Original Article

Evaluation of Oral Health-related Quality of Life for Adult Individuals with Cleft Lip and/or Palate Using OHIP-49 and Compared with a Control Group: A Cross-Sectional Study

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ABSTRACT

Objectives: This study aimed at evaluating oral health-related quality of life (OHRQoL) among adults with cleft lip and/or palate (CL/P) and compared it with adults with no orofacial cleft. The study also intended to find out the impact of cleft severity, gender, and age on the perceived OHRQoL. **Materials and Methods:** The study was composed of a sample of 70 adult participants who received and completed dental treatments: 35 participants with CL/P (CL/P group) and 35 participants with no orofacial cleft (control group) agreed to participate. Each participant completed the Oral Health Impact Profile (OHIP-49) with no missing data. The OHIP-49 data were analyzed using the Mann–Whitney U test, and a P-value <0.05 was considered as statistically significant. **Results:** Adults with CL/P reported higher scores in all the seven subscales of the OHIP-49. These results were statistically significant in physical disability (mean scores of 1.22, $p = 0.017$) and social disability (mean scores of 0.93, $p = 0.046$). Females with CL/P recorded better OHRQoL in the handicap domain ($p = 0.026$). Participants with cleft lip only recorded better OHRQoL compared with those with cleft lip and palate, and that was statistically significant at both the functional limitation ($p = 0.003$) and the physical pain ($p = 0.046$). There was a significant positive correlation between increasing age and functional limitation ($p = 0.025$). **Conclusion:** CL/P negatively affected OHRQoL for adults with CL/P mainly on physical and social disabilities of OHIP-49 when compared with a general non-cleft sample.

KEYWORDS: *Adults, dental treatment, oral health, orofacial cleft, quality of life*

INTRODUCTION

Orofacial cleft is the most frequent congenital craniofacial deformity, with a mean prevalence of between one in 500 and 1100 live births worldwide.[1-3] CL/P affects many aspects of patient health and well-being, which includes aesthetics, psychosocial aspects, and function, by affecting speech, hearing, and mastication.[4,5] For this reason, treatment should be conducted using a multidisciplinary team approach that begins immediately after birth to restore function and aesthetics as soon as reasonably possible.[6] Many studies have shown that individuals with CL/P had significantly worse outcomes in some aspects of their lives, especially in psychosocial aspects, when compared with individuals without CL/P.[2,7-9] Importantly, these aspects of life may not be detected by traditional clinical

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indicators, which, in turn, highlights the importance of the quality of life (QoL) concept and tools.

In 1995, QoL was defined by the World Health Organization (WHO) as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."[10] Therefore, a successful treatment outcome is not solely defined in terms of clinical repair, remission, or cure, but also with the improvement of patient QoL after treatment.[11] There are many tools designed to measure health-related quality of life (HRQoL), whereas there are fewer for OHRQoL. The primary reason for this is that the concept of OHRQoL appeared approximately 20 years after HRQoL in the literature.[12] The number of studies on OHRQoL for patients with CL/P are increasing in the literature, but they are still limited. The majority of these studies were designed to examine the impact of nasal appearance and surgical correction of dentofacial deformity related to QoL for patients with CL/P.[7] A decision must be made regarding which OHRQoL tool is appropriate for this study. However, the OHIP-49 was chosen in this study for many reasons. First, the OHIP-49 is one of the most widely used instruments in OHRQoL for patients with CL/P, and its validity and measurement properties have been well described.[7,13,14] Second, the OHIP-49 is designed for OHRQoL, unlike other common tools such as the 36-Item Short Form Survey (SF-36), which is designed for general HRQoL. In the literature, there is some evidence to indicate that, in general, adult males report better HRQoL across different societies and countries.[15] However, regarding OHRQoL for adults with CL/P, the results in the literature are inconclusive, as Mani, Carlsson[16] reported that males are affected more negatively by unilateral cleft lip and palate than females in "emotional role function" using the SF-36 scale. On the other hand, Pisula, Lukowska[17] reported that females had a lower QoL when the World Health Organization Quality of Life-brief (WHOQOL-BRIEF) was used. With regards to the difference in QoL perception for adults with CL/P in relation to their age, and whether advancing age causes them to have poorer QoL or vice versa, the initial literature review found only very limited numbers of relevant papers. Of these, the results largely support the hypothesis that assumes that younger adults will have poorer QoL compared with those patients in older age groups, as discussed by Mani, Carlsson[16] and Piombino, Ruggiero.[9]

Therefore, the aims of this study were:

1) To evaluate the level of OHRQoL for adults with CL/P (CL/P group) who completed dental treatments by using OHIP-49, and then compare their results with adults without CL/P (control group).
2) To assess whether there were any difference in the level of OHRQoL among different genders, age groups, and cleft severity levels.

MATERIALS AND METHODS

This was a cross-sectional study conducted within the Restorative Dentistry Department, University Dental Hospital of Manchester. This study was approved by the National Health Service (NHS), providing research ethical approval and health research authority (research and development reference: GN19OD441, research ethics committee reference: 19/SC/0463) and it was carried out between September 2019 and July 2020. All participants included in this study were treated by the same clinician, M.P.A, who is a Consultant and Honorary Professor in Restorative Dentistry. Dental restorative treatments were arranged into four categories, according to complexity:

1. Tooth/teeth reshaped by enamel reduction, composite addition, veneer, and/or crown.
2. Tooth/teeth replaced by partial denture, complete denture, and/or bridge.
3. Dental implant treatment, including crown, bridge, partial denture, and/or complete denture.
4. Palatal obturator or speech plate.

In cases where a participant received more than one type of treatment, the most complex treatment was recorded. Age was categorized into five age groups as described by Sweiry and Willitts,[18] who studied the perception of age for the UK population. The age groups in years were: (1) 16–24, (2) 25–49, (3) 50–64, (4) 65–79, and (5) ≥80.

The inclusion criteria for the participants of this study were:

1) All participants must be adults (≥16 years old) who were able to understand the questionnaire and provide consent.
2) Adult male or female individuals had to be healthy with no associated syndromes or severe medical issues (physical status according to the American Society of Anaesthesiologists (ASA) must be in class I or II).
3) All participants must have completed their dental restorative treatment at the University Dental Hospital of Manchester.
4) For the CL/P group, only participants with non-syndromic CL/P were included.

Participants' sample

The digital filing system under the Salud dental practice management software was used to identify potential participants. Multiple tasks were completed through Salud, such as checking patient information, medical and dental histories, diagnoses, and treatment plans. Potential participants were identified from 4 March 2016 (start date of using Salud within the Restorative Dentistry Department) until 19 September 2019. After applying inclusion/exclusion criteria, potential participants were assembled into two groups, the CL/P group and the control group. All potential participants were contacted by mail containing the participant information sheet to introduce the research project, a consent to contact form, a consent to participate in the research project, the OHIP-49 questionnaire, and a self-addressed prepaid envelope. In addition, they were given contact details to inform the research team should they not wish to participate, in which case their names were removed from the list. Further, they were assured that their future management would not be affected by their decision. For those who did not reply after three months from the date of sending the post, no further contact was made, and their names were removed from the list. The number of patients with non-syndromic CL/P who completed their dental treatments was 56; therefore, the ideal sample size was 36 with a 95% confidence level and a 10% margin of error.

Oral health impact profile-49

The OHIP-49 questionnaire was designed as a generic OHRQoL tool.[19,20] It has been based implicitly on Locker's conceptual model of oral health,[21] which states that, in order to understand oral disease and its impact, there are five sequentially related consequences involved: impairment; functional limitation; pain/discomfort; disability; and handicap.[22] Impairment (e.g. edentulousness) leads to functional limitation (e.g. difficulty chewing) and pain or discomfort, such as physical and psychological symptoms, which then leads to disability (limitation in performing daily activities, unsatisfactory diet) and then on to handicap (social disadvantage, e.g. social isolation). In addition, functional limitation may also lead directly to handicap.[23] The OHIP-49 questionnaire consists of 49 items/questions grouped into seven domains, with the aim of providing comprehensive information regarding self-reported discomfort, disability, and dysfunction related to oral health.[13,24] The seven domains are functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The answer for these questions is in a Likert scale form, which has five options, which are 0 "never," 1 "hardly ever," 2 "occasionally," 3 "often," to 4 "very often." Higher scores indicate a poorer OHRQoL.

Statistical methods

The statistical package for social sciences (SPSS 25.0) was used for descriptive statistics and analyses. The mean for subscale scores for each participant was calculated, and the Shapiro–Wilk test indicated that the data were not normally distributed. Therefore, a nonparametric test, the Mann–Whitney *U* test, was used to investigate the difference between the two independent groups (CL/P and control groups). Spearman correlation was used to find out the relationship between age and OHRQoL in the cleft group. All tests were two-tailed, and a *P*-value <0.05 was considered statistically significant.

Results

Only 35 patients with CL/P agreed to participate and complete the OHIP-49 (response rate: 62.5%). Overall, 106 patients without CL/P were identified as they had completed their dental treatment and only 51 patients agreed to participate (response rate: 48.11%). From those 51 participants without CL/P, 35 participants were randomly chosen for the control group, giving both groups an equal number of participants. There were no missing data in the groups. The mean age in the CL/P group was 40.80 years (age range 16–72), and the mean age in the control group was 46.20 years (age range 18–76). In the CL/P group, there were 23 females (65.7%) and 12 males (34.3%). In the control group, there were 21 females (60%) and 14 males (40%). For cleft types in the CL/P group, there were eight participants with cleft lip (22.9%), and the remaining 27 participants had cleft lip and palate (77.1%). Table 1 shows the participants' demographic characteristics in the CL/P and control groups, which included gender, age groups, and cleft types.

In Table 2, the mean scores of the seven subscales of OHIP-49 and overall score are shown. Participants with CL/P reported higher mean scores in all the subscales and the overall scores compared with the control group. Participants with CL/P had higher mean rank scores than the control group. However, these results showed no significant difference between CL/P and control groups in any of the OHIP-49 domains except in physical disability, with a mean score of 1.22 (*p* = 0.017), and social disability, with a mean score of 0.93 (*p* = 0.046). When the two domains were examined, adults with CL/P had scored the highest mean in the

Table 1: Participants' characteristics in the CL/P and control groups

Participants' profile		CL/P group		Control group	
		Frequency	Per cent	Frequency	Per cent
Gender	Male	12	34.3%	14	40%
	Female	23	65.7%	21	60%
Age groups in years	16–24	12	34.3%	7	20%
	25–49	11	31.4%	9	25.7%
	50–64	10	28.6%	14	40%
	65–79	2	5.7%	5	14.3%
Cleft types	Cleft lip	8	22.9%	-	-
	Cleft palate	0	0%	-	-
	Cleft lip and palate	27	77.1%	-	-
Types of dental treatment	Tooth/teeth reshaped	8	22.9%	5	14.3%
	Tooth/teeth replaced	15	42.9%	6	17.1%
	Dental implant treatments	5	14.3%	24	68.6%
	Palatal obturator/speech plate	7	20%	0	0%

physical disability subscale's questions, stating that their speech was unclear because of a problem with their teeth, mouth, or dentures (mean scores of 1.97). This was followed by how they avoided smiling because of a problem related to their teeth, mouth, or dentures (mean scores of 1.89). In the social disability subscale's questions, adults with CL/P reported the highest mean related to their oral health condition, making them avoid going out (mean scores of 1.29), followed by their oral health condition causing them to be a bit irritable with other people (mean scores of 1.00). Using the item impact method to allocate the highest ranking items to individual domains, a subset of OHIP-49 items specific to measure the highest frequency in participants with CL/P is shown in Table 3.

DIFFERENCES IN THE OHRQOL LEVELS BETWEEN MALE AND FEMALE PARTICIPANTS WITH CL/P

The number of female participants was almost double that of the males, with 23 females and 12 males. The mean age was approximately 40 years old for both males and females in this study. Males with CL/P reported higher mean scores in the total OHIP-49, and the five domains of the OHIP-49 except in "Functional limitation" and "Physical pain" in which females recorded higher scores. Table 2 shows that these were only statistically significant differences in the "Handicap" domain in which males with CL/P recorded statistically higher results ($p = 0.026$) compared with females. When this domain was explored, it was noted that males recorded the highest mean in regards to answering the question "Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?" with a mean score of 1.67, which was followed by "Have you been unable to enjoy other people's company as much because of

problems with your teeth, mouth or dentures?" with a mean score of 1.58.

DIFFERENCES IN THE OHRQOL LEVELS BETWEEN PARTICIPANTS WITH CLEFT LIP AND PARTICIPANTS WITH CLEFT LIP AND PALATE

In this study, cleft severity was classified as: cleft lip, cleft palate, and cleft lip and palate. Despite this, only two types of cleft conditions were observed within the participants of this study, specifically, cleft lip, and cleft lip and palate. The number of participants with cleft lip only was much lower (eight participants), and they had a mean age of 19 years old (age range of 16 to 21). Overall, this group was younger than the larger (27 participants) cleft lip and palate group, which had a mean age of 47.26 years old (age range of 17 to 72). As shown in Table 2, participants with cleft lip and palate exhibited higher records in all of the OHIP-49 domains when compared with participants with cleft lip only. These differences were statistically significant at functional limitation ($p = 0.003$) and physical pain ($p = 0.046$), and when these two were further explored to determine the area of the highest problem for participants with cleft lip and palate, the highest mean score was related to "Have you felt that your appearance has been affected because of problems with your teeth, mouth or dentures?" with a mean score of 2.48. In the physical pain category, the highest mean value was related to "Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?" with a mean score of 1.89.

CORRELATION BETWEEN AGE AND THE OHRQOL IN THE CLEFT GROUP

To test the correlation between age and OHRQoL, the Spearman Correlation was used, as the data were not normally distributed and therefore the nonparametric coefficient was calculated. The results are shown in

Table 2: Hypothesis test summary of differences between the CL/P and control groups, gender differences, and cleft severity differences in the CL/P using the Mann–Whitney U test

	Comparison of means between CL/P and control groups					Comparison of means between males and females in CL/P group					Comparison of means between participants with CL and CL/P in CL/P group				
	CL/P group (n=35)		Control group (n=35)		Mann–Whitney U (p-value)	Males (n=12)		Females (n=23)		Mann–Whitney U (p-value)	CL (n=8)		CL/P (n=27)		Mann–Whitney U (p-value)
	Mean (SD)	Median (SE)	Mean (SD)	Median (SE)		Mean (SD)	Median (SE)	Mean (SD)	Median (SE)		Mean (SD)	Median (SE)	Mean (SD)	Median (SE)	
Functional limitation	1.39 (0.84)	1.11 (0.14)	1.29 (1.04)	1.00 (0.2)	698.0 (0.3)	1.36 (0.92)	1.11 (0.3)	1.4 (0.8)	1.33 (0.17)	149.5 (0.69)	0.73 (0.33)	0.77 (0.11)	1.58 (0.84)	1.33 (0.16)	181.5 (0.003*)
Physical pain	1.26 (0.82)	1.01 (0.14)	1.25 (1.01)	1.11 (0.17)	633.5 (0.8)	1.2 (0.84)	1.17 (0.24)	1.27 (0.83)	1 (0.17)	146.5 (0.77)	0.77 (0.53)	0.55 (0.18)	1.38 (0.85)	1.11 (0.16)	158.5 (0.046*)
Psychological discomfort	2.28 (1.05)	2.2 (0.17)	1.91 (1.45)	1.8 (0.02)	709.0 (0.26)	2.3 (1.01)	2.4 (0.3)	2.25 (1.09)	2.2 (0.23)	130.5 (0.8)	2.02 (0.93)	2.1 (0.33)	2.35 (1.08)	2.4 (0.2)	118.5 (0.7)
Physical disability	1.22 (0.75)	1.00 (0.13)	0.8 (0.77)	0.77 (0.13)	814.5 (0.017*)	1.33 (0.84)	0.94 (0.24)	1.16 (0.7)	1.22 (0.15)	127.00 (0.8)	0.77 (0.22)	0.83 (0.08)	1.34 (0.79)	1.22 (0.15)	153.5 (0.07)
Psychological disability	1.66 (1.2)	1.16 (0.2)	1.21 (1.19)	0.83 (0.2)	771.0 (0.06)	1.86 (0.97)	1.92 (0.3)	1.56 (1.31)	1.17 (0.27)	109.50 (0.33)	1.18 (0.96)	0.91 (0.33)	1.8 (1.24)	1.66 (0.23)	138.0 (0.25)
Social disability	0.93 (1.02)	0.6 (0.17)	0.45 (0.69)	0.2 (0.12)	776.0 (0.046*)	1.03 (0.62)	0.9 (0.18)	0.88 (1.19)	0 (0.25)	98.00 (0.17)	0.4 (0.45)	0.3 (0.16)	1.08 (1.09)	0.8 (0.21)	147.0 (0.13)
Handicap	0.72 (0.77)	0.5 (0.13)	0.56 (0.79)	0.17 (0.13)	749.5 (0.1)	0.99 (0.66)	0.75 (0.19)	0.59 (0.8)	0.33 (0.17)	74.5 (0.026*)	0.58 (0.51)	0.5 (0.18)	0.76 (0.83)	0.5 (0.16)	114.5 (0.8)
OHIP-49 total	65.06 (38.1)	50 (6.44)	52.5 (42.3)	44 (7.15)	741.0 (0.13)	69.0 (36.99)	60.5 (10.68)	63.0 (39.35)	50 (8.2)	121.50 (0.57)	43.37 (22.4)	40 (7.9)	71.48 (39.7)	54 (7.6)	155.0 (0.07)

Abbreviations: SD; standard deviation, SE; standard error of mean.

*Statistically significant at level 0.05 (2-tailed).

Table 3: Subset of OHIP-49 items with highest frequency in participants with CL/P, by domain

Domain	Statement*	Mean (SD)	Median (SE)
Functional limitation	Appearance affected	2.49 (1.22)	2 (0.21)
	Food catching in teeth or dentures	2.00 (1.1)	2 (0.18)
Physical pain (discomfort)	Sensitive teeth	1.8 (1.13)	2 (0.19)
	Uncomfortable to eat	1.6 (1.03)	1 (0.17)
Psychological discomfort	Uncomfortable appearance	2.63 (1.14)	3 (0.19)
	Self-conscious	2.54 (1.15)	3 (0.19)
Physical disability	Unclear speech	1.97 (1.4)	2 (0.24)
	Avoided smiling	1.89 (1.1)	2 (0.19)
Psychological disability	Upset	2.23 (1.42)	2 (0.24)
	Embarrassed	2.17 (1.5)	2 (0.25)
Social disability	Avoided going out	1.29 (1.36)	1 (0.23)
	Irritable	1.00 (1.24)	1 (0.21)
Handicap	Life less satisfying	1.37 (1.03)	1 (0.17)
	Unable to enjoy company	1.06 (1.08)	1 (0.18)

*Statement format "Have you…..because of problems with your teeth, mouth or dentures?"

Abbreviations: SD; standard deviation

Table 4: Spearman test results of correlation between age and OHIP-49 domains in the CL/P group (35 participants)

Domains of OHIP-49	Correlation coefficient with age	*p*-value (2-tailed)
Functional limitation	0.379	0.025*
Physical pain	0.076	0.665
Psychological discomfort	0.012	0.945
Physical disability	0.233	0.179
Psychological disability	0.096	0.584
Social disability	0.109	0.532
Handicap	-0.044	0.800
OHIP-49 overall	0.155	0.373

*Correlation is significant at the 0.05 level (2-tailed).

Table 4, where one significant result was observed between age and functional limitation (*p* = 0.025).

DISCUSSION

This study aims at comparing the levels of OHRQoL for adults with CL/P who completed dental treatments with those without CL/P, using the OHIP-49. Almost 63% (44 out of 70) of participants in this study were female; this was an expected outcome since females made up 60% (98 out of 162) of individuals contacted who met the inclusion/exclusion criteria (potential participants). Overall, participants with CL/P had lower OHIP-49 values in the physical disability and social disability subscales compared with the control group. Although these differences were statistically significant, the clinical significance of these differences is, nonetheless, more dubious. The reason for this discrepancy is that some studies have stated that there is no universally accepted approach for determining the clinical significance of QoL data.[16] Participants' perspectives will remain core to interpreting the differences and changes found in OHRQoL scores, and results will be correlated to

clinical experience or confirmed with other clinical instruments.[16,25,26] Thus, prior studies of OHRQoL for patients with CL/P with various instruments corroborate the current study results.[27,28]

Figure 1 shows that the majority of the mean scores were less than 2, with the exception of psychological discomfort. This may indicate that there were no major problems regarding overall domains in both groups, as none among them scored 3–4 (the highest or most problematic scores). In fact, most of the mean scores were approximately 1, which meant that they barely disturbed the participant. In the CL/P group, the highest recorded scores were in the psychological discomfort domain, which had a mean score of 2.28, and the psychological disability domain, which had a mean score of 1.66. This indicated that adults with CL/P participating in this study had the lowest OHRQoL across these two domains when compared with the other aspects of the OHIP-49 scale. This result was confirmed with many other studies that looked at QoL for adults with CL/P related to different types of treatments, such as Piombino, Ruggiero,[9] Palmeiro, Bronstrup,[28] and Marcusson, Akerlind.[29] These studies indicated that adults with CL/P reported their poorest aspect in QoL within the psychological health domain, compared with the control group with no orofacial clefts, and their results were statistically significant (*p*-value <0.05).

With regards to differences in OHRQoL levels between females and males with CL/P, the literature showed that OHRQol for females was negatively affected by their dentofacial deformity (other than CL/P). Conversely, however, the results of the current study showed that there were some differences, but they were only statistically significant in the handicap domain (*p*-value
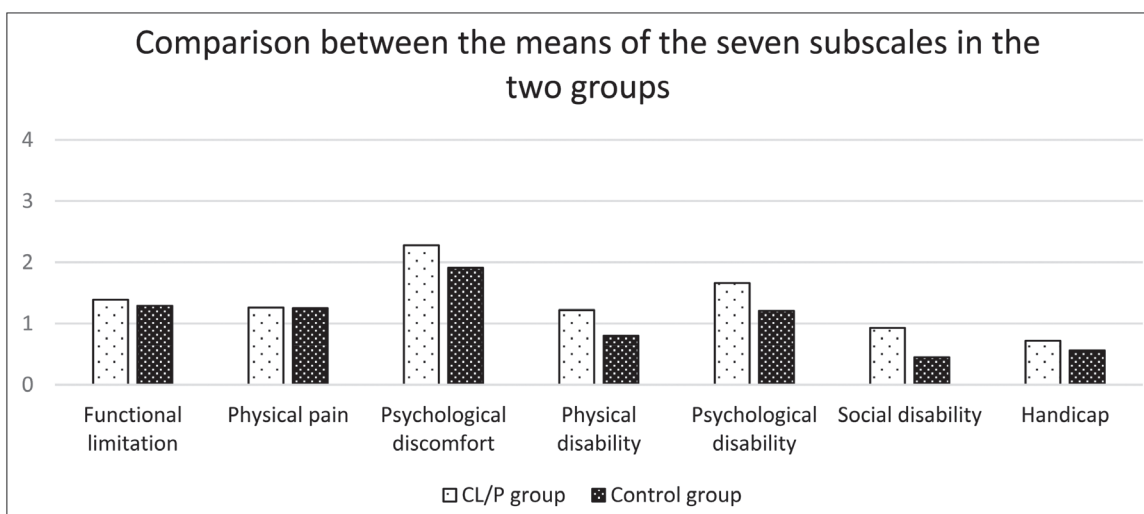
Figure 1: A histogram compares the mean difference in the seven subscales of OHIP-49 between the CL/P and control groups. The numbers from 0 to 4 on the left side represent the five options given for each item, where 0 represented "never thought about it," 1 "hardly ever," 2 "occasionally," 3 "often," and 4 "very often."

=0.026), within which females had better OHRQoL. This result corresponds with another study, which reported that males were affected more negatively by unilateral cleft lip and palate than females in "emotional role function" on the SF-36 scale.[16]

Another integral question underpinning this research project was whether cleft lip severity affected the OHRQoL. Participants were divided into groups depending on their cleft severities, specifically into cleft lip only, and cleft lip and palate, as there were no participants with cleft palate only. Table 2 shows that participants with cleft lip and palate scored higher on OHIP-49 compared with those with cleft lip only. This result is somewhat unsurprising and seems to adhere to logic, as greater cleft severity generally causes more problems, especially related to function and aesthetics, which, in turn, will affect the total QoL. These differences were only statistically significant in terms of functional limitations ($p = 0.003$) and physical pain ($p = 0.046$). Further, this study demonstrated a positive correlation between age and scores of the OHIP-49, meaning that as age increased, the participants reported more issues regarding their OHRQoL. The one exception to this was in the handicap domain, which showed a negative correlation. However, solely the functional limitation category showed a positive, statistically significant, correlation (p-value 0.025). This result stands in contrast to another study conducted by Mani, Carlsson,[16] which found that younger patients (20 to 32 years old) were affected more negatively by unilateral CL/P than the older group in terms of physical function, physical role of function, and the emotional role of function.

There are some limitations that ought to be acknowledged. First, participants were recruited from a single center and their numbers were relatively small, thus increasing the possibility of selection bias. Second, although participants of this study had no major illnesses that might have reduced confounding factors, other contributors, such as socioeconomic status, were not taken into consideration in the current study. These have been shown to play an important role in QoL in many studies.[30] Another limitation of this study was the length between completing the treatment or the patient's final visit and the date that the questionnaire was completed. For certain participants, their final visit was in the middle of 2016, but the questionnaire was not completed until the end of 2019. In turn, it was not clear as to whether this prolonged period had any impact on the perception of OHRQoL.

Conclusion

Although adults with CL/P who participated in this study had completed their dental treatments at the Dental University Hospital, they had lower OHRQoL in terms of physical disability ($p = 0.017$) and social disability ($p = 0.046$), with subscales of the OHIP-49, compared with adults with no orofacial clefts. The highest mean scores were in the psychological discomfort and disability subscales. However, the majority of the mean scores were not statistically significant and were less than 2, which indicates that the issues asked in the OHIP-49 questionnaire were in between "occasionally" and "hardly ever bothered." Male participants with CL/P had lower OHRQoL in comparison to females in the handicap subscale

(p = 0.026) of OHIP-9. Participants with cleft lip and palate had lower OHRQoL than those with cleft lip only, which was statistically significant at both the functional limitation (p = 0.003) and the physical pain areas (p = 0.046). In addition, the results of this study indicated that there was a significant positive correlation between increasing age and functional limitation (p= 0.025). Further studies with a larger population would be required to confirm the results of this study, especially owing to the aforementioned limitations.

CONFLICTS OF INTEREST

There are no conflicts of interest.

AUTHOR CONTRIBUTIONS

All authors listed have significantly contributed to the development and the writing of this article. All authors have read and approved the final manuscript.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

Ethical policy and Institutional Review board statement: The Research Ethics Committee of the University of Manchester, United Kingdom approved this research (research and development reference: GN19OD441, research ethics committee reference: 19/SC/0463) on 19/09/2019.

PATIENT DECLARATION OF CONSENT

Written informed consent was obtained from all participants.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the author Marwan Aljohani (Marwan.aljohani@postgrad.manchester.ac.uk).

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