word “adversely” was added to items 16, 17, and 19.
- The definition of the word **“intervention”** was provided at the end of the questionnaire based on the adjunctive treatment type.
- Addition of a new item: **“After the intervention, do you have feelings of”** with sub-items "Swelling" and "Numbness" and responses **“Yes and “No”**.

Step 3: Second Round of Content Validation by Experts

In this phase a follow-up validation process was performed to evaluate both the newly introduced and the modified questionnaire items. This validation included the same group of 12 experts in orthodontics and occurred one month after the initial evaluation in the first round. The results showed that all items achieved an I-CVI of 1.00. Furthermore, the questionnaire as a whole had a S-CVI/Ave score of 1.00 (Table 2).

Step 4: Translation Procedure

The final and revised version of the validated questionnaire was translated from English to Arabic by a certified translation bureau. To guarantee the content integrity, the authors carefully reviewed the translated version by back translation method and confirmed that the main concepts of each item were preserved (Table 3, 4).

Step 5: Patient Face Validation

Face validity of the questionnaire was carried out in 20 patients. Their feedback noted that the questionnaire was clear, well-structured and understandable. This process led to a perfect agreement in terms of face validity with an overall agreement rate of 100%.

Step 6: Reliability

A data of 30 patients who filled the questionnaire was tested for internal consistency reliability. The overall questionnaire achieved acceptable internal consistency with Cronbach’s alpha level of 0.70. Three sections could also be measured. The first section related to pain/discomfort (items 1–13) with Cronbach’s alpha level of 0.722. The second section related to pain/discomfort and function (items 1–17) with Cronbach’s alpha level of 0.708. In addition, the third section related to physical/social/emotional activities (item 18–20) with Cronbach’s alpha level of 0.750.

Table 2
Second round of content validation by 12 orthodontic experts

No.	Items	Responses				I-CVI	Validity
1	Did you have pain during the intervention*?	Yes	No			1.00	Valid
2	How would you describe the intensity of pain during the intervention?	None	Mild	Moderate	Severe	1.00	Valid
3	Have you taken analgesics for pain after the intervention?	Yes	No			1.00	Valid
4	After the intervention, do you have Pain/discomfort/soreness in:	Teeth	Yes	No		1.00	Valid
5		Jaws/Temporomandibular Joints	Yes	No		1.00	Valid
6		Gingiva	Yes	No		1.00	Valid
7		Muscles	Yes	No		1.00	Valid
8		Head	Yes	No		1.00	Valid
9	If you have pain in your teeth after the intervention, where did you feel the pain	Anterior teeth	Posterior teeth	All the dentition	Cannot locate	1.00	Valid
10	After the intervention, do you have pain in your teeth when they are in contact?	Yes	No			1.00	Valid
11	After the intervention, do you have the feelings of:	Swelling	Yes	No		1.00	Valid
12		Numbness	Yes	No		1.00	Valid
13	Did you stay at home from school or work specifically due to discomfort following the intervention?	Yes	No			1.00	Valid
14	After the intervention, do you have difficulty in:	Speech	Not at all	A little	A lot	1.00	Valid
15		Sleeping	Not at all	A little	A lot	1.00	Valid
16		Eating/Chewing	Not at all	A little	A lot	1.00	Valid
17		Tooth brushing	Not at all	A little	A lot	1.00	Valid
18	Has the following been adversely affected after the intervention ?	Physical activity (e.g. sport)	Not at all	A little	A lot	1.00	Valid
19		Social activity	Not at all	A little	A lot	1.00	Valid
20		Emotional Status (Happiness/Depression)	Not at all	A little	A lot	1.00	Valid
21	How would you describe the duration of the intervention visit	Normal	Lengthy			1.00	Valid
22	How would you describe the intervention visit	Normal	Annoying			1.00	Valid

Table 3
Revised and final version of the validated questionnaire (English version).

Items		Responses			
Did you have pain during the intervention*?		Yes		No	
How would you describe the intensity of pain during the intervention?		None	Mild	Moderate	Severe
Have you taken analgesics for pain after the intervention?		Yes		No	
After the intervention, did you have pain/discomfort/soreness in?	Teeth	Yes		No	
	Jaws/Temporomandibular Joints	Yes		No	
	Gingiva	Yes		No	
	Muscles	Yes		No	
	Head	Yes		No	
If you have pain in your teeth after the intervention, where did you feel the pain		Anterior teeth	Posterior teeth	All the dentition	Cannot locate
After the intervention, do you have pain in your teeth when they are in contact?		Yes		No	
After the intervention, do you have the feelings of:	Swelling	Yes		No	
	Numbness	Yes		No	
Did you stay at home from school or work specifically due to discomfort following the intervention?		Yes		No	
After the intervention, do you have difficulty in:	Speech	Not at all		A little	A lot
	Sleeping	Not at all		A little	A lot
	Eating/Chewing	Not at all		A little	A lot
	Tooth brushing	Not at all		A little	A lot
Has the following been adversely affected after the intervention?	Physical activity (e.g. sport)	Not at all		A little	A lot
	Social activity	Not at all		A little	A lot
	Emotional Status (Happiness/Depression)	Not at all		A little	A lot
How would you describe the duration of the intervention visit		Normal		Lengthy	
How would you describe the intervention visit		Normal		Annoying	

Table 4
Revised and final version of the validated questionnaire (Arabic version).

[illegible]

Discussion

The OHRQoL plays a vital role in clinical trials to evaluate the outcomes of preventive and therapeutic programs, aiding specialists in improving the quality of oral health treatments.⁴³ Recognizing its importance, the World Health Organization has emphasized the inclusion of quality-of-life measures in clinical studies.^{44,45,46}

Although extensive research has been conducted on patient experience, impact, and satisfaction with orthodontic treatment, there is limited emphasis on patient perception during adjunctive orthodontic treatment. Most of these studies have relied solely on the visual analogue scales (VAS) to assess pain and discomfort without addressing other aspects comprehensively through the use of questionnaires, so this study is considered the first to develop/utilize a questionnaire to comprehensively examine patient perception during adjunctive orthodontic treatment, providing valuable insights that can enhance compliance, address challenges, and optimize treatment protocols.

For content and face validity, experts were selected following guidelines from Grant and Davis⁴⁷ and Rubio *et al.*,⁴⁸ ensuring substantial clinical expertise and teaching experience. The validity of questionnaire content depends on expert evaluations, but including unqualified individuals can undermine the process.^{49,50}

Increasing the number of expert reviewers enhances reliability by incorporating diverse perspectives shaped by varying educational backgrounds and experience levels.^{11,33,51} While some studies may require a single validation round, this research conducted two rounds for refinement, aligning with the recommendations by Lynn¹¹, Haynes *et al.*⁵², Rubio *et al.*,⁴⁸ and Polit *et al.*⁵³ Polit *et al.*⁵³ suggests beginning with 8 to 12 experts before narrowing it down to 3 to 5 in later stages. In this study, 12 experts participated in both rounds, reinforcing the trustworthiness of the assessment.

During the first round of content validation, all questionnaire items were deemed valid and relevant to the underlying construct (I-CVI ≥ 0.78). The S-CVI for the overall questionnaire was 0.94, exceeding the 0.90 threshold for validity. Comparing these results with the standards established by Lynn¹¹ and Polit *et al.*,⁵³ the content validity is excellent. However, some experts suggested some modifications to certain items to enhance their appropriateness.

Face validity was assessed through feedback from professionals and patients, following the systematic approach outlined by Trochim *et al.*⁵⁴ While face validity can encourage respondent participation, it is considered the weakest form of validation and should not be used in isolation, as noted by Waltz *et al.*⁴¹ In this study, content and face validation complemented each other, with quantitative and qualitative feedback. This lines up with Lynn¹¹, who emphasized expert involvement in identifying omissions and suggesting improvements.

Clarity and readability were evaluated by experts, with the questionnaire achieving 96.4% agreement. Adjustments were made to streamline its content. Additionally, thirty patients reviewed the validated and translated questionnaire using a face validation form, following strategies from Zamanzadeh *et al.*,⁵⁵ Yassir *et al.*,¹⁹ and Haik and Yassir.¹⁴ Their assessments resulted in excellent agreement on readability and comprehension.

Regarding the translation process, A rigorous translation methodology was accomplished on the validated questionnaire, with linguistic accuracy and conceptual fidelity. The English to Arabic translation was accomplished by an official translation bureau using the services of highly qualified bilingual professionals. The English version was translated to Arabic by two translators and then a critical assessment and synthesis was carried out by the team leader. This approach to methodology is consistent with the suggestions of Goranson *et al.*,²² that recommend multi-translator validation as a way of increasing reliability and contextual accuracy. To further safeguard the original content, a back-translation procedure was adopted, following the standardized procedures of WHODAS 2.0.⁵⁶ This is a holistic approach to translation that ensures that the meaning is preserved, and that the methodology is accurate, as per the academic and linguistic standards.

Analysis of reliability revealed that the questionnaire demonstrated had a high degree of internal consistency, which is indicated by the Cronbach alpha coefficients of the three sections (0.722, 0.708, and 0.750, respectively), which support the reliability of the questionnaire and its structural consistency. But, as this scale is meant to measure a condition which by nature changes with time, test-retest reliability is not an appropriate measure of the stability of the scale.⁵⁷ Given that patients' responses and perceptions naturally change over time due to their progression through treatment, measuring repeatability through a test-retest approach becomes inherently challenging.¹⁹

Limitations of the study

- The study included only 12 experts and 30 patients, which was insufficient for conducting factor analysis or other advanced statistical tests. As a result, validity assessments relied on expert evaluations rather than statistical validation, limiting construct validity.
- Test-retest reliability is not applicable due to the conditional variability.

Conclusions

This study successfully developed and validated a bilingual questionnaire to assess patient perceptions during adjunctive orthodontic therapy. The instrument showed strong validity and acceptable reliability, providing a practical framework for integrating patient perspectives into orthodontic research and clinical protocols. This validated tool addresses a key gap in orthodontic patient-reported outcome measures and is expected to facilitate systematic evaluation of patient experiences, contributing to evidence-based optimization of adjunctive care. And thus, this represents the first study to provide a culturally adapted instrument specifically designed to capture patient experiences with adjunctive orthodontic modalities in the region, marking an important step toward advancing patient-centered orthodontic research and practice.

Declarations

Source of Funding

The study is self-funded.

Supplementary material

Supplementary data are available upon request.

Conflicts of interest

None to declare.

Ethical approval

This study was part of a randomized clinical trial that registered at ClinicalTrials.gov on 26February 2025 (Registration number: NCT06847880). The Ethics Committee of the College of Dentistry at the University of Baghdad approved the study under reference number 1014 in January 21, 2025.

Consent

All participants, or their legal guardians in the case of minors, provided written informed consent to participate in the study and for the publication of anonymized data in scientific reports.

Data availability statement

Data is available upon request.

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