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ORIGINAL ARTICLE

Impact of Quality of Life on Oral Health in Brazilian Young People with and without Cleft Lip/Palate

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ABSTRACT
Objective: To identify the most common clefts in patients at a craniofacial deformity rehabilitation center, to evaluate the impact on oral health-related quality of life in different cleft types, and to compare it between children and adolescents with cleft lip and palate (CL/P) and a control group without clefts. **Material and Methods:** A quantitative cross-sectional design was used, involving 150 patients with CL/P from the center and 150 individuals in the control group from a public school, all aged between 8 and 18 years old. Data were collected using the Child Oral Health Impact Profile (COHIP) questionnaire and information on the orofacial cleft type. Bivariate analyses (Pearson's chi-squared test) examined the relationship between cleft types and COHIP domains and between the two groups, with a significance level of $\alpha=5\%$.**Results:** Cleft lip and palate were the most prevalent (61.3%). However, there was no significant difference in oral health-related quality of life between cleft types ($p>0.05$). General oral quality of life scores did not differ between the groups, but the control group showed higher scores in the 'functional well-being' and 'personal image' domains. **Conclusion:** There are no differences in the impact of oral health-related quality of life between children and young people with cleft lip and palate and the control group.

Keywords: Cleft Lip; Cleft Palate; Quality of Life; Oral Health.

Introduction

The variety of malformations in human birth presents a complex range of characteristics and manifestations. Among these malformations, orofacial clefts are among the most significant and diverse conditions [1]. These anomalies affect children and their families, leading to challenges related to appearance and sometimes functional difficulties such as speech problems, feeding issues, social interaction, and child development [2]. Surprisingly, 70% of children born with cleft lip and/or palate (CL/P) do not have other associated syndromes [3], suggesting a complex interplay of familial hereditary factors and environmental influences [3].

Worldwide, orofacial clefts affect approximately one in every 600 to 700 live births [4]. In Brazil, the prevalence is 1.54 per 1000 live births [5]. Individuals born with orofacial clefts may be diagnosed with either cleft lip, cleft lip and palate, or cleft palate. The gender distribution of isolated cleft lip shows a higher prevalence in females, while cleft lip with cleft palate is more common in males [6].

The formation and development of the face typically occur between the fourth and ninth weeks of embryonic development; orofacial clefts result from the inadequate merging of the maxilla and medial nasal processes, resulting in a variety of lesions ranging from cleft lip [7], which is the simplest, to cleft lip and palate, which is the most complex [8]. The causes of clefts are still unknown; variations are related to racial, geographic, and environmental factors and socioeconomic status [9]. In addition, the authors describe that deformities can be triggered by factors such as exposure to environmental substances, infectious diseases, nutritional deficiencies, and maternal drug use during pregnancy [3,10]. Genetic factors also play an essential role, with more than half of congenital malformation cases occurring in families with a similar history [10].

Management of these abnormalities requires a multidisciplinary approach from childhood to adulthood, with specific interventions such as orthodontics, speech therapy, dentistry, plastic surgery, and psychological counseling [11,12]. Multidisciplinary management aims to improve physical functioning and psychological and social well-being, thus providing a better quality of life for people with CL/P throughout their lives [13]. In Brazil, thirty centers accredited by the Ministry of Health currently offer treatment for people with CL/P, distributed across different Brazilian regions: Southeast (n=12), South (n=8), Northeast (n=5), Midwest (n=4), and North (n=1) [14].

However, despite comprehensive care, patients with CL/P often face ongoing challenges related to oral health that negatively impact their quality of life [15]. Effective communication between professionals and patients with CL/P is essential to enable them to express their expectations and satisfaction with their oral health [16,17]. Patients' perceptions are crucial since changes in speech, facial aesthetics, and treatment outcomes may not meet their expectations, leading to emotional and social imbalances [18]. Analyzing patients' perceptions through self-assessment tools provides a better understanding to professionals, thus improving the approach to mitigate associated psychosocial challenges [17].

This study aimed to identify the most prevalent type of cleft in children and young people at a Craniofacial Deformities Rehabilitation Center to assess the impact of oral health on their quality of life with different types of clefts (lip, palate, and cleft lip and palate), and to compare the oral health-related quality of life of cleft children and young people with a non-cleft control group.

Materials and Methods

Ethical Clearance

The Research Ethics Committee with Human Subjects approved the research under protocol 4,602,101 on March 19, 2021.

Study Location

The study with the group of individuals with CL/P was conducted at the Craniofacial Deformities Rehabilitation Center (FUNDEF), located in Lajeado, in the south of Brazil. The FUNDEF is a charitable institution that provides rehabilitation services for individuals with cleft lip, cleft palate, and hearing impairment. The institution has a multidisciplinary team of surgeons, social workers, psychologists, nutritionists, speech therapists, pediatricians, nurses, physiotherapists, otolaryngologists, orthopedic surgeons, educators, dentists, administrators, and support staff.

The other group of individuals without deformities consisted of children and young people enrolled in a school in Lajeado. For practical reasons, a single school in the municipality was chosen by convenience, as it provided a sufficiently representative sample for the study's purposes, given that the age range and municipality of the student population matched that of the patient group. In addition, the school is the largest and is in the center of the town, facilitating data collection access.

Study Design and Sample

This study adopted a quantitative approach with a cross-sectional design, including two groups of individuals: one group with CL/P individuals and another group with healthy individuals, during July and August 2021.

All individuals had to be between 8 and 18 years old and able to speak and read to participate in the study. Exclusion criteria for the CL/P group included having any condition from disability and inability to read or talk, being enrolled in a special class for mental problems, disability, or learning difficulties. Participants in the control group were excluded if they had a serious health problem or a history of craniofacial congenital disabilities.

The dental clinic at the FUNDEF rehabilitation center sees approximately 100 new patients with orofacial clefts per month. Based on this information and considering that data collection would take two months (200 patients), the sample size was calculated using the online program 'http://www.berrie.dds.nl/calcss.htm", with a confidence level of 95% and a margin of error of 5%. This generated a total result of 130 patients, to which an additional 20% was added to account for potential losses, resulting in 150 patients with orofacial clefts. The same sample size was used for the control group, which consisted of a random selection of 150 people enrolled in the central public school of the municipality.

Patients with CL/P were recruited at the FUNDEF dental clinic until we reached 150 participants. During the recruitment period (July and August 2021), eligible patients attending the clinic were invited to participate in the study, and after giving informed consent, they were included in the research. To ensure impartiality in selecting healthy schoolchildren (controls), we conducted a lottery of names until the desired number of 150 participants was reached. First, all eligible healthy schoolchildren from the school were listed, and their names were written on identical pieces of paper. These papers were then folded and placed in an urn. One by one, the papers were randomly drawn from the urn until we reached the predetermined number of 150 healthy students. The people whose names were drawn were invited to participate in the study as controls. Individuals in both groups met the inclusion and exclusion criteria:

- Group 1 – Consists of 150 children and young people (both male and female, aged between 8 and 18 years old) with clefts (lip, palate, or cleft lip and palate) treated at the Rehabilitation Centre for Craniofacial Deformities (FUNDEF) in Lajeado, Rio Grande do Sul, Brazil.
- Group 2 – Consists of 150 non-cleft children and young people, male and female, of the same age as Group 1, enrolled in a public school in the same municipality.

Data Collection Methods and Instruments

The questionnaires were administered in the waiting room of the dental clinic of the rehabilitation center for people who received dental care during the research period and sent to the selected children and young people enrolled in the municipal school. Guardians of children aged 8 to 10 were asked to assist in filling out the questionnaire after the researchers explained the questions.

The research instrument included questions from the Child Oral Health Impact Profile (COHIP) questionnaire and demographic questions about gender and age for both groups. Data on the types of clefts in the CL/P group were collected from the dental records at the rehabilitation center.

The Child Oral Health Impact Profile (COHIP) was developed by Broder, McGrath, and Cisneros [19] and has been used in research to assess the well-being and quality of life of children and adolescents with any deformity that may affect chewing function, as well as the consequences and detrimental effects of missing teeth or an anatomically normal smile. The COHIP questionnaire has shown high test-retest reliability and internal consistency, indicating that it is a valid tool for assessing oral health as a measure of the quality of life in affected children [20].

The instrument consists of 34 items divided into five domains: 'oral health,' 'functional well-being,' 'socioemotional well-being,' 'school/environment,' and 'self-image.' Oral health included specific and not necessarily related oral symptoms (e.g., pain, tooth discoloration). Functional well-being included the child's ability to perform specific daily tasks or activities (e.g., speaking clearly, chewing) and socioemotional well-being related to peer interactions and mood states. The school environment included tasks associated with this environment. Self-image refers to positive feelings about oneself.

For each question, the respondent was asked to indicate how often a particular problem had occurred in the last 3 months. Responses were scored as never = 0, hardly ever = 1, sometimes = 2, quite often = 3, and almost all the time = 4. Scores can range from 0 to 140 on the total COHIP scale. Higher COHIP scores reflect a more positive oral health-related quality of life, while lower scores reflect a lower quality of life.

Classification of orofacial clefts: Bilateral cleft lip and palate, unilateral cleft lip and palate, bilateral cleft lip, unilateral cleft lip, cleft palate, and cleft soft palate.

Study Variables

The variables were categorized for statistical analysis as follows:

1. Impact of Oral Health (COHIP)

The "impact of oral health" variable in this study was derived by summing the scores from the questions included in the COHIP instrument. These scores were categorized for statistical analysis based on the frequencies observed (approximately 50%): 1. Lower scores: from 0 to 60 points, and 2. Higher scores: above 60 points. They were labeled as: 1. Positive impact on oral health, and 2. Negative impact on oral health. Likewise, the five domains (D1, D2, D3, D4, D5) were grouped and categorized into two sets, based on their frequency distribution (approximately 50%): 1. Positive oral health domains - lower scores, and 2. Negative oral health domains - higher scores.

2. Type of Cleft

The types of orofacial clefts were divided into three categories: 1. Unilateral and bilateral cleft lip: Cleft lip. 2. Palatal and soft palate clefts: Palatal clefts. 3. Unilateral and bilateral cleft lip and palate: Cleft lip and palate.

Data Analysis

Data were organized in an Excel spreadsheet and analyzed using the Statistical Package for the Social Sciences version 20,0 (IBM Corp., Armonk, NY, USA). Descriptive analyses were used to determine the prevalence of clefts. Measures of central tendency were applied to the COHIP scores in both groups. Finally, Pearson's chi-squared test was used to assess associations between cleft types and COHIP scores and its domains, with a significance level of $\alpha=5\%$.

Results

The mean age of children and young people with CL/P was 13.43 years (SD=3.9), and that of those without cleft was 13.49 years (SD=2.8). In the CL/P group, 59.3% (n=89) were male, and 40.7% (n=61) were female. In the non-cleft group, 44% (n=66) were male, and 56% (n=84) were female.

Regarding the three types of clefts, the labiopalatal cleft was the most prevalent (61.3%, n=92), followed by the labial cleft and the palatal clefts, with a prevalence of 22% (n=33) and 16.7% (n=25), respectively. Table 1 shows the bivariate analysis results between the types of clefts and the lower and higher COHIP scores and their five domains in the group of children and young people with CL/P (n=150). There was no statistically significant difference between cleft types regarding the impact on oral health-related quality of life (p>0.05).

Table 1. Bivariate analysis between the types of clefts and the lower and higher scores of COHIP and its five domains in the group of children and young people with CL/P.

Domains	**Type of Clefts**						**p-value***
	Lip		Palatal		Lip and Palate		
	N	%	N	%	N	%	
D1. Oral Health							
Positive	15	21.1	14	19.7	42	59.2	0.869
Negative	18	22.8	11	13.9	50	63.3	
D2. Functional Well-Being							
Positive	22	27.5	13	16.3	45	56.3	0.213
Negative	11	15.7	12	17.1	47	67.1	
D3. Socioemotional Well-Being							
Positive	20	21.3	17	18.1	57	60.6	0.825
Negative	13	23.2	8	14.3	35	62.5	
D4. School/Environment							
Positive	18	23.4	12	15.6	47	61.0	0.883
Negative	15	20.5	13	17.8	45	61.6	
D5. Body Image							
Positive	16	20.8	13	16.9	48	62.3	0.933
Negative	17	23.3	12	16.4	44	60.3	
COHIP							
Positive impact	21	24.1	15	17.2	51	58.6	0.698
Negative impact	12	19.0	10	15.9	41	65.1	

*Pearson's Chi-square.

Table 2 shows the bivariate analysis results of the lower and higher COHIP scores and their five domains between individuals with CL/P and without clefts (n=300), showing a statistically significant association in domains 2 and 5. Individuals without cleft have a greater positive impact on their oral health in the 'functional well-being' domain at 78.7% and in the 'body image' domain at 74.7%, with p<0.001.

Table 2. Bivariate analysis between the variables among cleft and non-cleft individuals and the categories of oral health-related quality of life impact according to COHIP scores.

Domains	**Groups**				**p-value***
	Cleft Individuals		Non-Cleft Individuals		
	N	%	N	%	
D1. Oral Health					
Positive impact	71	47.3	73	48.7	0.454
Negative impact	79	52.7	77	51.3	
D2. Functional Well-Being					
Positive impact	80	53.3	118	78.7	<0.001
Negative impact	70	46.7	32	21.3	
D3. Socioemotional Well-Being					
Positive impact	94	62.7	79	52.7	0.510
Negative impact	56	37.3	71	47.3	
D4. School/Environment					
Positive impact	77	51.3	67	44.7	0.159
Negative impact	73	48.7	83	55.3	
D5. Body Image					
Positive impact	77	51.3	112	74.7	<0.001
Negative impact	73	48.7	38	25.3	
COHIP					
Positive impact	87	58.0	98	65.3	0.117
Negative impact	63	42.0	52	34.7	

*Pearson's Chi-square.

Table 3 shows the means and standard deviations of each domain and COHIP for children and young people with CL/P and those without (n=300). Domain 2 (functional well-being) and Domain 5 (body image or personal) were the only domains that showed statistical differences. This table describes the scores, but the statistical differences have already been shown in Table 2.

Table 3. Measures of central tendency (mean and standard deviation) of COHIP and its five domains of children and young people with and without orofacial clefts.

Domains	**Mean (Standard Deviation)**	
	Cleft Individuals	Non-Cleft Individuals
D1.Oral Health	16.66 (6.87)	15.95 (5.60)
D2. Functional Well-Being	9.09 (5.68)	5.56 (4.06)
D3. Socioemotional Well-Being	10.06 (6.77)	11.26 (5.89)
D4. School/Environment	4.89 (3.65)	5.27 (3.47)
D5. Body Image	18.86 (4.50)	16.53 (4.05)
COHIP	59.57 (17.71)	54.57 (13.93)

Discussion

The results of this study, which was carried out on CL/P patients at the Craniofacial Deformities Rehabilitation Center in South Brazil, are remarkable and provide a better understanding of this condition. There was a significant predominance of labiopalatal clefts, a common finding in these cases as seen in other studies [21,22]. When analyzing the demographics of the investigated orofacial cleft patients studied, a predominance of males was observed, which may be justified by the higher frequency of these deformities in boys, as shown in previous studies [23,24].

However, it is noteworthy that there are no differences in the impact of oral health-related quality of life between cleft in children and young people with FL/P, as no statistical differences were found in the comparative analysis between cleft types. This finding is particularly encouraging, given the different lifelong implications of each cleft type. However, it is essential to note discrepancies in the data, as mentioned by Moura et al. [21], who found a similar occurrence in both sexes.

In the bivariate analysis between oral health-related quality of life in the CL/P group and the control group, no significant differences were observed, suggesting that children and young people positively influence their oral health, irrespective of the malformations. The local context, particularly in a city with a high quality of life, may have positively influenced the overall perception of oral health, especially in healthy individuals without facial deformities. However, when comparing only the domains of the instrument were compared between the two groups, differences were observed in "functional well-being" and "personal image ."These results should be interpreted cautiously, as the overall result showed no difference. It is important to note that the literature offers different perspectives on how people with CL/P perceive their condition. Some studies indicate significant concerns about self-image and facial appearance, while others emphasize the importance of self-acceptance and social support [25]. This diversity of experiences highlights the need for a personalized approach to management. In a study comparing oral health-related quality of life in children with CL/P and healthy children, the authors reported that surgically treated children with clefts had a poorer quality of life than children and young people without clefts [26]. However, according to Sundell et al. [27], children with CL/P have the same quality of life as children without clefts. Thus, it is observed that there is a lack of consensus on some aspects related to understanding how people with CL/P perceive and experience their treatment process and how these perceptions and experiences change throughout life [28].

The satisfactory results regarding oral health-related quality of life reported by people with CL/P in this study may be explained by the fact that these people have been treated and followed up since early childhood with long-term multidisciplinary interventions provided by FUNDEF. Interventions from early life, including surgical procedures and psychological and dental follow-up, have positively impacted patients' self-perception [29]. Personalized and continuous care, starting even before birth and continuing throughout life, is essential to ensure adequate quality of life for these individuals [30].

It is worth noting that the use of the COHIP scale as a research tool was chosen because of its good reliability [19,31-35] as it is a validated and widely used tool for assessing oral health-related quality of life in children with CL/P. This allowed essential aspects of the research to be observed, such as parents not being able to substitute children's responses but being able to help and provide additional information [35].

Alansari et al. [28] emphasized that the course of treatment and medical care received by people with CL/P may influence their self-perception of the condition, with negative or inadequate medical and dental care potentially making them more vulnerable to feeling different during the treatment process, which may result in a negative perception of treatment, revealing feelings of burden and dissatisfaction. It is clear, therefore, that the perceptions of people with CL/P regarding medical follow-up can evolve throughout their lives, depending on the individual experiences of each patient [36]. Promoting effective communication between doctors, dentists, nurses, and the whole multidisciplinary team with patients is vital. This dialogue should address their expectations, perceptions, satisfaction, and quality of life regarding the procedures and treatments provided. Such practice improves patients' oral health-related quality of life and helps mitigate the challenges they face throughout treatment [16,17].

It is crucial to acknowledge some of the limitations of this study. Firstly, the sample may not fully represent the diversity of the CL/P patient population, which may affect the generalizability of the results. In addition, the study's cross-sectional nature precludes any inference of causality between the variables assessed. Another limitation is the reliance on self-report measures to evaluate the quality of life, which may introduce a recall bias or subjectivity in participants' responses. Moreover, unmeasured factors such as cleft severity and access to treatment may influence the results but were not controlled for in this study. Therefore, longitudinal studies with more representative samples and comprehensive assessment methods are needed to fully elucidate the impact of CL/P on oral health-related quality of life in patients.

We emphasize the need for a personalized and continuous approach to treating people with CL/P. It is essential to value patients' individual experiences, use multidisciplinary interventions, and provide social support to ensure a satisfactory quality of life throughout their treatment journey and life. By recognizing the complexity of this condition and the diversity of its needs, we can provide more comprehensive and effective care that promotes the physical, emotional, and social well-being of people with CL/P.

Conclusion

The most prevalent type of cleft was the labiopalatal cleft, followed by the labial cleft and palatal clefts. It was observed that there was no significant difference in the impact of the type of cleft on oral health-related quality of life in children and adolescents, suggesting that the specific kind of cleft did not influence the perception of oral health-related quality of life. The results showed no difference in the overall oral health-related quality of life scores between the groups studied. However, people with cleft lip and palate had lower scores in the 'functional well-being' and 'personal image' domains compared to the control group. This finding highlights areas requiring additional attention when addressing oral health-related quality of life in people with cleft lip and palate.

Authors' Contributions

TV	https://orcid.org/0009-0002-0444-3485	Methodology, Investigation, Data Curation, Writing - Original Draft, Writing - Review and Editing, and Project Administration.
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LR	https://orcid.org/0000-0003-3725-3047	Conceptualization, Validation, Formal Analysis, Writing - Original Draft, Writing - Review and Editing, Visualization, and Supervision.
All authors declare that they contributed to the critical review of intellectual content and approval of the final version to be published.		

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None.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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