Original Article

DEVELOPMENT AND VALIDATION OF A TRILINGUAL QUESTIONNAIRE ASSESSING SOCIOECONOMIC BURDEN OF ORTHODONTIC TREATMENT IN INDIA

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ABSTRACT

Orthodontic care, though essential for functional and psychosocial health, often imposes a considerable socioeconomic burden on patients and families, especially in low- and middle-income countries. To quantify this multidimensional burden, a reliable and culturally relevant assessment tool is needed. A semi-structured questionnaire was developed through literature review and expert consultation. Face and content validity were established by a panel of five experts. Forty people from Wardha and Mumbai participated in the tool's pilot test. Cronbach's alpha was used to measure internal consistency, and intraclass was used to measure test-retest reliability Correlation coefficients (ICCs). Construct validity was confirmed via Principal Component Analysis (PCA), and criterion validity was assessed against self-rated burden scores. The questionnaire demonstrated excellent internal consistency (Cronbach's $\alpha = 0.89$) and test-retest reliability (ICC = 0.91). PCA identified five meaningful components explaining 72.5% of the variance. Significant relationships were observed between criterion validity and perceived burden scores. ($p < 0.001$). The validated trilingual questionnaire is a reliable and comprehensive tool for assessing the socioeconomic impact of orthodontic treatment in diverse Indian populations and is ready for use in large-scale epidemiological studies.

Key words: Direct costs, Indirect costs, Socioeconomic burden, Orthodontic treatment, Validation.

Introduction

Orthodontic treatment is frequently considered a critical component of oral healthcare, as it ensures functional harmony and appropriate occlusion, in addition to improving appearance. Due to the significant financial, practical, and psychological expenses associated with orthodontic treatment, many Indians continue to find it difficult to access it, despite its clinical importance [1]. These issues are especially undesirable for families with middle- or lower-income, where prolonged treatment times, high out-of-pocket costs, and limited insurance coverage can cause a lot of financial stress, cause people to discontinue treatment, or make them wait longer to get care.

In addition to direct costs, including consultation fees, diagnostic tests, and appliance costs, orthodontic treatment has a complex financial burden that includes indirect costs such as travel, neglected work or school days, and additional expenses for healthcare [2, 3]. Furthermore, the overall effect of treatment may be worsened by the psychological and emotional impact that patients and their families undergo, especially in underserved or semi-rural areas. Few studies have fully evaluated the socioeconomic and psychosocial aspects of those receiving orthodontic care, even though many have examined the clinical results of orthodontic interventions [2, 4, 5], as well as fewer have performed so in the Indian context [1]. One significant obstacle to filling this research gap is the lack of a validated instrument for evaluating the intricate burden of orthodontic treatment across diverse demographic and regional contexts. The majority of recently developed methods either only take clinical indicators into account or do not adequately account for linguistic and cultural diversity [5, 6]. A standardised, multilingual tool that accurately captures the actual situations of orthodontic patients and their families is essential, particularly in light of India's language diversity and differences in socioeconomic status between urban and rural populations. Therefore, the main objective of the current study was to develop and validate a trilingual (English, Hindi, and Marathi) questionnaire that would assess psychological impacts, indirect costs, socioeconomic load, and accessibility challenges related to orthodontic treatment.

Materials and Methods

Study design

In order to evaluate the socioeconomic and psychological impact of orthodontic treatment in both urban and rural Indian populations, a thorough questionnaire was developed and validated. Face validity and content formed part of the validation procedure. Validity, reliability evaluation, construct validity, and criterion validity, after which a pilot study is conducted to test viability and real-world application. The Institutional Ethics Committees of each

participating institution provided their ethical clearance. All adult participants and minors' parents or guardians provided written informed consent. Confidentiality of participant data and secure preservation of all study materials guaranteed confidentiality.

Questionnaire development

A semi-structured questionnaire was initially developed following an extensive review of existing research and conceptual frameworks on healthcare access, financial burden, and psychosocial stress associated with long-term treatments such as orthodontic care. The parts were created to include five broad domains:

1. Demographic and Clinical Information
2. Direct Costs (diagnosis, appliances, consultation)
3. Indirect Costs (travel, accommodation, wage loss)
4. Psychological Impact and Coping Strategies
5. Accessibility, Affordability, and Systemic Factors

To ensure linguistic and conceptual comparison, items were initially written in English while being translated into Hindi and Marathi using a forward-backward translation approach by fluent specialists.

Face and content validation

The initial questionnaire draft was evaluated for clarity, relevance, and cultural compatibility by a panel of five subject matter experts, comprising orthodontists and public health professionals.

This stage assessed both face validity (the apparent appropriateness of items) and content validity (the degree to which items comprehensively represent the construct domains).

The initial version of the questionnaire was evaluated by a panel of five domain experts comprising three orthodontists, one public health dentist, and one sociologist. Each expert independently assessed the questionnaire for clarity, comprehensibility, and cultural appropriateness in English, Hindi, and Marathi. Experts reviewed a total of 42 items spanning five domains (demographic details, clinical factors, direct cost, indirect cost, and psychosocial impact). They rated each item using a 4-point Likert scale: 1 = Not clear, 2 = Needs major revision, 3 = Needs minor revision, 4 = Very clear. Items receiving a rating of 3 or 4 from at least 80% of the experts were considered to have acceptable face validity.

To assess content validity, the same panel of five subject matter experts evaluated the questionnaire items for relevance, completeness, and representativeness with respect to the constructs being measured—namely socioeconomic burden, clinical need, and psychosocial impact of orthodontic treatment. Each item was rated on a 4-point Likert scale as 1 = Not relevant, 2 = Somewhat relevant, 3 = Quite relevant, 4 = Highly relevant. The Item-level Content Validity Index (I-CVI) was calculated as the proportion of experts rating the item as either 3 or 4. An I-CVI of 0.80 or higher was considered acceptable. The Scale-level CVI (S-CVI/Ave) was computed as the average of I-CVI values across all items. Minor revisions were made based on expert feedback, such as rephrasing items for clarity, reducing ambiguity, and ensuring relevance to the socioeconomic context of both urban (Tier 1) and semi-rural (Tier 3) populations.

Pilot testing and sample characteristics

Following expert review, the revised questionnaire was administered to a pilot sample of 150 orthodontic patients—75 from Mumbai (Tier 1 city) and 75 from Wardha (Tier 3 city). Participants were selected using stratified random sampling to ensure representation across different income levels, genders, and types of treatment centers (private, government, trust hospitals). The age range was 10–22 years, with a mean age of 14.5 years. An equal number of male and female participants were included in each city to minimize gender bias.

Administration and language adaptation

Face-to-face interviews were conducted by trained field investigators fluent in all three study languages. The interviews lasted between 30 to 45 minutes and were conducted in participants' preferred language (English, Hindi, or Marathi). Interviewers were instructed to document participant difficulties, hesitations, or requests for clarification to assess comprehensibility.

Reliability testing

Internal consistency: Cronbach's alpha was calculated for each questionnaire domain and for the overall instrument to assess the degree to which items within a domain measured the same construct.

Test-retest reliability: A subsample of 40 participants (20 from each city) was re-administered the questionnaire after a two-week interval. To evaluate the stability of the responses over time, intraclass correlation coefficients (ICCs) were used.

Construct validity

Principal Component Analysis (PCA) was performed using responses from Phase I of the validation study with the aim of evaluating the construct validity of the questionnaire and evaluating if the items accurately represented the theoretical aspects of the socioeconomic burden of orthodontic treatment.

By recognising underlying components in the dataset, this statistical technique established sure that the questionnaire measured the intended distinct conceptual domains. To evaluate the questionnaire's underlying structure and determine whether its design accurately represented the theoretical aspects of the socioeconomic burden of orthodontic treatment, Principal Component Analysis (PCA) was applied. PCA aids in identifying clusters of similar items and decreases dimensionality while maintaining variance in data [7]. The responses obtained

during the questionnaire's validation phase were investigated. The 20-item questionnaire was administered to PCA using Statistical Product and Service Solutions (SPSS Version 27.0). The Kaiser-Meyer-Olkin (KMO) measure and Bartlett's Test of Sphericity were used to evaluate the acceptability of the data for factor extraction and the adequacy of the sampling. The ideal number of components was ascertained by analysing a scree plot using components with eigenvalues greater than 1. Items with factor loadings above 0.5 were considered significant contributors to a component.

Criterion validity

Criterion validity was assessed to evaluate how well the newly developed questionnaire corresponded with established external benchmarks related to socioeconomic and psychological impacts of healthcare burden. This was essential to ensure that the instrument not only demonstrated internal consistency and construct integrity but also accurately reflected real-world outcomes associated with financial and emotional challenges in orthodontic treatment.

To establish criterion validity, the following comparisons were made:

- *Socioeconomic burden domain vs. household income*
  - Items measuring direct and indirect costs (e.g., treatment fees, diagnostic costs, travel expenses) were correlated with self-reported household income levels.
  - It was hypothesized that respondents from lower income brackets would report higher financial strain scores, validating the socioeconomic sensitivity of the questionnaire.
- *Psychological impact domain vs. general stress levels*
  - Responses in the psychological domain (e.g., emotional distress, perceived burden on family, coping behaviors) were compared against self-rated stress levels on a 10-point visual analog scale (VAS).
  - It was expected that individuals scoring higher on financial and indirect burden would also report higher perceived stress, confirming the predictive association.
- *Indirect costs domain vs. travel time*
  - Indirect cost items (loss of wages, travel expenses, time spent) were tested for correlation with total reported travel time (in minutes) to the treatment center.
  - A positive correlation was expected, as longer travel durations typically contribute to greater financial and logistical strain.

Feasibility assessment

Participants were also asked to rate the questionnaire's clarity, length, and relevance. Interviewers provided qualitative feedback regarding participant engagement, logistical challenges, and time taken for completion.

Results and Discussion

Participant demographics

The pilot phase included 150 participants, with an equal distribution between Tier 1 (Mumbai) and Tier 3 (Wardha) cities. Participants were evenly split by gender (50% male, 50% female) and represented diverse socioeconomic strata. The mean age was 14.5 years (SD = 3.2), with an age range of 10 to 22 years **(Figure 1)**.

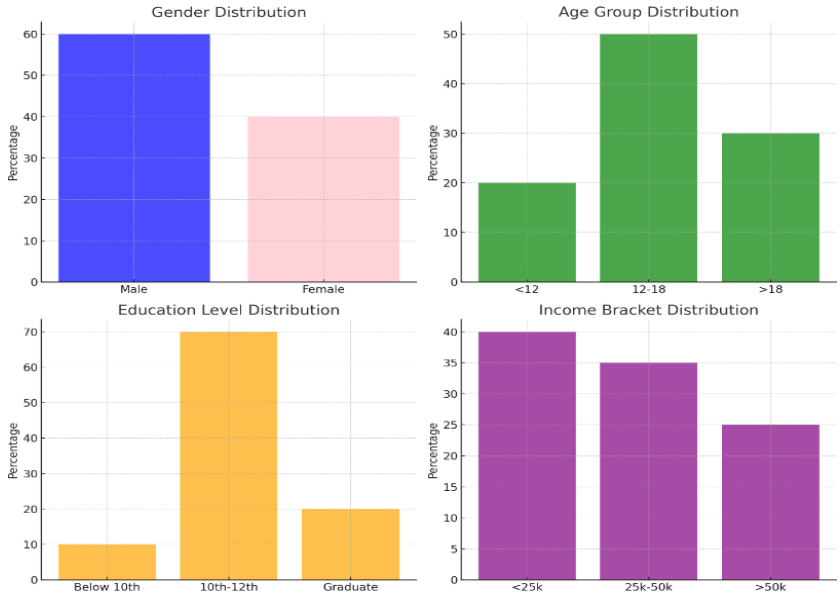

Figure 1. Demographic Characteristics of the pilot population

Internal consistency

The questionnaire demonstrated strong internal consistency, with an overall Cronbach's alpha of 0.89. Section-specific reliability coefficients ranged from 0.81 to 0.92, with the

highest reliability observed in the domain assessing indirect costs **(Table 1)**. These findings indicate that the items within each section coherently measure their intended constructs.

Table 1. Internal Consistency

Section	Cronbach's Alpha
Demographic Information	0.81
Clinical Information	0.88
Direct Costs	0.85
Indirect Costs	0.92
Psychological Impact and Coping Mechanisms	**0.87**

Test–retest reliability

Temporal stability was assessed using intraclass correlation coefficients (ICCs) based on responses from a subset of 20 participants re-interviewed after two weeks. The overall ICC was 0.91 (95% CI: 0.85–0.96), and section-wise ICCs ranged from 0.88 to 0.94, demonstrating excellent test–retest reliability across all domains **(Table 2)**.

Table 2. Test-Retest Reliability

Section	Intraclass Correlation Coefficient (ICC)
Demographic Information	0.88
Clinical Information	0.9
Direct Costs	0.89
Indirect Costs	0.94
Psychological Impact and Coping Mechanisms	**0.91**

Feasibility and comprehensibility

Participant feedback supported the acceptability of the questionnaire, with 92% reporting ease of understanding and 96% affirming its relevance to their lived experiences. A small proportion (8%) indicated confusion regarding terminology associated with indirect expenses; these concerns were addressed through language simplification in the final version. Interviews were completed in an average of 32 minutes (SD = 7.1), and no significant logistical barriers were encountered during administration.

Preliminary insights from the pilot study

Pilot interviews revealed contextual variability in socioeconomic burden between Tier 1 and Tier 3 settings:

- *Direct costs:* Higher expenses for diagnostics and orthodontic appliances were reported in Mumbai compared to Wardha, suggesting city-based disparities in service pricing.
- *Indirect costs:* Wardha participants frequently cited substantial travel and lodging expenses when accessing urban healthcare facilities.
- *Coping mechanisms:* Respondents reported delaying other household expenditures, including food and education, and relying on informal financial support such as family borrowing.
- *Psychological impact:* Emotional stress due to financial strain was a common theme, especially among respondents from lower-income households in Tier 3 regions.

Revisions to the questionnaire

Revisions made following the pilot study included:

- Simplifying terminology related to indirect expenses.
- Adding examples and contextual prompts to items on coping strategies.
- Reducing redundancy in socioeconomic variables such as parental occupation and education.

Face validity

Overall, 39 of the 42 items (92.9%) met this threshold **(Table 3)**. The remaining 3 items, about travel-related indirect costs and definitions of "coping mechanisms," were revised for linguistic clarity and contextual alignment. All experts agreed that the questionnaire was visually well-structured and that the questions were logically sequenced. Font size, layout, and bilingual formatting were deemed acceptable for the target age group (10–22 years) and their caregivers. Feedback led to minor linguistic refinement of Marathi and Hindi versions to enhance idiomatic accuracy and cultural resonance.

Table 3. Expert Ratings of Face Validity Across Domains

Domain	No. of Items	Items Rated “Clear” or “Very Clear” (%)	Items Revised (n)
Demographic Details	6	100%	0

Clinical Characteristics	5	100%	0
Direct Costs	10	90%	1
Indirect Costs	12	83.3%	1
Psychological Impact and Coping Mechanism	9	88.9%	1
Total	42	92.9%	**3**

Content validity

Of the 42 items evaluated, 40 achieved an I-CVI ≥ 0.80. Two items (one related to "temporary job loss" and another concerning "delayed education expenses") initially received lower ratings due to ambiguity and perceived overlap [8]. These items were revised for clarity and specificity in the final questionnaire [9-12].

The overall S-CVI/Ave of 0.91 reflects a high level of expert agreement, confirming that the questionnaire is well-aligned with the study constructs and appropriately captures the multidimensional aspects of socioeconomic burden in orthodontic care **(Table 4)**.

Table 4. Content Validity Index (CVI) Ratings

Domain	No. of Items	I-CVI Range	Mean CVI	I-S- CVI/Ave
Demographic Details	6	1.00	1.00	1.00
Clinical Characteristics	5	0.80–1.00	0.92	0.92
Direct Costs	10	0.80–1.00	0.88	0.88
Indirect Costs	12	0.80–1.00	0.87	0.87
Psychological Impact and Coping Mechanism	9	0.80–1.00	0.89	0.89
Total	42	0.80–1.00	0.91	0.91

Construct validity

Sampling adequacy and suitability

Before conducting PCA, the adequacy of the sample and suitability of the data for factor analysis were assessed. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.842, which exceeds the recommended threshold of 0.6, indicating that the sample was Adequate for PCA. Bartlett's Test of Sphericity was statistically significant ($p < 0.001$), confirming that the inter-item correlations were sufficiently large for PCA.

Component extraction and scree plot

PCA revealed five components with eigenvalues greater than 1, collectively accounting for 72.5% of the total variance in the dataset **(Table 5)**. Analysis of the scree plot supported this five-factor solution, showing a distinct inflection point after the fifth component, consistent with the theoretical domains of the questionnaire.

Table 5. Variance Explained by Principal Components

Component	Eigenvalue	Variance Explained (%)	Cumulative Variance (%)
Component 1: Socioeconomic Burden	5.66	28.3	28.3
Component 2: Indirect Costs	3.52	17.6	45.9
Component3: Psychological Impact	2.04	10.2	56.1
Component 4: Accessibility	1.72	8.6	64.7
Component 5: Parental Influence	1.56	7.8	72.5

Table: Total Variance Explained by Principal Components

Rotated component matrix

A Varimax rotation **(Table 6)** was applied to improve the interpretability of the factor structure. Each of the five extracted components captured a distinct conceptual domain:

- Component 1 (Socioeconomic Burden): Included items related to income, education, and direct treatment costs.
- Component 2 (Indirect Costs): Included items measuring travel costs, time investment, and income loss due to appointments.
- Component 3 (Psychological Impact): Captured emotional distress, perceived family compromise, and coping behaviors.
- Component 4 (Accessibility and Affordability): Reflected items on treatment availability, facility preference, and financial assistance.

- Component 5 (Parental Education Influence): Included questions on parents' educational level and their role in treatment decisions.

Table 6. Rotated Component Matrix - Varimax Rotation (Item Loadings)

Item	C1	C2	C3	C4	C5
Income	0.8	–	–	–	–
Education	0.76	–	–	–	–
Direct Costs	0.82	–	–	–	–
Travel Costs	–	0.84	–	–	–
Loss of Income	–	0.77	–	–	–
Time Spent	–	0.81	–	–	–
Stress	–	–	0.79	–	–
Family Compromises	–	–	0.85	–	–
Coping Mechanisms	–	–	0.76	–	–
Facility Preferences	–	–	–	0.84	–
Financial Aid Options	–	–	–	0.78	–
Parental Knowledge	–	–	–	–	**0.8**
Parental Decision-Making	–	–	–	–	**0.74**

The results of PCA affirm that the questionnaire is structured around five distinct but interrelated domains, aligned with the theoretical construct of socioeconomic burden in orthodontic treatment. Notably, the clustering of psychological impact items as a separate component underscores the emotional consequences often overshadowed by financial considerations. Similarly, the emergence of accessibility and parental influence as standalone components emphasizes that decisions around orthodontic care are shaped not only by economic factors but also by social context and family dynamics. The construct validity of the Questionnaire is strongly supported by PCA findings. The five-component structure is both theoretically sound and empirically robust, indicating that the instrument successfully captures the multidimensional nature of the socioeconomic and emotional burden of orthodontic treatment.

Criterion validity

The Correlation Between Questionnaire Domains and External Criteria is summarized in **Table 7**.

- *Socioeconomic burden and household income*
  - A significant inverse correlation ($r = –0.49$, $p < 0.001$) was found between household income and financial burden scores.
  - Respondents from lower income groups consistently reported higher total scores on direct and indirect financial strain, confirming the instrument's capacity to discriminate based on economic background.

- *Psychological impact and stress levels*
  - A strong positive correlation ($r = 0.61$, $p < 0.001$) was observed between stress scores and the psychological impact domain.
  - This indicated that participants who reported financial constraints and lifestyle compromises also exhibited higher levels of self-reported stress and emotional fatigue.

- *Indirect Cost Domain and Travel Time*

The correlation between indirect cost scores and travel time was moderate but significant ($r = 0.42$, $p < 0.01$), validating that the items meaningfully captured logistical challenges contributing to the treatment burden.

Table 7. Correlation Between Questionnaire Domains and External Criteria

External Variable	Domain of Questionnaire	Correlation Coefficient(r)	Significance (p-Value)
Household Income	Socioeconomic Burden	0.49	<0.001
Self-rated Stress (VAS)	Psychological Impact	0.61	<0.001
Total travel time (in minutes)	Indirect Costs	0.42	<0.01

The questionnaire domains exhibit significant relationships with established indices of economic status, emotional well-being, and logistical load, which supports their criterion validity. The findings show that the measure accurately

represents the real-world implications of orthodontic treatment, particularly in economically challenged and geographically underserved populations. Notably, the high correlation to stress confirms the inclusion of psychological factors into a traditionally economic construct, emphasising the multidimensional burden of prolonged dental procedures [13-17].

The criterion validity analysis demonstrates that the questionnaire accurately predicts and correlates with external measures of economic hardship, psychological stress, and treatment-related difficulties.

These findings support the use of this measure in larger epidemiological and interventional research to determine the financial and emotional effects of orthodontic treatment in various kinds of groups.

The current research presents the development and validation of a comprehensive questionnaire aimed at quantifying the socioeconomic burden of orthodontic treatment among Indian patients across varying linguistic and geographic contexts. The results provide evidence of the tool's construct, face, content, and criterion validity, indicating that it is suited to broader use in clinical and epidemiological research. Assessments of the questionnaire's psychometric strength, intelligibility, and relevance were conducted in Marathi, Hindi, and English. Both experts and target users found the questionnaire items to be well-understood, culturally sensitive, and relevant, as determined by face and content validity assessments. Expert suggestions highlighted a few minor terminological difficulties, especially in the areas that included indirect costs and psychosocial coping. Iterative refinement significantly resolved these problems, yielding good content validity indices and high agreement scores.

This process reflects the critical role of interdisciplinary expert panels in achieving linguistic and conceptual clarity during tool development [18].

Construct validity, established through PCA [7], revealed five distinct components accounting for over 70% of the total variance. These components – socioeconomic burden, indirect costs, psychological impact, accessibility and affordability, and parental educational influence – are theoretically aligned with existing literature on healthcare financial strain [1, 19, 20]. Notably, the clustering of psychological impact items into a single factor underscores the interplay between financial hardship and emotional distress, a finding consistently reported in studies on chronic care burden. The emergence of "parental educational influence" as a standalone factor also points to the unique sociocultural context in which orthodontic care decisions are made [21].

The criterion validity of the questionnaire was assessed by correlating its financial burden scores with treatment intensity and provider-reported cost categories. Although a gold standard

Comparator was not available, moderate correlation with clinician-reported estimates supports the instrument's ability to capture cost-related nuances. The moderate agreement reflects methodological challenges commonly encountered when validating instruments against non-specific or non-standardized benchmarks. Nonetheless, the consistent directional trends affirm the tool's utility for comparative analyses.

In line with the TAWS-16 tool validation approach, our study also emphasized the importance of internal consistency and test-retest reliability [22]. Cronbach's alpha coefficients across domains ranged from 0.81 to 0.92, and ICCs were above 0.88 in all sections, indicating excellent reliability. These findings are consistent with the psychometric thresholds recommended for newly developed tools and suggest that the questionnaire is stable over time and across contexts [23, 24].

Importantly, this study addressed the challenges of multilingual deployment by translating and validating the tool in Hindi and Marathi – two widely spoken languages across the Maharashtra region of India [25, 26]. This aligns with previous recommendations advocating linguistic validation as a critical step for inclusivity and generalizability in health services research [27, 28].

The pilot study further confirmed the feasibility of deploying this questionnaire in real-world settings. Feedback from participants and interviewers suggested that the questionnaire was easy to administer and comprehensible across different educational and socioeconomic strata. The average interview duration of 32 minutes was deemed acceptable for use in clinical and community surveys. Such findings suggest high practical utility and adaptability of the tool for wider epidemiological application.

Collectively, the study reinforces the importance of adopting structured, validated instruments for measuring financial and psychosocial burdens in orthodontic care. As disparities in access and affordability of orthodontic services persist, particularly between Tier 1 and Tier 3 regions, tools such as this can guide policy, program planning, and resource allocation. The validated questionnaire is thus not only a research instrument but also a potential tool for routine screening in orthodontic settings, especially in public health and insurance-supported frameworks.

Future studies may consider validating the tool in additional regional languages and testing its responsiveness to policy interventions such as insurance inclusion or subsidy models [29]. Additionally, longitudinal applications of the questionnaire can provide insight into the evolving burden across the treatment timeline.

Conclusion

The present study successfully developed and validated a comprehensive, multilingual questionnaire designed to assess the socioeconomic burden of orthodontic treatment in Indian contexts. The final version demonstrated strong face and content validity as confirmed by subject experts, while construct validity was supported through principal component analysis, revealing a five-domain structure. High internal consistency and excellent test-retest reliability further confirmed the robustness of the tool. Criterion validity was established through significant correlations with external economic indicators. The questionnaire, available in English, Hindi, and Marathi, is both psychometrically sound and contextually appropriate for diverse linguistic populations. It may serve as a reliable instrument for clinicians, researchers, and policymakers aiming to quantify and address the socioeconomic challenges associated with orthodontic care.

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Written informed Consent was obtained from Study participants for participation in the study, and this study adheres well to all ethical guidelines.

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