



www.bioinformation.net
Volume 22(9)



Research Article

Received September 1, 2026; Revised September 30, 2026; Accepted September 30, 2026, Published September 30, 2026

DOI: 10.6026/973206300225962

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478

2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

Declaration on Publication Ethics:

The author's state that they adhere with COPE guidelines on publishing ethics as described elsewhere at <https://publicationethics.org/>. The authors also undertake that they are not associated with any other third party (governmental or non-governmental agencies) linking with any form of unethical issues connecting to this publication. The authors also declare that they are not withholding any information that is misleading to the publisher in regard to this article.

Declaration on official E-mail:

The corresponding author declares that lifetime official e-mail from their institution is not available for all authors

License statement:

This is an Open Access article which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited. This is distributed under the terms of the Creative Commons Attribution License

Comments from readers:

Articles published in BIOINFORMATION are open for relevant post publication comments and criticisms, which will be published immediately linking to the original article without open access charges. Comments should be concise, coherent and critical in less than 1000 words.

Disclaimer:

Bioinformation provides a platform for scholarly communication of data and information to create knowledge in the Biological/ Biomedical domain after adequate peer/editorial reviews and editing entertaining revisions where required. The views and opinions expressed are those of the author(s) and do not reflect the views or opinions of Bioinformation and (or) its publisher Biomedical Informatics. Biomedical Informatics remains neutral and allows authors to specify their address and affiliation details including territory where required.

Edited by Ruby Singh

E-mail: bioinformationruby@gmail.com

Citation: Sangi *et al.* Bioinformation 22(9): 5962-5966 (2026)

Oral health-related quality of life in patients with cleft lip and palate: A cross-sectional observational study

Nun Sangi¹, Mayank Malik², Nikil Kumar Jain^{3,*}, Prajwal Prabhu⁴, D. Chethan Kumar⁵ & Ananya Madiyal⁶

¹Department of Orthodontics, Vul Zual Dental Clinic, Chanmari, Aizawl, Mizoram; ²Department of Oral & Maxillofacial Surgery, Kalinga Institute of Dental Sciences, Bhubaneswar, Odisha, India; ³Department of Oral and Maxillofacial Surgery, Yogita Dental College and Hospital, KHED (Ratnagiri), Maharashtra, India; ⁴Department of Orthodontics, Dayananda Sagar College of Dental Sciences, Bengaluru, India; ⁵Department of Orthodontics, Sri Siddhartha Dental college, Affiliated to Sri Siddhartha Academy of Higher Education, Tumkur, Karnataka, India; ⁶Department of Oral Medicine and Radiology, AB Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangalore-575018, India; *Corresponding author

Affiliation URL:

<https://aizawl.idbf.in/4074766/vul-zual-dental-clinic>

<https://www.esic.nic.in/>

<https://yogitadentalcollege.com/>

<https://dscds.edu.in/orthodontics.htm>

<https://ssahe.edu.in/ssdc/>

<https://nitte.edu.in/absmids/>

Author contact:

Nun Sangi - E-mail: drnunsangi@gmail.com

Mayank Malik - E-mail: mayankamalik97@gmail.com

Nikil Kumar Jain - E-mail: nikiljainomfs@gmail.com

Prajwal Prabhu - E-mail: dr.prajwalprabhu@gmail.com

D. Chethan Kumar - E-mail: drchethankumar83@gmail.com

Ananya Madiyal - E-mail: ananyamadiyal@gmail.com; Phone: +91 9538840189

Abstract:

Cleft lip and palate adversely affects oral health, function, speech, esthetics and oral health-related quality of life. A cross-sectional study evaluated 36 repaired cleft lip and palate patients aged 10–18 years using clinical and functional outcome measures. Patients with bilateral clefts had significantly higher DMFT, OHI-S, speech impairment and poor oral health-related quality of life than unilateral cleft patients ($p < 0.05$). Severe oral health-related quality of life impairment was observed in 50.0% of bilateral cases compared with 11.1% of unilateral cases ($p = 0.006$). Thus, bilateral cleft lip and palate is associated with poor oral health and function, emphasizing the need for comprehensive multidisciplinary rehabilitation.

Keywords: Cleft lip and palate (CLP), oral health-related quality of life (OHRQoL), oral rehabilitation, craniofacial anomalies, multidisciplinary rehabilitation

Background:

Cleft lip and palate (CLP) is one of the most common congenital craniofacial anomalies resulting from failure of fusion of the facial processes during embryonic development. It affects oral function, facial growth, speech, esthetics and psychosocial well-being, often requiring long-term multidisciplinary care involving surgeons, pediatric dentists, orthodontists, prosthodontists and speech therapists [1, 2]. Although advances in surgical techniques and interdisciplinary rehabilitation have improved clinical outcomes, successful management extends beyond anatomical closure and esthetic correction to include restoration of function and quality of life [3]. Oral health-related quality of life (OHRQoL) has emerged as an important patient-centered outcome measure that evaluates the impact of oral conditions on functional ability, psychological health, social interaction, self-esteem and daily activities. Unlike conventional clinical indices, OHRQoL provides a comprehensive assessment of treatment outcomes by incorporating patients' perceptions of their oral health and overall well-being [4, 5]. Despite completion of primary surgical treatment, many individuals with CLP continue to experience dental caries, malocclusion, altered craniofacial growth, speech impairment, feeding difficulties, residual esthetic concerns and repeated clinical interventions. These challenges may adversely affect oral function, social participation and emotional health throughout childhood and adolescence, resulting in reduced OHRQoL compared with unaffected individuals [6, 7]. Furthermore, long-term rehabilitation outcomes are influenced by functional performance, esthetic satisfaction and psychosocial adaptation,

emphasizing the importance of continuous evaluation during growth and development [8]. Therefore, it is of interest to evaluate the oral health-related quality of life in patients with cleft lip and palate using clinical and functional outcome measures in a hospital-based cross-sectional observational study.

Materials and Methods:**Study design and study setting:**

The present study was designed as a cross-sectional observational original study and was conducted in the Department of Orthodontics. The study was carried out over a period of 12 months following approval from the Institutional Ethics Committee. All procedures performed in the study were conducted in accordance with institutional ethical standards and the principles of the Declaration of Helsinki. Written informed consent was obtained from the parents or a legal guardian of participants aged below 18 years and assent was obtained from eligible children wherever applicable.

Study population:

The study included patients diagnosed with repaired cleft lip and palate (CLP) who attended regular follow-up visits during the study period. Consecutive eligible patients fulfilling the selection criteria were recruited until the required sample size was achieved.

Sample size determination:

Sample size estimation was performed based on comparison of mean oral health-related quality-of-life clinical scores between

studies groups using data assumptions obtained from previously published cleft outcome literature. Considering:

- [1] confidence level: 95%
- [2] study power: 80%
- [3] effect size: 0.90
- [4] alpha error: 5%

the minimum estimated sample size obtained was 32 participants. To compensate for incomplete clinical records and possible exclusion during analysis, the final sample size was increased and rounded to 36 participants.

Group allocation:

Participants were divided into two groups based on cleft presentation:

- [1] Group I (n = 18): Unilateral cleft lip and palate (UCLP)
- [2] Group II (n = 18): Bilateral cleft lip and palate (BCLP)

Grouping was confirmed using institutional treatment records and clinical examination.

Eligibility criteria:

Inclusion criteria:

- [1] Patients aged 10–18 years.
- [2] Patients with previously repaired unilateral or bilateral cleft lip and palate.
- [3] Patients undergoing routine follow-up care.
- [4] Patients cooperative for complete clinical examination.
- [5] Availability of complete institutional clinical records.

Exclusion criteria:

- [1] Syndromic cleft conditions.
- [2] Isolated cleft lip or isolated cleft palate.
- [3] Presence of systemic disease affecting oral health.
- [4] Ongoing orthodontic treatment interfering with oral evaluation.
- [5] Patients with incomplete documentation.
- [6] Patients unwilling to participate.

Clinical examination protocol:

All examinations were performed by a single calibrated examiner under standardized clinical conditions to reduce inter-examiner variability. Prior to commencement of the study, calibration was performed on five patients not included in final analysis and acceptable agreement was achieved. Participants underwent detailed oral and functional assessment.

Demographic and clinical variables:

The following variables were recorded:

- [1] Age (years)
- [2] Sex
- [3] Type of cleft
- [4] Number of previous surgical procedures
- [5] Presence of speech therapy history
- [6] Oral hygiene practices

Oral health assessment:

Dental caries status:

Dental caries experience was recorded using the Decayed, Missing and Filled Teeth (DMFT) index according to standardized WHO diagnostic criteria. Total DMFT score was calculated for each participant.

Oral hygiene status:

Oral hygiene was assessed using the Simplified Oral Hygiene Index (OHI-S). Debris and calculus components were recorded and cumulative scores were categorized into:

- [1] Good
- [2] Fair
- [3] Poor

Gingival health:

Gingival condition was assessed using the Löe and Silness Gingival Index. Mean gingival scores were calculated for each participant.

Functional assessment:

Functional evaluation was performed clinically and through institutional records under the following domains:

- [1] Speech intelligibility
- [2] Feeding efficiency
- [3] Masticatory ability
- [4] Presence of oral discomfort
- [5] Oral functional limitation

Each domain was graded using predefined institutional clinical criteria:

- [1] 0 – No impairment
- [2] 1 – Mild impairment
- [3] 2 – Moderate impairment
- [4] 3 – Severe impairment

Assessment of oral health-related quality of life (OHRQoL):

OHRQoL was assessed through a composite clinical outcome score derived from objective oral and functional findings rather than questionnaire-based patient reporting. The final OHRQoL composite score was generated by integrating:

- [1] DMFT score
- [2] OHI-S score
- [3] Gingival Index score
- [4] Functional limitation score

Higher cumulative scores represented poorer oral health-related quality of life.

Based on total score, participants were categorized into:

- [1] Mild impact
- [2] Moderate impact
- [3] Severe impact

Data collection and management:

All observations were entered into a standardized data collection sheet and cross-verified before analysis. Data confidentiality was maintained throughout the study and participant identifiers were removed before statistical processing.

Statistical analysis:

Collected data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) software version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as mean $\pm$ standard deviation for continuous variables and frequency with percentage for categorical variables. Normality of data distribution was evaluated using the Shapiro-Wilk test.

Intergroup comparison was performed using:

- [1] Independent t-test for normally distributed continuous variables
- [2] Mann-Whitney U test for non-parametric variables
- [3] Chi-square test for categorical variables

Correlation between clinical variables and OHRQoL score was assessed using Pearson correlation analysis. A multivariable linear regression model was constructed to identify independent predictors of reduced oral health-related quality of life. Statistical significance was set at $p < 0.05$.

Results:

A total of 36 patients with repaired cleft lip and palate were included in the present study and completed clinical evaluation. Participants were categorized into Group I (Unilateral cleft lip and palate; $n = 18$) and Group II (Bilateral cleft lip and palate; $n = 18$). No participant was excluded after final enrollment. The mean age of the study population was 13.89 ± 2.41 years, with comparable age distribution between groups. Male participants constituted a slightly greater proportion of the study sample. Clinical evaluation demonstrated differences in oral health status and functional outcomes between unilateral and bilateral cleft groups. The demographic characteristics were comparable between both groups with no statistically significant difference in age or sex distribution ($p > 0.05$). However, participants with bilateral cleft involvement underwent significantly more surgical interventions compared with unilateral cleft patients ($p = 0.002$). A greater proportion of bilateral cleft patients also required speech therapy, although this difference did not reach statistical significance (Table 1). Comparison of oral health parameters demonstrated significantly poorer oral health among patients with bilateral cleft involvement. The mean DMFT score was higher in Group II (3.39 ± 1.24) compared with Group I (2.11 ± 1.02) indicating increased caries burden. Similarly, oral hygiene and gingival scores were significantly worse in the bilateral cleft group ($p < 0.05$), suggesting greater challenges in maintaining oral health (Table 2). Functional assessment demonstrated significantly increased impairment among patients with bilateral cleft lip and palate. Speech limitations showed the greatest intergroup difference, followed by masticatory difficulty and oral discomfort. Feeding-related limitations were also more pronounced in bilateral cleft cases. These findings indicate that increasing cleft severity was associated with greater functional compromise (Table 3). Composite oral health-related quality-of-life assessment revealed a significant difference between groups ($p = 0.006$). Nearly half of participants with unilateral cleft

demonstrated mild-to-moderate impact, whereas 50% of bilateral cleft patients showed severe OHRQoL impairment. This suggests that bilateral cleft involvement was associated with greater oral disease burden and reduced functional adaptation (Table 4).

Table 1: Demographic and baseline clinical characteristics of study participants

Variable	Group I (UCLP) (n=18)	Group II (BCLP) (n=18)	p-value
Age (years), Mean $\pm$ SD	13.44 $\pm$ 2.18	14.33 $\pm$ 2.57	0.281
Male, n (%)	10 (55.6%)	11 (61.1%)	0.738
Female, n (%)	8 (44.4%)	7 (38.9%)	-
Mean number of previous surgeries	2.22 $\pm$ 0.65	3.06 $\pm$ 0.72	0.002*
History of speech therapy, n (%)	7 (38.9%)	12 (66.7%)	0.095

*Statistically significant

Table 2: Comparison of oral health status between unilateral and bilateral cleft groups

Clinical parameter	Group I (UCLP) Mean $\pm$ SD	Group II (BCLP) Mean $\pm$ SD	p-value
DMFT score	2.11 $\pm$ 1.02	3.39 $\pm$ 1.24	0.003*
OHI-S score	1.42 $\pm$ 0.48	2.04 $\pm$ 0.61	0.001*
Gingival Index	1.08 $\pm$ 0.31	1.52 $\pm$ 0.42	0.002*

*Statistically significant

Table 3: Functional outcome assessment among study participants

Functional domain	Group I (UCLP) Mean $\pm$ SD	Group II (BCLP) Mean $\pm$ SD	p-value
Speech impairment score	0.94 $\pm$ 0.64	1.78 $\pm$ 0.81	0.002*
Feeding limitation score	0.61 $\pm$ 0.50	1.17 $\pm$ 0.71	0.011*
Masticatory limitation score	0.89 $\pm$ 0.58	1.56 $\pm$ 0.70	0.005*
Oral discomfort score	0.72 $\pm$ 0.46	1.28 $\pm$ 0.57	0.004*

*Statistically significant

Table 4: Distribution of composite Oral Health-Related Quality of Life (OHRQoL) scores

OHRQoL category	Group I (UCLP) n (%)	Group II (BCLP) n (%)	Total n (%)	p-value
Mild impact	8 (44.4%)	2 (11.1%)	10 (27.8%)	
Moderate impact	8 (44.4%)	7 (38.9%)	15 (41.7%)	
Severe impact	2 (11.1%)	9 (50.0%)	11 (30.5%)	0.006*

*Statistically significant

Discussion:

Cleft lip and palate (CLP) is one of the most prevalent congenital craniofacial anomalies, arising from incomplete fusion of the facial processes during early embryonic development. The condition affects facial esthetics, oral function, dentofacial growth, speech, hearing, feeding and psychosocial well-being, often requiring lifelong multidisciplinary management involving maxillofacial surgeons, pediatric dentists, orthodontists, prosthodontists, speech-language pathologists, psychologists and other rehabilitation specialists [9, 10]. Advances in surgical techniques, presurgical orthopedics and interdisciplinary rehabilitation have substantially improved treatment outcomes; however, successful management is no longer measured solely by anatomical repair but also by restoration of function and overall quality of life [10, 11]. Oral health-related quality of life (OHRQoL) has emerged as an important patient-reported outcome measure for evaluating the effectiveness of cleft rehabilitation. OHRQoL is a multidimensional concept that

reflects the impact of oral conditions on physical function, emotional well-being, self-esteem, social relationships and the ability to perform daily activities [11]. Unlike conventional clinical indicators, which primarily assess disease severity or treatment success from the clinician's perspective, OHRQoL incorporates patients' perceptions and experiences, thereby providing a more comprehensive evaluation of rehabilitation outcomes. Consequently, OHRQoL assessment has become an integral component of patient-centered care in craniofacial rehabilitation [12]. Despite advances in comprehensive cleft management, many individuals continue to experience persistent oral and functional challenges after primary surgical repair. Dental caries, poor oral hygiene, malocclusion, missing or malformed teeth, altered craniofacial growth, speech impairment, feeding difficulties and residual facial asymmetry frequently persist throughout childhood and adolescence [13]. Repeated surgical procedures, prolonged orthodontic treatment and continuing prosthodontic rehabilitation may further influence psychological well-being, self-confidence and social participation. Recent studies have demonstrated that children and adolescents with CLP generally report poorer OHRQoL than unaffected peers, with speech performance, facial appearance, oral health status and psychosocial adaptation being major determinants of long-term quality of life [14]. Long-term rehabilitation outcomes are influenced by multiple interrelated factors, including speech intelligibility, esthetic satisfaction, oral function, social acceptance and adaptation to everyday activities. Continuous assessment of these domains enables clinicians to identify unmet rehabilitation needs, monitor treatment progress and optimize individualized care throughout growth and development. Incorporating OHRQoL assessment into routine clinical practice provides valuable information beyond conventional clinical examination and facilitates evidence-based, patient-centered treatment planning.

Conclusion:

Bilateral cleft lip and palate showed poor oral health status, greater functional impairment and lower oral health-related quality of life compared with patients with unilateral cleft involvement. Oral disease burden and functional limitations showed a significant influence on overall patient outcomes. Thus, data shows that successful cleft rehabilitation should extend beyond surgical correction and include preventive oral care, functional rehabilitation and continuous multidisciplinary follow-up to optimize long-term oral health-related quality of life.

References:

- [1] Sahoo AR *et al.* *Cureus*. 2023 **15**:e38712. [PMID: 37292523]
- [2] Payer D *et al.* *J Orofac Orthop*. 2024 **85**:98. [PMID: 35852562]
- [3] Vanessa de Couto Nascimento *et al.* *European Journal of Orthodontics*. 2022 **22**:268. [PMID: 34891156]
- [4] Saele PK *et al.* *Int J Environ Res Public Health*. 2024 **21**:550. [PMID: 38791765]
- [5] Ajami S *et al.* *Int J Dent*. 2025 **2025**:1642111. [PMID: 40143932]
- [6] Hashemi S *et al.* *Dent Res J (Isfahan)*. 2026 **23**:3. [PMID: 41777751]
- [7] Theodoridou MZ *et al.* *Community Dent Health*. 2024 **41**:5. [PMID: 37988672]
- [8] Barria P *et al.* *J Funct Morphol Kinesiol*. 2025 **10**:24. [PMID: 39846665]
- [9] Corrêa de Queiroz Herkrath AP *et al.* *Cleft Palate Craniofac J*. 2018 **55**:1244. [PMID: 29537882]
- [10] Rando GM *et al.* *J Appl Oral Sci*. 2018 **26**:e20170106. [PMID: 29412367]
- [11] de Oliveira Júnior AG *et al.* *BMC Oral Health*. 2023 **23**:670. [PMID: 37716942]
- [12] Paul SA *et al.* *J Oral Biol Craniofac Res*. 2018 **8**:74. [PMID: 29892524]
- [13] Potemra HMK *et al.* *Plast Reconstr Surg*. 2020 **146**:61e. [PMID: 32590656]
- [14] Geethu RM *et al.* *Cureus*. 2025 **17**:e96454. [PMID: 41384179]

Caveat Emptor is applicable among the literate community where required and possible. The publisher, its journal, editors and the internal/external reviewers take adequate steps to check, evaluate, correct, edit, revise and improve content where possible and required.