ORAL –HEALTH RELATED QUALITY OF LIFE AMONG CLEFT LIP AND PALATE PATIENTS – QUESTIONNAIRE

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DECLARATION BY THE CANDIDATE

I hereby declare that the dissertation title " **ORAL – HEALTH RELATED QUALITY OF LIFE AMONG CLEFT LIP AND PALATE PATIENTS – QUESTIONNAIRE"** is a bonafide record and genuine research work carried out by me under the guidance of **Prof. Dr. M. Veerabahu M.D.S., IBOMS** Head of department and professor of department of Oral & Maxillofacial Surgery, Ragas Dental College and Hospital, Chennai.

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This Dissertation is submitted to **THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY**, in partial fulfilment for the award of Degree of **Master of Dental Surgery – ORAL AND MAXILLOFACIAL SURGERY, BRANCH-III**. It has not been submitted (partial or full) for the award of any other degree or diploma.

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CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

List of Abbreviations

LIST OF ABBREVIATIONS

OHRQoL	Oral Health Related Quality Of life
CLP	Cleft Lip And Palate
SF-36	36 item Short-Form Health Survey
HRQoL	Health Related Quality Of life
PF	Physical Function
MH	Mental Health
RE	Emotional Role function
CEP	Cleft Evaluation Profile
PedsQL	Pediatric Quality of Life inventory
SWAP	Satisfaction With Appearance Questionnaire
DS14	Type-D scale questionnaire
COHIP	Child Oral Health Impact Profile,
CES	Clinical Esthetic Score
OHIP-G14	German short version of the Oral Health Impact Profile
UCLP	Unilateral Cleft Lip and Palate
VAS	Visual Analogue Scale
CP	Cleft Palate
BCLP	Bilateral Cleft Lip and Palate
CL + A	Cleft lip and alveolus
MOHRQoL	Michigan Oral Health-Related Quality of Life Scale

CPQ11-14	Child Perception Questionnaire for 11- to 14 years
SLPs	Speech and Language Pathologists
VPI	Velo Pharyngeal Insufficiency
ROE	Rhinoplasty Outcomes Evaluation
CFA	Congenital Craniofacial Anomalies
WHOQOL-BREF	World Health Organization Quality of Life – Bref
P-CPQ-16	Caregivers Perception Questionnaire
FIS-8	Family Impact Scale
OHIP-14	Oral Health Impact Profile - 14
IOFS	Impact on Family Scale
OrSg	Orthognathic Surgery
OP	Overlay Prosthesis
QoL	Quality of Life
NOT-S	Nordic Orofacial Test-Screening
CLPG	Cleft Lip and Palate Group

Introduction

INTRODUCTION

Cleft lip / palate (CL/P) is the most common congenital defect of the face. CL/P has a worldwide prevalence of 0.8 /1000 live births (World Health Organisation, Human Genetics Programme, 2002). Its incidence worldwide varies according to the difference in geography, gender, race and ethnicity[1]. Being the fourth most common birth defect it affects 1 in 600 children in the European population but more commonly affects the Asians (1:500) and Native Americans (1:300). About 46% of the patients present with CL/P, 32% have isolated cleft palate and 21% have isolated cleft lip. Inherited genetic abnormalities are also associated with CL/P (25%).[2]

The face first starts to develop at the end of 4th week and is completed by 8th week while the palate gets completed by the end of the 10th week. By 4th week, a series of swelling appears around the stomedeum which is the front nasal process, two maxillary process and mandibular process. On either side of the frontonasal process arises a thickening which becomes the nasal placodes. By the 5^{th} week a horse shoe shaped ridge consisting of medial and lateral nasal processes with nasal pit in the middle. Rupture of the nasal pits forms communication between the oral and nasal cavities. The upper lip is formed in the 7^{th} week by the fusion of the maxillary process that advances medially that fuses with the medial nasal swelling. The nose is formed by the fusion of the lateral nasal process. The primary palate consists of the maxillary

arch with the four incisors and hard palate anterior to the incisive foramen forms before the secondary palate by the fusion of the medial nasal process.[1, 2]

The secondary palate develops during the 6th week from the bilateral maxillary processes which grows vertically down on both sides of the tongue and forms a shelf like outgrowth.

The tongue moves inferiorly during the 7th week making the palatal shelves migrate to a horizontal position above the tongue. The palatal fusion begins from the anterior to posterior region includes the posterior hard palate, Soft palate along with uvula formation. Cleft can result in any stage where there maybe disruption in the developmental processes.

From infancy through adolescence even upto young adulthood the repair of CL/P takes a large time period as its treatment seeks to facilitate normal development and growth of the face , complete closure of the orofacial cleft, achieve comprehensible speech, hearing and good aesthetics consequently aiding in good socialisation **(Eberlinc and Koˇzelj, 2012).**[3] It requires a team effort of Specialists in oral surgery, plastic surgery, otolaryngology, general dentistry, primary care, orthodontics, audiology, speech pathology, psychology, genetic counselling, and social work.

The question of whether the sequence of comprehensive treatment for cleft lip and palate patients provide a positive Oral Health Related Quality Of Life (OHRQOL) arises to evaluate how their satisfaction with the treatment

and the treatment outcomes is related to their OHRQOL. Definitive results are often clearly assessed after young adulthood due to the development, growth factors and adherences to series of treatment plan.

Oral Health-Related Quality Of Life (OHRQOL) is defined as a person's assessment of how psychological factors (including appearance and self-esteem), the experience of pain or discomfort, functional factors (Speech, difficulty in eating and breathing), and social factors that are related to a patient's oral health affect a person's well-being.

Facial scarring and facial distortion despite elegant repair and reconstruction techniques imposes a life-long burden on peer and family relationships, body image, and psychosocial development. Some studies have reported an increased frequency of anxiety, low self esteem, and depression in CLP patients due to inadequate treatment that affect facial function and aesthetic harmony. Most families, are affected psychologically even with early treatment. Many cleft lip and palate patients suffer serious functional sequel like hypernasal voice, difficulties in eating, poor oral hygiene, poor aesthetics, and other physical problems such as ear infections, alterations in hearing, and a psychosocial burden which affects the patient 's quality of life **(Ward et al., 2013).**[4]

Furthermore, it has been reported that CL/P patients have lower achievements in school due to cognitive deficiency. Oral health complications

are numerous, including dental agenesis and supernumerary and poorly positioned teeth **(Chapados, 2000)**[5]which cause speech disorders. Other facial deformities causes problems such as hyper nasality, facial alterations such as nose and mouth asymmetry, which also affect the individual's self-image, social affiliation, and adaptation **(Broder et al., 1994; Berk et al., 2001).**[6,7]

When considering comprehensive CL/P care, team members must consider the patients' and even the parents' background, cultural upbringing, current or past experiences with oral disease and health care, current state of mind, and expectations for treatment and outcomes along with hopes for the future because of the cumulative effect on the person's well-being. The overall goal of treatment in CL/P patients is to achieve psychological and social well-being of patients along with their parents. Treat the patient as a whole than merely the treatment site. Understanding the entire complex needs of the patients and parents will aid in better results and optimal cooperation in the team of clinicians.

Research showed that patients with more negative OHRQOL scores were more likely to desire further treatment than patients with more positive OHRQOL scores. The measurement of oral health–related quality of life becomes an important health indicator that reveals the functional and psychosocial results of oral diseases and conditions **(Cohen, 1997, quoted by Do and Spencer, 2008).**[8]

In this study, we are evaluating the health-related quality of life (HRQoL) in patients with CLP, treated in our unit in the past 25 years. Understanding the impact of clefts on these patients will facilitate development of policies to reduce the negative impact of this malformation at the individual, familial, and societal levels.

Aims and Objectives

AIMS AND OBJECTIVES

The aim of this study is to assess the oral health quality of life of patients treated for cleft lip and palate using oral health related quality of life (OHRQol) scale and profile evaluation questionnaire.

The following hypotheses were tested.

1. It was hypothesized that no difference would be found between cleft male and female patients in terms of OHRQoL
2. It was hypothesized that no significant difference between different types of cleft lip and palate patients would be found in terms of OHRQoL.
3. It was hypothesized that there is no difference between different age group of cleft lip and palate patients in terms of OHRQoL.
4. It was hypothesized the children with cleft do not differ in oral health related quality of life compared with healthy subjects.
5. Caregivers' perceptions of their child's oral health related quality of life do not differ from those of their children with repaired orofacial clefts
6. It was hypothesized that caregivers' perceptions of their child's oral health related quality of life has no significant difference between with different types of cleft lip and palate patients would be found

7. It was hypothesized that caregivers' perceptions of their child's satisfaction between various aspects of face do not differ from those of their children with repaired orofacial clefts

Review of Literature

REVIEW OF LITERATURE

S. R. Turner, P. W. N. Thomas, et al (1997)[9]In this study 242 interviews of 112 patients and 130 parents were taken into account in nine base hospitals. 73% of patients under the age group of 15- and 20-year subjects felt their self-confidence was affected due to cleft. 60% of the patients were mocked about speech or cleft related features. 23% of subjects were excluded from treatment planning decisions. No agreement was established between parent/child for their satisfaction with clinical outcome of cleft related features was found. Differences between parents' and their child's satisfaction ratings for cleft related features were not significant except for the ratings for 'lip' and 'teeth' for 15-year-old subjects (Wilcoxon signed rank sum test). Patients' views on planned treatment should therefore be independently sought from their parents' views, as no agreement was found within the groups for satisfaction with clinical outcome. This study shows the necessity of identifying 'psychological outcome' as well as 'clinical outcome' in order to enhance the rehabilitation for cleft lip and palate patients. Seven families were referred for counselling for cleft-associated emotional problems as a result of this survey.

S. L. A. Jeffery, J. G. Boorman et al (2001)[10] The authors requested the parents of 478 children aged between 3 and 14 years who are under the care of the cleft team at the Queen Victoria Hospital, East Grinstead, to fill a questionnaire and received 341 replies. The questions were based on aspects

of patient satisfaction, and the results are reported and discussed. The results provided showed that 30% of parents would like to be more involved in treatment-planning decisions; 33% thought they had either not enough or no knowledge about cleft lip and palate and its treatment. Only 8% of parents would rather have seen the specialists separately than together in the joint clinic.

Klaus Sinko, Reinhold Jagsch , et al (2005) [11]70 patients under the age group of 18-30 years who reported with a repaired complete cleft lip and palate, were included in the study. Their Esthetic and functional outcomes were evaluated by the patients themselves and by five experts using a visual analog scale. Patients completed the MOS Short-Form 36 questionnaire to evaluate health-related quality of life. Patients rated their esthetic outcome significantly worse than the experts did. No significant differences were observed in the ratings for function. Female patients, especially, were dissatisfied with their esthetic outcomes. When interviewed personally nearly 63% of the subjects asked treatment or upper-lip and nose corrections. The health-related quality-of life questionnaire revealed low scores for social functioning and emotional role. It was fascinating to find that 1/3rdof the conflicting scores for men were because the patients desired no further treatment.

Siti Noor FazliahMohd Noor, Sabri Musa et al (2006)[12]A group of 60 cleft lip and palate patients between the age group of 12-17 years from Hospital Universiti Sains Malaysia and their parents were selected and asked to fill a questionnaire. The questionnaires used were the Child Interview Schedule, the Parents Interview Schedule, and the Cleft Evaluation Profile (CEP), administered via individual interviews. Patients were frequently teased about cleft-related features such as speech, teeth, and lip appearance and felt their self-confidence was affected. Parents also reported the same.

Both showed a significant level of satisfaction with the treatment provided by the cleft team.

Petra Landsberger, Peter Proff, et al (2006)[13] The study includes Thirty-three cleft patients with total clefts of lip, alveolus and palate. All the patients underwent osseous bridging of the alveolar cleft (osteoplasty) followed by different types of subsequent treatment. All patients then answered a questionnaire to assess treatment result and their satisfaction with their facial appearance. The type of alveolar cleft repair was correlated with patients satisfaction. In 20 patients out of the 33 patients the lateral incisor in the cleft area was either missing or markedly hypoplastic and the resulting gap needed closure. In 22 patients the space was closed orthodontically. In 6, the gap was closed with a bridge; in 2 an implant had been placed. 3 wore a denture with one tooth and were scheduled for an implant. Most satisfied with their facial appearance were patients wearing a plate or an implant. With

respect to their occlusal conditions and cleft patients wearing a denture were least satisfied followed by patients with orthodontic space closure. Treatment with a bridge or an implant was judged equally positive. Regarding dental aesthetics, implants were judged as the most aesthetic type of treatment and denture was rated as least appealing, followed by orthodontic gap closure and bridge construction .There was no significant difference between right- or left-sided clefts on facial appearance .Female patients were more satisfied than males.

Maria Mani, Marianne Carlsson, et al (2010)[14]With the SF36 questionnaire, the life of health-related quality of 109 unilateral cleft lip and palate patients were measured. The total patient group when compared with lower values in Mental Health subscale to norm data (p = .005). Values in norm data did not differ from all other subscales. Compared with the matched norm population (p, .001), women had a higher positive difference in the subscale emotional role function than men. In emotional role function men were affected more negatively by UCLP than women. The younger age group (20 to 32 years old) had a consistently larger negative difference to match norm data compared with the older age group (33 to 47 years old) in the subscales physical role function (p , .001), social function (p = .009), and emotional role function (p , .001). According to Skoog (1958) surgical protocol included lip closure at the age of 3 to 6 months. The palate was closed either in a two-stage or in a one-stage procedure. At the time of the

study these patients were referred to as the ‘‘older age group” and are 33 to 47 years of age .As described by Veau and Wardill and later modified by Skoog, patients in this age group at mean age of 1.9 years, underwent palatal closure in one stage .Patients who were born between 1976 and 1987 were 20 to 32 years of age at the time of the study and were operated on according to the two-stage protocol. These patients are referred as ‘‘younger age group.’’ In the two-stage procedure first the soft palate was closed , and in the second stage the residual cleft in the hard palate was closed The first stage was performed at the age of 6 to 18 months, and the second step at the age of 2 to 6 years. In several of the SF-36 subscales, younger patients were affected more negatively by UCLP than were the older patients.

Annemieke Bosa; Charlotte Prahlb, et al (2011)[15]A study conducted on sample consisted of 122 patients with clefts (age range, 8–15 years) and their parents. Respondents were recruited from the cleft palate team of Amsterdam. They completed the Child Oral Health–Related Quality of Life questionnaire (COHIP). Items were divided into five different subscales, and scores on all subscales were compared between and within groups. Patients’ and parents’ perceptions differed significantly on three of the five subscales. Girls and boys did not differ significantly with regard to their perception of

reported OHRQoL. The cleft lip and cleft lip and alveolus [CL(A)] subgroup scored significantly higher on the functional wellbeing subscale. The cleft patients aged 12 years and older scored significantly lower on the emotional well-being and oral symptoms subscales when compared with their younger peers

S. M. Munz, S. P. Edwards, et al (2011)[2]27 patients and 30 parents who completed CL/P treatment were included in the study with the Michigan Oral Health-Related Quality of Life (MOHRQoL) Scale, Patients' ohrqol was assessed , with Kiyak's Post-Surgical Patient Satisfaction Questionnaire the treatment satisfaction, and with Noor and Musa's Cleft Evaluation Profile the satisfaction with treatment outcomes were assessed. The results of this study, shows that on average the ohrqol of young patients with CL/P was quite positive, and that they also had a positive post-surgical treatment satisfaction. The findings showed that the more positive was the pain- and function-related ohrqol as the patients were more satisfied with their treatment,. The patients' social ohrqol and psychological scores did not correlate with their treatment satisfaction. Overall, patients reported a positive ohrqol. The satisfaction scores of patients ranged from low to high. Patient and parent treatment satisfaction was related, while their outcome satisfaction did not correlate. Patients' MOHRQoL scores correlated with parents' outcome satisfaction and parent and patient treatment satisfaction. Patients' MOHRQoL scores did not correlate with the patients' outcome satisfaction. The patients' level of

discomfort was strongly correlated with the patients' and parents' treatment satisfaction and the parents' outcome satisfaction. In conclusion, the treatment completion, regardless of the outcome satisfaction, young patients with CL/P report a quite positive ohrqol. There is a clear relationship between the ohrqol of the patients with CL/P and their own as well as their parents' treatment satisfaction assessments.

NedaEslami , Mohammad Reza Majidi, et al (2013)[16] A group of 50 children who were referred to Cleft lip/Palate Research Centre of Mashhad Dental School (Iran) were requested to furnish the Child Oral Health Impact Profile questionnaire. The questionnaire contained 38 questions which was categorized over 5 subheadings. The scores on all subheading were evaluated in accordance with patients' age, sex, and type of cleft. They came to conclusion that Oral health related quality of life of cleft lip and palate patients did not change based on patients' age and the impact of unilateral and bilateral clefts was similar. The Quality of life of girls were found to be much affected by oral health**.**

Ewa Pisula, Ewa Lukowska, et al (2014)[17]48 subjects were selected with cleft lip and palate of age 16 to 23 years; (31 males, 17 females) and 48 controls without cleft lip and palate of age16 to 23 years; (28 males, 20 females) were asked to complete Self-report questionnaires measuring self-esteem (Multidimensional Self-Esteem Inventory), coping styles (Coping Inventory for Stressful Situations), and health related quality of life

(WHOQOL-BREF). Regarding self-esteem, the scoring was high on body functioning and defensive self-enhancement on subjects who had cleft lip and palate. In regard with Self-control, females with cleft lip and palate scored higher than controls. Males with cleft lip and palate scored lower than controls in personal power but higher in body functioning; females showed no differences between groups. Late adolescents and young adults with and without cleft lip and palate had differences in relation to psychological adjustment measures.

Hillary L. Broder, Maureen Wilson-Genderson, et al (2014)[18]A longitudinal study was done among 1200 participants who were asked to completed the Child Oral Health Impact Profile, During the baseline clinical evaluations, plastic surgeons analyzed whether surgical interventions were necessary within the year and based on this two groups were considered: recommended for surgery within 1 year versus not recommended for surgery There was no significant difference in age and gender distribution between the two recommendation groups. There was also a higher scoring by the surgeons for both nose and lip severity for patients for whom surgery was recommended. There was also a significant difference in racial distribution between the groups with surgery recommended, for a greater proportion of minority. Those with a surgical recommendation had lower mean scores on the oral symptoms subscale than those without a recommendation .Those with a surgical recommendation had lower mean scores on the functional wellbeing

subscale than those without. Although socio-emotional well-being subscale scores for both male and female patients decrease as they age, the decrease is larger for girls than for boys. For the school/environmental subscale, those with a surgical recommendation have lower mean school/environment scores than those without. According to this finding, girls' (but not boys') school/environmental scores decrease as they age. For the self-esteem subscale, there was a statistically significant main effect for sex such that boys had lower scores on this subscale than girls .Finally, for the total Child Oral Health Impact Profile score, recommendation group had a lower mean score than those subjects for whom surgery was not recommended; there was also a reduction of −0.73 total score point per year of age.

Jessy Y. Dabit, Paul A. Romitti, et al (2014)[19]A Population-based sample of children with isolated oral clefts aged 4 to 9 years was enumerated. The Mothers of 294 children who had completed the Aggravation in Parenting Scale and Mental Health Inventory 5-item questionnaire comparison between the mean scores for each instrument and proportion of mothers with high aggravation or poor mental health with those reported in the National Survey of American Families were done. results showed than the Mothers with poor mental health tend to have lower household incomes, tended to be less educated , and to rate their child's health and their health lower than those in better mental health. And Mothers with high aggravation tends to have more children, tended to have lower household incomes, and to rate their child's

health and their health lower than those with low or moderate aggravation .Socio-demographic characteristics were also associated with maternal psychosocial adaptation. The Mothers of Poor mental health were not able to help their children with oral cleft, thus decreasing the social adaptation of cleft child.

Pasquale Piombino, Federica Ruggiero, et al (2014)[20]Our multidisciplinary team collaborated a group of questionnaire emphasising on the physical, psychological, and social satisfaction of adolescents and young adults who had cleft lip and palate, from 36-item Short-Form Health Survey. The questionnaire was distributed among 2 groups of randomized sample of40 adolescents and young adults each within the age group of 16–24 yrs with CLP who had completed treatment protocols and who were not affected by CLP. The content was categorized into two divisions based on the clinical profile (which included: first/second name, age, sex, education level, parents' educational level, cleft type, and surgery performed) and on physical, psychological, and social health. When analysing the scores obtained in the study and the control group we obtain that the patients with cleft lip and palate have more issues with self-esteem and social skills. Moreover it was interesting to find that the patients with CLP reported to have difficulty in analysing information and specialized centres about their pathology .There was a decrease in Oral function difficulties to 2.4% and Food reflux to only 5% after treatment. For the subset "language," a median of 3.65% of the

samples showed frequent or persistent difficulties in articulating words and frequent misunderstanding by interlocutors (before treatment, 57.5%; after treatment, 10%).Timbre was perceived as nasal in 17.5% of patients before treatment, which decreased to 2.5% after treatment. 90% of patients did not report pain after treatment.

Tovah P. Klein, Alice Pope, et al (2014)[21]A study was done with Mothers of nine children, aged 9 to 14 years with congenital craniofacial anomalies. Thematic narrative coding categories, mothers' advice and interpretations regarding challenging hypothetical social tasks (from the coaching task) and focusing on mothers' perspectives on children's actual social experiences (from the interview) .When interviewed, mothers reported their children s positive and negative social experiences. Multiple approaches were used by mothers to interpret hypothetical social situations (coaching task) and social interactions experienced by children (interview) .Those included are motivations of others, factors within own child and consideration of situational factors. Mothers' hypothetical advice was often prosocial, to avoid hurtful situations to foster self-reliance, to plan ways to avoid problems, and concrete strategies to resolve conflict.

Mothers showed active concern and interest in their children's peer relationships and were thoughtful in devising strategies to successfully manage potential social challenges.

Nikolaos Gkantidis, Despina A. Papamanou, et al (2015)[22]The sample consisted of 30 parents and 33 patients (7 CP, 6 bilateral CLP, 20 unilateral CLP median age: 17.1, range: 9.0–33.1 years) who responded to the questionnaire in an interview-guided session and whose answers were registered on a 100 mm Visual Analogue Scale (VAS). All participants received their orthodontic treatment in the University of Athens at the Department of Orthodontics. Patients and their parents were of quite satisfied with function and esthetics. Patients with UCLP who were primarily concerned about nose esthetics (CP about speech and BCLP about lip esthetics). With decreased influence of the cleft in everyday life ($P< 0.05$), increased satisfaction was associated. The effect of the cleft on social activity of the patient was significantly greater for the BCLP group when compared to the other two groups. Patients did not reported significant influence of the cleft on family life, while parents did. Tendency for improved satisfaction from hearing and speech with increasing age, while the opposite was true for lip esthetics. These functional problems like hearing and speech affect the social and the professional/school life.

Canice E. Crerand, David B. Sarwer et al (2015)[23]A study was conducted with 70 adolescents with visible craniofacial conditions and a demographically matched sample of 42 adolescents without craniofacial conditions. Adolescents completed the measures of quality of life and the

body image including satisfaction with weight, investment in appearance (importance of appearance to self-worth) facial and overall appearance, and body image disturbance (impairment in functioning and appearance-related distress) using Multidimensional Body-Self Relations Questionnaire Appearance Scales, Youth Quality of Life Instrument ,Body Image Disturbance Questionnaire, Derriford Appearance Scale, Satisfaction With Appearance Scale,. Adolescents with craniofacial conditions were more likely to report concerns about facial features (P, .02) and reported lower appearance investment (P , .001) when compared with nonaffected youth. Compared with males females in both the groups reported a greater investment in appearance with greater body image disturbance, and a lower weight satisfaction (P, .01). Within both the groups, the greater body image disturbance was associated with the lower quality of life (P, .01). The two groups did not differ significantly on satisfaction with appearance, measures of quality of life and the body image disturbance. In adolescents with craniofacial conditions body image and quality of life are similar to nonaffected youth

Nicola Marie Stock, Katie Stoneman, et al (2015)[24]An Individual qualitative interviews were conducted over the telephone/Internet with 5 siblings and 8 parents, including 5 sibling-parent pairs from the same family. Thematic analysis identified a three key themes applicable across both parent and sibling interviews: factors affecting the degree of impact, perceptions of positive and negative impacts, and support for families. Participants reported a

close and strong bond between the children with CL/P and their sibling(s). Particularly siblings were acknowledged as being caring and kind, often helping and supporting others. Participants also identified a sibling rivalry, which was generally concerned in comparison to that spent with the sibling(s), the time and amount of attention the child with CL/P received from parents and other family members.

Rosany Larissa Brito de Oliveira, Thiago de Santana Santos et al , (2015)[25]The author did a descriptive, observational, cross-sectional study with 3 groups consisting of 97 subjects each: CLP, family, and control. An initial cognitive evaluation was performed with the Mini-Mental State Examination, and the Medical Outcomes Study 36 item Short-Form Health Survey (SF-36) was applied to evaluate HRQoL in individuals with sufficient cognitive capacity. The status of the individuals with cleft lip and palate usually had a primary education, and had incomes between 1 and 2 minimum wages, and slightly more than half presented with a transforamen cleft (59.8%).No markable difference was noted in the overall HRQoL score among the 3 groups (cleft: 72.2; family: 70.6; control: 72.5).Individuals with CLP had a lower average on the Emotional Aspects domain and had higher averages in the Vitality domain when compared with their relatives. Men had higher averages on the Physical Function (PF) and Mental Health (MH) domains. The author came to a conclusion that patients with cleft lip and palate operated at <12 months of age, had higher mean PF scores, which shows the necessity of

establishing a cleft care reference center in Sergipe state, there were in particular no variation in global HRQoL between individuals with cleft lip and Palate, relatives, and the controls. It was also found that patients with cleft lip and palate had a lower average than the control group for the RE domain. In comparison with other surveys it was found that some emotional problems can persist even after surgery to repair the cleft. Women with cleft lip and palate are less contented with their facial appearance and the aesthetic results of surgical repair and stated to have psychologic deficits, particularly in relation to self-concept, and have lower HRQoL than women.

Terhi Kortelainen, Mimmi Tolvanen, et al (2015)[26]A cross-sectional questionnaire survey study were conducted in children aged 11 to 14 years from two groups. All children of this age who had had CLP selected from the regional treatment register (N ¼ 51) were included in The CLP sample. Children from four school classes (N ¼ 82) were included in the school sample. Oral health–related quality of life was measured with the CPQ11-14. The CPQ11-14 total and functional limitations, social wellbeing, emotional well-being subscores were poorer among patients with the CLP than among the schoolchildren without CLP (mean scores: 55.5 versus 15.0; 11.9 versus 5.1; 14.0 versus 2.8; 12.6 versus 4.2; and 17.1 versus 2.9, respectively; all P .001 for Mann-Whitney tests). The oral health–related quality of life of Finnish children with CLP was considerably poorer than that of their peers in all dimensions, especially social well-being. According to age and gender no

statistically significant differences were found between the school samples and CLP.

Adam Blancher, Mary Ann Goodwyn, et al (2016)[27]A modified version of the Multidimensional Attitudes Scale toward Persons with Disabilities for 189 participants without cleft lip and palate were assessed. The study included a child cohort (n ¼ 78; Mean age ¼ 10.01 years) and a young adult cohort (n ¼ 111; Mean age ¼ 19.58 years). The Results from the child data suggest that for 9 to 11 year old children, their attitudes can be significantly improved by using educational information in conjunction with a brief personal contact with someone with CLP. This information alone did not significantly impact children's attitudes in the current study; however, a significant (22.54%) increase in attitudes was observed when information was paired with personal contact,. It was found that with the information and personal contact with individuals with CLP, the children's cognitive attitudes were significantly improved (22.54%). Unfortunately, the young adult attitudes were not significantly influenced by either information only or information paired with personal contact and were resistant to change. This finding came as a surprise, although resistance to attitude change within the young adult cohort, and findings were inconsistent with prior research where the information and personal contact did not significantly affect their attitudes. Between the age cohorts there were no significant differences in attitudes;

however, data suggests that children responded differently to experimental intervention.

Adam R. Sawyer, Stephen Robinson, et al (2016)[28]27 secondary cleft rhinoplasty patients completed evaluation forms preoperatively and 3 to 6 months postoperatively completed Rhinoplasty Outcomes Evaluation (ROE) questionnaire. This contains6 questions that include three quality-of-life domains: physical, mental/emotional, and social. There was marked changes in the total ROE evaluation scoring in secondary cleft rhinoplasty. Specific scores for nasal aesthetic appearance were improvised in secondary cleft rhinoplasty. No changes was seen in breathing capacity in secondary cleft rhinoplasty. All patients said they would undergo the procedure again. The results seem to have high patient satisfaction after cleft rhinoplasty in accordance to cosmetic appearance.

Alice Lee, Fiona E. Gibbon, et al (2016)[29]A total of 90 children, 30 in each age group of 7 to 8 years, 9 to 10 years, and 11 to 12 years. Speech intelligibility scores and typically developing children's attitudes were measured using eight social and personal categories on a three-point rating scale. There was a significant correlation between the speech intelligibility scores and attitude judgments: ''sick-healthy'' as rated by the children aged 7 to 8 years, ''no friends-friends'' by the children aged 9 to 10 years, and ''ugly-good looking'' and ''no friends-friends'' by the children aged 11 to 12 years. Children who were under the age group of 7 to 8 years gave lower scoring for

‘‘mean-kind’’ but higher scoring for ‘‘shy-outgoing’’ when compared with the other two groups. That is, children who were less intelligible were perceived as less healthy, not as good looking, and probably had no or fewer friends. Typically developing children tended to make negative social and personal attribute judgments about children with cleft palate based solely on the intelligibility of their speech. Society, educators, and health professionals should work together to ensure that children with cleft palate are not stigmatized by their peers.

Alice W. Pope, Tovah P. Klein, et al (2016)[30]9 children with congenital CFA aged 9 to 14 years. Thematic coding categories were introduced using an open coding strategy; these categories focused on aspects of children’s interactions with their associate and their assessment in the role of their CFA in their lives. Children reported comfort with most aspects of their relationships and expressed confidence in their ability to manage challenges. They acknowledged some difficulties with living with a CFA but tended to hold an equal aspect on the impact of a CFA on their lives, and they anticipated in their future lives. This sample of children with CFA exhibited much pliancy

Jill Nyberg, Christina Havstam, et al (2016)[31]Nineteen patients who were 10-year-olds participated in three focus group interviews where they listened to 10 to 12 speech samples with different types of cleft speech characteristics which were assessed by speech and language pathologists

(SLPs) and described what they heard. With qualitative content analysis, the interviews were analyzed and transcribed. The analysis resulted in a three interlinked categories encompassing different aspects of personality, speech, and social implications: descriptions of speech, thoughts on causes emotional reactions and associations. Each category contains another four subcategories that are exemplified with quotes from the children's statements. More pronounced signs of VPI were perceived but referred to in terms relevant to 10-year-olds. Even minor articulatory difficulties were noted. Peers reflected on the risk to bullying and teasing and on how children with impaired speech might experience their situation. The SLPs and peers did not agree on the minor signs of VPI, but they were unanimous in their analysis of clinically normal and more severely impaired speech. Based on what peers says, the articulatory impairments may be more important to treat than minor signs of VPI.

Kavitha Ranganathan, Danielle Shapiro, et al(2016)[32] Children between age group of 5-19 years were surveyed with cleft lip, with or without cleft palate, at The University of Michigan Cleft and Craniofacial Anomalies Multidisciplinary Clinic along with their immediate caregivers (n¼71 families). The cleft evaluation profile (CEP) was used to analyse cleft-specific HRQOL and general HRQOL domains, we used to assess the pediatric quality of life inventory (PedsQL) and satisfaction with appearance questionnaire (SWAP). In this cohort study, 54.9% of children required revision, primarily

of the nose, lip, and dentoalveolar structures. Children above 11 years were 3 times more likely to acquire revision than younger children and among Children who reported poorer HRQOL with respect to appearance, social development, and communication. Overall, caregivers were more likely to believe that their children would benefit from revision compared with the children themselves. Among children who wanted revision, 91.3% of caregivers also required for the child. 22 children did not desire revision, whereas their 11 caregivers believed that their children would benefit from it.

Kristin Billaud Feragen, Nicola Marie Stock, et al (2016)[33]The study was to investigate whether there were associations between different realms of risk at age 10 and to examine the appraisal of measures of psychological adjustment. All children who under 10- year-old follow-up did Personality Inventory for Children, Child Experience Questionnaire, Strengths and Difficulties Questionnaire, Satisfaction with Appearance scale. The number of children at high risk in more than one domain of adjustment was less than 15%. However, emotional and social risk were more closely related than other risk groups. Subjects with cleft visibility did not seem to be an important factor at age 10. The results showed the importance of early screening and assessment of children born with a cleft to identify possible associated conditions

Kristin BillaudFeragen, Tone Kristin Saervold, et al (2016)[34] Children with cleft palate of age10 years from three birth cohorts (N ¼ 170) and their parents were included in the study. Speech: SVANTE-N. Language: Language 6-16 (sentence recall, serial recall, vocabulary, and phonological awareness). Reading: Word Chain Test and Reading Comprehension Test. Psychological measures: Strengths and Difficulties Questionnaire and extracts from the Satisfaction with Appearance Scale and Child Experience Questionnaire. Reading skills were associated with self- and parent-reported psychological adjustment in the child. Subjective satisfaction with speech was associated with psychological adjustment, but not associated with speech therapists' assessments. Parent-reported teasing was found to be associated with lower levels of reading skills. Having a medical and/or psychological condition in addition to the cleft was found to affect speech, language, and reading significantly.

Marli Luiz Beluci, Katia Flores Genaro, et al (2016)[35]Approximately 3 days before and 3 to 12 months after surgery , a total of 50 participants responded the questionnaires World Health Organization Quality of Life - Bref (WHOQOL-Bref) and Oral Health Impact Profile - 14 (OHIP-14). After surgery, differences were found in the domains: Physical, Psychological, Environmental and General Questions of the WHOQOL-Bref and domains: Psychological Discomfort, Psychological Disability, Social Disability, Handicap and Overall Score of OHIP-14.

Results showed that the surgical correction of dentofacial deformity improved quality of life and had positive impact of oral health condition, which can be attributed to physical changes with the change in facial appearance caused by surgery.

Pedro C. Aravena, Tania Gonzalez, et al (2016)[1]A cross-sectional study with 48 children (mean age 11.3 years) with a history of CL/P from three cities in Chile and one group of 96 children (mean age 11.2 years) was taken as a control. The COHIP-Sp was applied to both groups. Quality of life was compared according to the overall score and the average score. A lower score was observed in the group with cleft lip and palate in the subgroup ‘‘functional well-being’’ and ‘‘school environment’’; the only average score in the subgroup ‘‘self-image’’. The oral health–related quality of life of children with cleft lip and palate was similar to that of the control group.

Ross E. Long, Maureen Wilson-Genderson, et al (2016)[36]Three groups of patients were surveyed: with alveolar cleft, without previous repair (Group 1); with alveolar cleft, previously repaired (Group 2); no congenital alveolar cleft (Group 3).Presence of any fistula and other subgroup classification were correlated to oral health–related quality of life (Child Oral Health Impact Profile [COHIP]) and perceived speech outcomes. Patients with fistula was about 5.52% (62 of 1198 patients). The significant difference in fistula rate between the three groups: Group 1 (11.15%), Group 2 (4.44%), Group 3 (1.90%). Patients with fistula had significantly worse self reported

speech scores and lower COHIP scores. Group 1 patients with fistula were the one who had the lowest speech scores and lowest COHIP scores. Presence of any palatal fistulas was associated with lower oral health–related quality of life and perceived speech among young patients with cleft.

Shiwen Zhu, Jayakumar Jayaraman, et al (2016)[37]This study is about assessment of the full facial appearance of patients with cleft lip and palate based on two-dimensional (2D) photographs, 3D images, or clinical examination by outsider and professionals using a visual analog scale (VAS) or a categorical rating scale. 11 articles were included in qualitative synthesis. Three studies found that outsider seem to be more critical than professionals, three found there was no significant difference between outsider and professionals, and five reported that professionals were more critical than outsider when evaluating facial appearance of patients with CLP. Professionals are more familiar with the aesthetic outcomes and difficulties of treating patients.

Christian I. Emeka , Wasiu L. Adeyemo, et al (2017)[38]95 subjects with families who needs either primary or secondary orofacial cleft repair and who satisfied the inclusion criteria were recruited. A preoperative and postoperative health-related QoL questionnaire, the 'Impact on Family Scale' (IOFS), was applied in order to detect the subjectively perceived QoL in the affected family before and after surgical intervention. Pre- and postoperative mean scores were compared across the 5 domains of the IOFS. The proportion

of families whose QoL was affected before surgery was 95.7%. The domains with the greatest impact preoperatively were the social domains and the financial domain. Families having children with bilateral cleft lip showed QoL effects mostly in the 'impact on sibling' domain and social domain. Postoperatively, the mean total QoL score was lower than the mean preoperative QoL score, indicating the significant improvement in QoL

Karen W. Y. Wong Riff, Elena Tsangaris et al (2017)[39]A total of 136 individual were interviewed in-depth, the participants were patients with clefts of any age, presenting for cleft care, across 6 countries. If the child was more comfortable parents were also involved in the study. Interviews were audio-recorded, transcribed verbatim, and coded using constant comparison. Appearance and speech were the most frequently discussed in the interviews. Individuals with CL/P may struggle with social and psychological sequelae of having differences in their speech and appearance. . All participants expressed both positive and negative concepts related to their psychological function. Their Confidence improved with positive treatment outcomes. Participants also felt anger, fear, sadness, worry, hurt, and embarrassment as a result of the cleft. Participants often noted the appearance of their smile or laugh and the smile represented a manifestation of participants' perceptions of their lips, teeth, jaws, and nose. Participants also mentioned difficulty in blowing or whistling, and their inability to drink through a straw. The eitology of problems with eating/drinking included symptoms consistent with suboptimal

orthodontic alignment and palatal fistula. Participants avoided certain foods being unable to chew and needing to take small bites when eating. With respect to breathing, participants described difficulty in breathing through their mouths or breathing through their noses

Rebecca S. Bickham, Kavitha Ranganathan, et al (2017)[40]A group of 108 children with a diagnosis of cleft palate (with or without cleft lip) along with their parents were surveyed regarding their perception of speech and their HRQOL. However, 24.1% to34.3% of patients and parents responded yes to difficulties with family understanding their speech, others understanding their speech, having a conversation with a group of familiar listeners, or having a conversation on the telephone. A separate subgroup analysis was performed to analyse differences between self-perceived speech and trained observer-perceived speech. The subgroups were divided into 3 groups: cleft palate with revision, cleft palate without revision, and cleft lip without palate. No significant differences were identified between groups Parent reported HRQOL scores were significantly worse in the domains of anxiety, anger and peer relationships in patients who were rated as poor or moderately impaired on SLP scales of speech intelligibility and speech acceptability. Patient-reported HRQOL scores were significantly worse in the domains of anger, peer relationships, and depression in patients who were rated as poor or moderately impaired on SLP scales of speech intelligibility and speech acceptability.

Shabnam Ajami, Farzaneh Toraby, et al (2017)[41]In this study, a group of 50 CLP children (31 boys and19 girls) under the age group of 8 to 15 years from Shiraz Dental School were included. In an inclusion, 50 more children who attended routine dental care were considered as a control group. Each CLP patient was cross-matched with the similar control group patient in terms of age and sex. The DS14 and COHIP questionnaires were distributed to participants . A significant difference between boys and girls was found based on "emotional well-being''. However, a positive significant correlation between ''oral symptoms'' and age (P¼0.029) was found. There was no significant difference between CLP patients and the control group and also between unilateral and bilateral cleft type. The risks for type-D personality and negative affectivity were almost twice in girls among CLP patients. However, in patients with type-D personality, a significant difference was found in all subscales and in the overall COHIP except for the ''functional wellbeing".

F. Stelzle, M. Rohde, et al (2017)[42]A group of 36 patients with unilateral or bilateral cleft lip and palate were considered after secondary/tertiary alveolar bone grafting and orthodontic/prosthetic implant treatment an to rate gingival esthetics. The patient's OHRQoL was determined using the German short version of the Oral Health Impact Profile questionnaire (OHIP-G14). The results demonstrated marked rating in patients with their own teeth in situ than in patients with implants or prosthetics. It was

fascinating that there was increased OHRQoL in cases with higher oral esthetics in the cleft area. The OHIP-G14 scores of male and female patients and between different ages did not differ significantly .it was also noted that the subjects reported 'fairly often' or 'very often' experienced the following problems: trouble pronouncing words, having felt tense , finding it difficult to relax, and having been irritable with other people**.**

Ana Paula Correa de QueirozHerkrath, Fernando Jose Herkrath, et al (2018)[43]at the referral center for craniofacial anomalies in Manaus, Brazil, a cross-sectional study was conducted with enrolled patients. Non syndromic CL/P adults aged 18 years or more were selected. Both OHRQOL and HRQOL and were assessed using the Oral Impacts on Daily Performance and 36-item Short-Form Health Survey on 96 participants. On an average Participants had schooling of 10 years and 50% of the sample reported the family income greater than 2 bmws, and 71.9% of the sample who were single. 53% of the individuals reported impact on "speaking" and "smiling" and Low family income, low social support, female sex, and dental caries were associated with poor OHRQOL and poor HRQOL ($P < .05$). Poor HRQOL was also associated with the chronic diseases ($P < .05$). Adults who were smokers, and those with low education, low social network, were more likely to have worse OHRQOL ($P < .05$). Satisfaction with the treatment of CL/P was reported by 63.4% of the sample, ranging from 54.2% (CP) to

86.6% (CL + A). Nevertheless, 78.1% informed they would need an additional treatment, usually related to "nose," and "teeth" and "speech,".

Andreas Naros , Annekathrin Brocks, et al(2018)[44]A total of 134 participants were included in the study. the evaluation revealed a significantly higher 'total QoL0 in all self-report groups (Kiddy-, Kid-, Kiddo-KINDLR) and a significantly higher proxy rating for children aged 7 to 13 years when Compared with German normative data. a significant disparity between self-reports and parents' conceptions of HRQoL, as well as a deterioration of the ratings with increasing age was verified in the Multivariate analysis. Other contributing factors e.g. cleft type and gender had no significant effects .The survey revealed a higher HRQoL in cleft patients compared with normative data from healthy controls. It is concluded at least that the HRQoL in our cleft patients was not significantly lower than in healthy children. On the other hand, it can be assumed that the special attention of the parents, other medical professionals and the support from speech therapy may have contributed to a positive effect on self-esteem, communication skills and family interaction.

Natalia Cristina Reinaldo Mariano, Mariana Naomi Sano, et al (2018)[45]A sample of 120 patients were studied which included 60 adults in the cleft lip and palate group (CLPG) and 60 adults in the control group with no craniofacial anomalies. Using the Nordic Orofacial Test-Screening (NOT-S) and the 36-Item Short Form Survey, all patients underwent an interview and clinical examination. The CLPG had significant associations between higher

Orofacial dysfunction and lower QoL for general health (P ¼ .004), emotional role function (P ¼ .028), and vitality (P ¼ .05). Orofacial dysfunctions were more prevalent in adults with a cleft, that negatively impacts their QoL in general health, emotional role function, and vitality. However, when compared to adults without a cleft, adults with a cleft also had significantly higher QoL, reflecting possible resiliency.

Michelly Lima Moro Alves , José Fernando Scarelli Lopes, et al (2019)[46]A study conducted among 40 BCLP patients, out of which 20 patients were in treatment with orthognathic surgery (OrSg) group and 20 patients in prosthetic rehabilitation in the form of overlay prosthesis (OP) group. Epidemiological survey and application of two questionnaires (World Health Organization Quality of Life-brief [WHOQOL-bref] and Oral Health Impact Profile-14 [OHIP-14]) were done. On comparing with the WHOQOL-bref, no significant statistical differences between groups were found. In the analysis of the OHIP-14, only in "psychological limitation" field difference could be observed, when compared to the OP group the OrSg group showed more negative impact. Both rehabilitations provided a satisfactory quality of life for patients.

Materials and Methods

MATERIALS AND METHODS

A cross-sectional study in matching with a case-control design was conducted in Ragas dental college and Hospital in the Department of Oral and Maxillofacial Surgery during the period of December 2017 to December 2019. The study protocol was accepted by Institutional Review Board (IRB) in November 2017. A study was designed to assess the oral health quality of life of patients treated for cleft lip and palate using oral health related quality of life (OHRQol) scale and profile evaluation questionnaire.

Sixty patients in the age group of 8 to 25 years with a history of CL/P participated in the study and were treated surgically in Ragas dental college and Hospital. In addition, sixty children and adolescents in the age group of 8 to 25 years unaffected by CL/P from public schools and colleges in Chennai, India were in the control group. To match the two study groups, a number of children were selected at a ratio of 1:1 between children with a history of CL/P and unaffected children those of similar age group.

Through convenience sampling a group of patients with a history of CL/P was selected. Those children between the age group of 8 and 25 years of were included, who voluntarily agreed to participate through a written informed consent, and whose parents signed an informed consent. Children or adolescents excluded were those who presented a disabling medical condition, syndromic CL/P, or mental disorders. The children in the control group were

selected by means of simple random sampling from public schools and colleges in Chennai, India.

The third group in the study were caregivers. Caregivers of the cleft patients consented to participate themselves in the study. The accompanying caregiver of the patients with oro- facial clefts completed the COHIP reworded for caregivers (taken from **Ralstrom E, 2009)**[47]

COHIP Subscale	Number of items	Explanation
Oral Health	10	Measures specific oral symptoms that are not necessarily related to one another(eg- spots on teeth ,pain
Functional well being	6	Relates the patient's ability to carry out specific everyday tasks or activities (eg. eating ,Speaking clearly,)
Social-Emotional Well being	8	Pertains to peer interactions and mood states
School environment	4	Pertains with task associated with school environment
Self-image	6	Addresses positive feeling about self

The COHIP instrument is has a total of 34 items with five domains (well-being in oral health, social-emotional well-being, functional well-being, self-image and school environment). Each item is valued on a 5-item

Likerttype scale ranging from 0 to 4 (4 - never, 3 - almost never, 2 - sometimes, 1 - fairly often, and 0 - always), **(Broder, 2007)[48].** The questions with no response are scored as zero. The total score of the scale varies between 0 and 136, where a higher score corresponds to a better oral health–related quality of life **(Broder and Wilson-Genderson, 2007).[48]**

Cleft Evaluation Profile

The CEP originated from the Royal College of Surgeons Cleft Lip and Palate Audit Group **(Turner et al., 1997)[9]**and was used to assess perceived satisfaction for individual features related to cleft care. It consists of seven-item list: hearing, speech, breathing, lip, nose, teeth, and profile. For each item in the CEP, all the subjects should rate their satisfaction on a 5-point Likert scale ranging from very happy (a rank of 4) to not at all happy (a rank of 0). The Differences between parental and child ratings for four features related to facial appearance (teeth, lip, nose, and profile) were analyzed. All items in the CEP are related to facial features that plays a major role in assessing facial appearance among cleft lip and palate patients that are used to determine the perceived satisfaction of the patients and their parents with the clinical outcome of cleft treatment. The CEP determines any significant differences in the parent and child ratings of the features related to facial appearance, namely facial profile ,teeth, lips, nose, and. These are the features patients and parents felt that needed attention and were examined for differences of responses between patients and their parent

FOR CLEFT GROUP

INCLUSION CRITERIA:-

- All patients having craniofacial cleft and palate who has undergone treatment for the same
- Age group between 10 to 25 years
- Both sexes to be included

EXCLUSION CRITERIA:-

- Patient with neurological impairment.
- Patient with disabling medical condition.
- Patient associated with syndrome.
- Patients with Mental disorders

FOR CONTROL GROUP

INCLUSION CRITERIA:

- Patient age 8-25 years
- Both genders included

EXCLUSION CRITERIA:

- Patients with significant medical history
- Patient with neurological impairment.
- Patient with disabling medical condition.
- Patients with Mental disorders

RAGAS CLEFT LIP AND PALATE UNIT

CLEFT LIP AND PALATE CASE HISTORY

NAME: REG NO: RELIGION:

AGE/DOB GENDER: LANGUAGE:

OCCUPATION OF FATHER MOTHER:

TEL: E-MAIL

CLEFT DETAILS	dx	Right									Left					
	Simonart's band	Y									Y					
	Lip		I	C					I	C		Vomer attached to hard palate	Y	N		
	Alveolus				I	C			I	C		Submucous Cleft	Y	N		
	Hard Palate						I	C				No cleft but seen for VPI	Y	N		
	Soft Palate						I	C								
	Cleft Summary															
	Other congenital malformation / Syndrome															

H/O CLEFT SURGERY:

TYPE OF SURGERY	DATE	AGE

FAMILY HISTORY OF CLEFT:

DOES MOTHER HAVE A CLEFT	Y	N	
DOES FATEHR HAVE A CLEFT	Y	N	
MATERNAL HISTORY OF CLEFT	Y	N	
PATERNAL HISTORY OF CLEFT	Y	N	

NUMBER IF SIBLINGS WITHOUT CLEFT	M		F	
NUMBER OF SIBLINGS WITH CLEFT	M		F	

TWINS WITH CLEFT	Y	N	

ORDER OF BIRTH:

PARENTS- CONSANGUINITY:

IF YES, EXACT RELATIONSHIP:

AGE OF MOTHER AT PARTURITION:

MENARCHE AGE OF MOTHER:

I TRIMESTER

FEVER/ILLNESS/MEDICATIONS/ALCOHOL/SMOKING/SURGERIES UNDER GA/ATTEMPT AT ABORTION/GENERAL ANESTHESIA/IRRIDIATION

FEEDING DIFFICULTIES:

PAST MEDICAL HISTORY:

ALLERGIES:

OTHER NON-CONGENITAL ABNORMALITIES:

CURRENT MEDICATIONS:

EXAMINATION:

HEIGHT: WEIGHT:

EXAMINATION OF FACE:

INTRA ORAL EXAMINATION:

DENTAL EVALUATION:

D:

M:

F:

MISC:

STUDY CASTS:

PHOTOGRAPHS:

RADIOGRAPHS AND EVALUATION:

PEDIATRIC EVALUATION:

ENT EVALIUATION:

SPEECH EVALUATION:

CLEFT CLINIC RECOMMENDATION:

QUESTIONNAIRE

NAME: **AGE:**

ADDRESS: **GENDER:**

DIAGNOSIS:

NUMBER OF SURGERIES DONE:

ORAL HEALTH IMPACT PROFILE QUESTIONNAIRE

KEY : 5 POINT LIKERT SCALE

4 -never, 3 - almost never, 2-sometimes, 1-fairly often, and 0-always

DOMAIN -1 : ORAL HEALTH

	(0)	(1)	(2)	(3)	(4)
1. Had pain in your teeth	☐	☐	☐	☐	☐
2. Been breathing through your mouth or snoring	☐	☐	☐	☐	☐
3. Had discoloured teeth or spots on your teeth	☐	☐	☐	☐	☐

4. Had crooked teeth or spaces between your teeth	☐	☐	☐	☐	☐
5. Had sores/sore spots in or around your mouth	☐	☐	☐	☐	☐
6. Had bad breath	☐	☐	☐	☐	☐
7. Had bleeding gums	☐	☐	☐	☐	☐
8. Had food sticking in or between your teeth	☐	☐	☐	☐	☐
9. Had pain or sensitivity in teeth with hot/cold things	☐	☐	☐	☐	☐
10. Had dry mouth or lip	☐	☐	☐	☐	☐

DOMAIN -2 : FUNCTIONAL WELL BEING

1. Had trouble biting/chewing apple, carrot/ firm meat	☐	☐	☐	☐	☐
2. Had difficulty eating food you would like to eat	☐	☐	☐	☐	☐
3. Had trouble sleeping	☐	☐	☐	☐	☐
4. Had difficulty in saying words	☐	☐	☐	☐	☐

5. People had difficulty understanding what you are saying ☐ ☐ ☐ ☐ ☐

6. Had difficulty your teeth clean ☐ ☐ ☐ ☐ ☐

DOMAIN-3 SOCIO-EMOTIONAL WELL BEING

(0) (1) (2) (3) (4)

1. Been unhappy or sad ☐ ☐ ☐ ☐ ☐

2. Felt worried or anxious ☐ ☐ ☐ ☐ ☐

3. Avoided smiling or laughing with other children ☐ ☐ ☐ ☐ ☐

4. Felt that you look different ☐ ☐ ☐ ☐ ☐

5. Felt worried about what other people think ☐ ☐ ☐ ☐ ☐

6. Felt shy or withdrawn ☐ ☐ ☐ ☐ ☐

7. Been teased by other people ☐ ☐ ☐ ☐ ☐

8. Got angry ☐ ☐ ☐ ☐ ☐

DOMAIN - 4 SCHOOL/WORK ENVIRONMENT

	(0)	(1)	(2)	(3)	(4)
1. Missed school/work	☐	☐	☐	☐	☐
2. Had difficulty in paying attention in school or work	☐	☐	☐	☐	☐
3. Did not want to speak/ read out loud in class	☐	☐	☐	☐	☐
4. Did not want to go to school or work	☐	☐	☐	☐	☐

DOMAIN -5 SELF IMAGE

	(0)	(1)	(2)	(3)	(4)
1. Been reassured	☐	☐	☐	☐	☐
2. Felt that you are good looking	☐	☐	☐	☐	☐
3. Felt you have good teeth	☐	☐	☐	☐	☐
4. felt good about himself	☐	☐	☐	☐	☐
5. When I am older, I believe that I will have good heath	☐	☐	☐	☐	☐
6. When I am older, I believe that I will have good teeth	☐	☐	☐	☐	☐

EVALUATION PROFILE QUESTIONNAIRE (Noor &Musa)

KEY: 5 POINT LIKERT SCALE

4 – Very happy; 3 – somewhat happy; 2 – neutral; 1- not very happy; 0 – not at happy

How satisfied are you with

	(4)	(3)	(2)	(1)	(0)
a) Speech	☐	☐	☐	☐	☐
b) Hearing	☐	☐	☐	☐	☐
c) Appearance of teeth	☐	☐	☐	☐	☐
d) Appearance of nose	☐	☐	☐	☐	☐
e) Breathing through nose	☐	☐	☐	☐	☐
f) Appearance of lip	☐	☐	☐	☐	☐
g) Profile of face	☐	☐	☐	☐	☐

CONSENT FORM

Date:

I am giving my willing consent for participating in the study and willing consent for clinical examination procedure.

I am informed about the questionnaires to be filled. I am aware of past medical history and past dental history; cleft lip and palate deformity are to be recorded by using questionnaire.

I am informed about the clinical examination procedure & type of questionnaire being given to me. I am informed that adequate safety precautions are taken to avoid or manage any possible complications arising.

This undertaking is given upon my own accord, I have been explained by the operating surgeon in English and in my own regional language.

NAME OF PATIENT:

SIGNATURE OF PATIENT

Figures

Case1: UNILATERAL CLEFT LIP AND PALATE

FIG1.a AND 1.b: PREOPERATIVE PHOTOGRAPHS

FIG1.c AND 1.d: LIP REPAIR

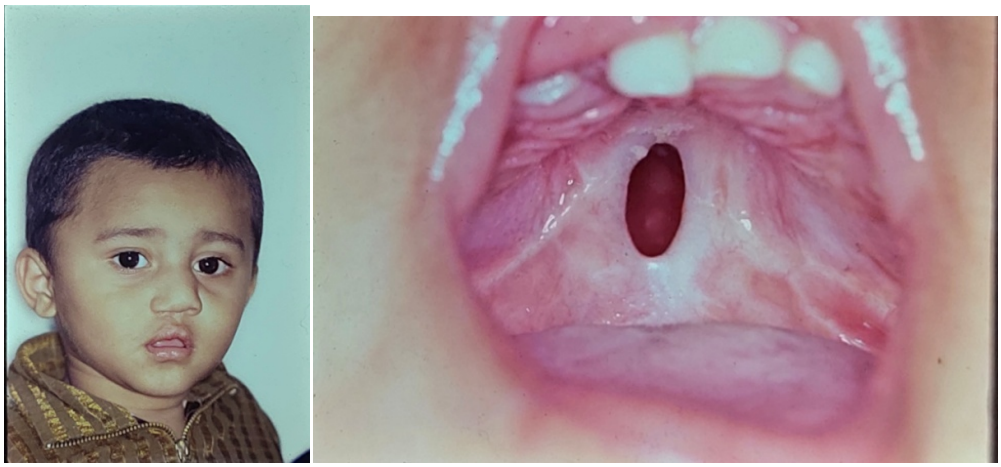


FIG1.e AND 1.f: PALATE REPAIR

FIG 1.G AND 1.h:AT THE TIME OF ALVEOLAR BONE GRAFTING

FIG1.i and 1. J: PREOPERATIVELY BEFORE RHINOPLASTY

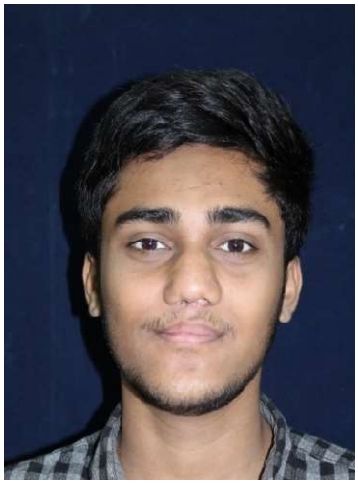


FIG1.k and 1.l: POSTOPERATIVELY AFTER RHINOPLASTY

CASE2: PALATAL FISTULA CLOSSURE USING TONGUE FLAP IN A BILATERAL CLEFT LIP AND PALATE CASE

FIG 2.A,B: PREOPERATIVE PHOTOGRAPHS

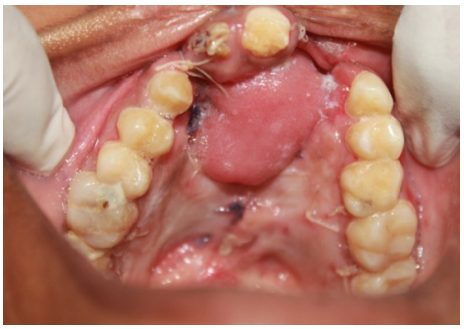


FIG 2.C: POSTOPERATIVEPHOTOGRAPH AFTER TONGUE FLAP PLACEMENT

CASE3:BILATERAL CLEFT LIP AND ALVEOLUS

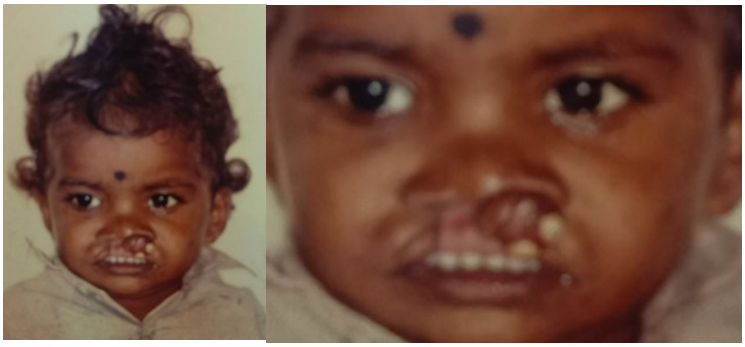


FIG3.a AND b: AT THE TIME OF CLEFT LIP REPAIR

FIG 3.c,d,e: AT THE TIME OF ALVEOLAR BONE GRAFTING FROM ILLIAC BONE

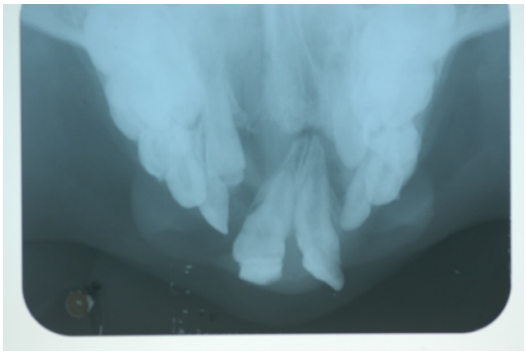


FIG 3.f: OCCLUSAL RADIOGRAPH

FIG3.G: PATIENT AT THE TIME OF ORTHODONTIC TREATMENT

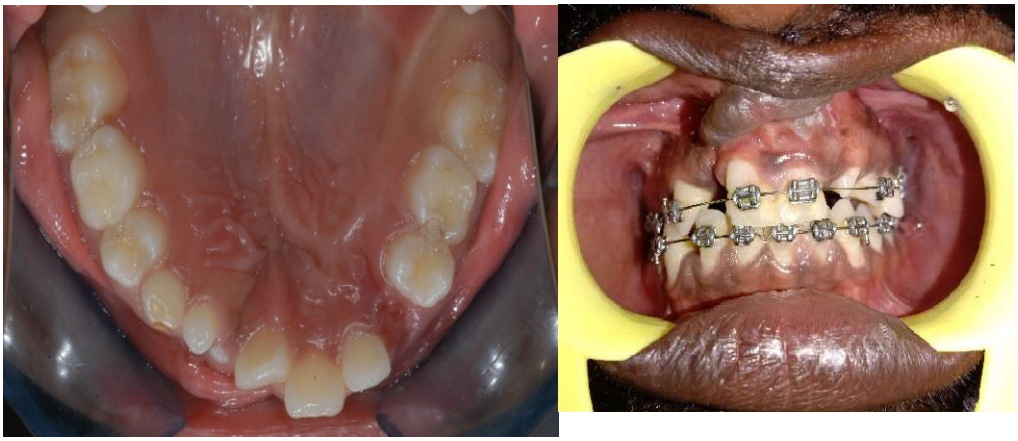


FIG 3.H: INTRA ORAL PHOTOGRAPHS OF THE PATIENT DURING ORTHODONTIC TREATMENT

Results

RESULT

This study was done in Ragas dental college and Hospital in the Department of Oral and Maxillofacial Surgery during the period of December 2017 to December 2019. We designed a study to assess the prevalence and severity of the oral health and quality of life of patients treated for cleft lip and palate. It was done using oral health related quality of life (OHRQol) scale and profile evaluation questionnaireand clinical examination in cleft patients. The study was conducted on 60 cleft participants, 60 caregiver of cleft participants and 60 control participants. All the study participants satisfied the inclusion criteria.

ABOUT THE FIRST QUESTIONNAIRE – CHILD ORAL HEALTH IMPACT PROFILE (COHIP)

The COHIP instrument is used to evaluate the overall health related quality of life and it issubdivided into five domains. The following are the domains

1. **Oral Health** - Measures specific oral symptoms that are not necessarily related to one another(eg - spots on teeth ,pain)
2. **Functional well being** - Relates the patient's ability to carry out specific everyday tasks or activities (eg. eating ,Speaking clearly,)
3. **Social- Emotional Well being** - Pertains to peer interactions and mood states

4. **School/ work environment** - Pertains with task associated with school environment
5. **Self image** - Addresses positive feeling about self.

Cleft group:

Male to female ratio in cleft participants were 32:28 and there is no significant gender difference within cleft group. Among 60 participants, 14(23.3%) were in 8-11 years age group, 20(33.3%) participants were in 12-18 years age group; 26(43.3%) participants were in19-26 years**(Table:4, Graph:4).**

Out of 60cleft participants, Unilateral cleft lip and palate participants were 21(35%), bilateral cleft lip and palate patients were 20 (33.3%) and 11 participants (18.3%) were cleft lip patients, 8 participants (13.3%) were cleft palate patients.**(Table:3, Graph:3).**

There is no significant difference between the male and female cleft group in the overall COHIP score and in all the sub domains. There is no significant statistical difference between the different age group in the overall COHIP score among the cleft patients. **(Table:7, Graph:7)**However, the age group between 11 – 18 years showed lowest mean in the "overall – COHIP" score except in self image domain but there is no statistical significant difference between different age groups**(Table:8, Graph:8).**

When COHIP score was compared between different types of cleft patients (Unilateral or bilateral cleft lip and palate or isolated cleft palate), statistically significant difference was found. The Functional well-being, the socio-emotional wellbeing and total COHIP score was highest for Cleft lip (alveolus) group and lowest for the bilateral cleft lip and palate. This shows that the oral related health quality of cleft lip(alveolus) are better than the rest of the types of cleft lip and palate and the bilateral cleft lip and palate has the least oral health related quality of life among the different types of cleft. **(Table:9, Graph:9)**

According to Cleft evaluation profile (CEP) questionnaire, the cleft lip and palate patients are least satisfied withprofile of face,appearance of noseand appearance of lip. And these patients are more contented with the hearing. **(Table:12, Graph:12)**

Control group:

The male to female ratio in control group was 35: 25. Distributions of control study subjects among age group : 22(36.6%) participants were in 8-11 years; 12(20%) control participants were in 12-18 years age group; 26(43.3%) participants were in19-26 years**(Table:5, Graph:5)**

Control group versus cleft group:

CHILD ORAL HEALTH IMPACT PROFILE (COHIP) score was found to be lower for the cleft patients when compared to the control group in all the domains namely Oral health, Functional well being, and social and emotional well being, School / work environment and self image. The study shows that overall quality of life of cleft patients is lower in comparison to the control group and the difference is statistically significant. **(Table:6,Graph:6)**

CAREGIVER GROUP versus Cleft group:

Care givers response shows that they feel the "overall quality of life" of their kin is better and their COHIP score was higher when compared to the cleft patients. Even the subdomains categorically Oral health, Functional well being, social and emotional well being, School / work environment and self image are better and their scores are higher in caregivers group than the cleft group except in the school or work environment.The caregivers responses of the unilateral cleft lip (alveolus) has a better oral health related quality of life than the other types of clefts. A significant difference is seen in the 'Functional well-being, the socio-emotional wellbeing and total COHIP score where the p value was .031, .050,.014. **(Table:10, Graph:10)**

There is no significant responses between the cleft patients and the caregivers towards treatment and satisfaction with various aspects of form and function of face. Boththe cleft lip and palate patients and their caregivers are

least satisfied withprofile of face,appearance of noseand appearance of lip. And these patients and their caregivers are more contented with the hearing. **(Table:12, Graph:12).**

Tables and Graphs

TABLE 1: GENDER DISTRIBUTION IN CLEFT PARTICIPANTS

GENDER	NUMBER OF PARTICIPANTS	PERCENTAGE
MALE	32	53.3%
FEMALE	28	46.6%

TABLE 2: GENDER DISTRIBUTION IN CONTROL PARTICIPANTS

GENDER	NUMBER OF PARTICIPANTS	PERCENTAGE
MALE	35	58.3%
FEMALE	25	41.6%

TABLE 3: TYPE OF CLEFT DISTRIBUTION IN CLEFT PARTICIPANTS

TYPE OF CLEFT	NUMBER OF PARTICIPANTS	PERCENTAGE
UNILATERAL CLEFT LIP AND PALATE	21	35%
BILATERAL CLEFT LIP AND PALATE	20	33.3%
CLEFT LIP	11	18.3%
CLEFT PALATE	8	13.3%

TABLE 4: AGE DISTRIBUTION IN CLEFT PARTICIPANTS

AGE GROUP	NUMBER OF PARTICIPANTS	PERCENTAGE
8-11 YEARS	14	23.3%
12-18 YEARS	20	33.3%
19-25 YEARS	26	43.3%

TABLE 5: AGE DISTRIBUTION IN CONTROL PARTICIPANTS

AGE GROUP	NUMBER OF PARTICIPANTS	PERCENTAGE
8-11 YEARS	22	36.6%
12-18 YEARS	12	20%
19-25 YEARS	26	43.3%

TABLE 6: COMPARISON OF OVERALL AND SUBSCALE SCORES FOR CLEFT PARTICIPANTS AND CONTROL PARTICIPANTS

	CONTROL (n=60)			CLEFT (n=60)				
	AVERAGE	MEAN	STANDARD DEVIATION	AVERAGE	MEAN	STANDARD DEVIATION	T VALUE	P VALUE
TOTAL COHIP	6057	100.95	6.33	5123	85.38	19.42	-5.902	.000
ORAL HEALTH	1837	30.62	2.26	1469	24.48	4.94	-8.735	.000
FUNCTIONAL WELL BEING	1322	22.03	2.39	1034	17.23	5.69	-6.020	.000
SOCIO-EMOTIONAL WELLBEING	1764	29.40	4.74	1238	20.63	8.89	-6.737	.000
SCHOOL /WORK ENVIRONMENT	914	15.23	0.98	688	11.46	3.72	-7.573	.000
SELF IMAGE	220	3.67	2.54	694	11.56	2.90	15.826	.000

P VALUE significance seen at .001

TABLE 7: COMPARISON OF OVERALL AND SUBSCALE SCORES FOR CLEFT MALE PARTICIPANTS AND CLEFT FEMALE PARTICIPANTS

	MALE (n=32)			FEMALE(n=28)				
	AVERAGE	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**T VALUE**	**P VALUE**
TOTAL COHIP	2691	84.09	19.74	2432	86.85	19.29	.611	.543
ORAL HEALTH	785	24.53	4.79	684	24.42	5.20	1.065	.291
FUNCTIONAL WELL BEING	542	16.93	5.76	492	17.57	5.69	-.008	.994
SOCIO-EMOTIONAL WELLBEING	644	20.12	9.39	594	21.21	8.41	.287	.775
SCHOOL /WORK ENVIRONMENT	349	10.9	3.64	339	11.75	3.77	1.031	.307
SELF IMAGE	371	11.59	3.18	323	11.53	2.61	.104	.917

TABLE 8: COMPARISON OF OVERALL AND SUBSCALE SCORES AONGDIFFERENT CLEFT AGE GROUP PARTICIPANTS

	Age 8-11 years (n=14)			Age 12-18 yrs (n=20)			Age 19-25 yrs (n=26)				
	AVERAGE	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**F VALUE**	**P VALUE**
TOTAL COHIP	1379	98.5	5.01	1189	59.45	5.20	2555	98.26	7.04	.132	.877
ORAL HEALTH	348	24.85	4.01	464	23.2	4.36	657	25.26	5.73	.138	.871
FUNCTIONAL WELL BEING	289	20.64	1.82	189	9.45	1.23	556	21.38	0.85	.121	.886
SOCIO-EMOTIONAL WELLBEING	374	26.71	1.63	169	8.45	2.03	695	26.73	1.97	.035	.965
SCHOOL /WORK ENVIRONMENT	196	14	1.56	132	6.6	1.14	360	13.84	1.43	.274	.761
SELF IMAGE	172	12.28	3.12	235	11.75	2.89	287	11.06	2.80	1.310	.278

TABLE 9: COMPARISON OF OVERALL AND SUBSCALE SCORES AMONGDIFFERENT TYPE OF CLEFT GROUP PARTICIPANTS

	UCLP (n=21)			BCLP (n=20)			CL (n=11)			CP (n=8)				
	AVERAGE	MEAN	STANDARD DEVIATION	AVERAGE	MEAN	STANDARD DEVIATION	AVERAGE	MEAN	STANDARD DEVIATION	AVERAGE	MEAN	STANDARD DEVIATION	F VALUE	P VALUE
TOTAL COHIP	1754	83.52	20.29	1549	77.45	17.70	1081	98.27	15.29	739	92.37	17.00	3.542	.020
ORAL HEALTH	512	24.38	4.87	480	24	3.85	295	28.81	6.86	182	22.75	4.23	1.225	.309
FUNCTIONAL WELL BEING	356	16.95	5.66	296	14.8	6.20	225	20.45	3.64	157	19.62	4.27	3.201	.030
SOCIO-EMOTIONAL WELLBEING	403	19.19	8.76	356	17.8	10.04	276	25.09	5.62	203	25.37	6.45	2.770	.050
SCHOOL/WORK ENVIRONMENT	241	11.4	4.19	202	10.1	3.66	146	13.27	2.83	99	12.37	2.72	2.016	.122
SELF IMAGE	242	11.52	2.71	215	10.75	3.20	139	12.63	1.74	98	12.25	3.69	1.182	.325

TABLE 10:COMPARISON OF OVERALL AND SUBSCALE SCORES

FOR CLEFT PARTICIPANTS AND CAREGIVER PARTICIPANTS

	CLEFT (n=60)			CAREGIVER (n=60)				
	AVERAGE	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**T VALUE**	**P VALUE**
TOTAL COHIP	5123	85.38	19.42	5806	96.76	13.70	-3.709	.000
ORAL HEALTH	1469	24.48	4.94	1737	28.95	4.04	-5.414	.000
FUNCTIONAL WELL BEING	1034	17.23	5.69	1144	19.07	3.69	-2.092	.039
SOCIO-EMOTIONAL WELLBEING	1238	20.63	8.89	1416	23.6	6.38	-2.099	.038
SCHOOL /WORK ENVIRONMENT	688	11.46	3.72	717	11.95	3.10	-.772	.442
SELF IMAGE	694	11.56	2.90	792	13.2	2.77	-3.149	.002

TABLE 11: COMPARISON OF OVERALL AND SUBSCALE SCORES AMONG DIFFERENT TYPE OF CLEFTACCORDING TO CAREGIVER PARTICIPANTS

	UCLP (n=21)			BCLP (n=20)			CL (n=11)			CP (n=8)				
	AVERAGE	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**AVERAGE**	**MEAN**	**STANDARD DEVIATION**	**F VALUE**	**P VALUE**
TOTAL COHIP	1986	94.57	14.89	1832	91.6	11.47	1171	106.45	10.68	817	102.12	12.52	3.858	.014
ORAL HEALTH	596	28.38	3.43	575	28.75	3.53	339	30.81	4.55	227	28.37	4.50	.989	.405
FUNCTIONAL WELL BEING	393	18.71	3.77	352	17.60	3.96	233	21.18	2.52	166	20.75	2.43	3.187	.031
SOCIO-EMOTIONAL WELLBEING	464	22.09	6.38	440	22.6	7.09	297	27	3.84	215	26.87	4.99	2.778	.050
SCHOOL /WORK ENVIRONMENT	249	11.85	3.69	216	10.6	2.98	150	13.63	1.91	102	12.75	1.98	2.326	.085
SELF IMAGE	284	13.54	2.48	249	12.45	3.17	152	13.81	1.94	107	13.75	3.46	.767	.517

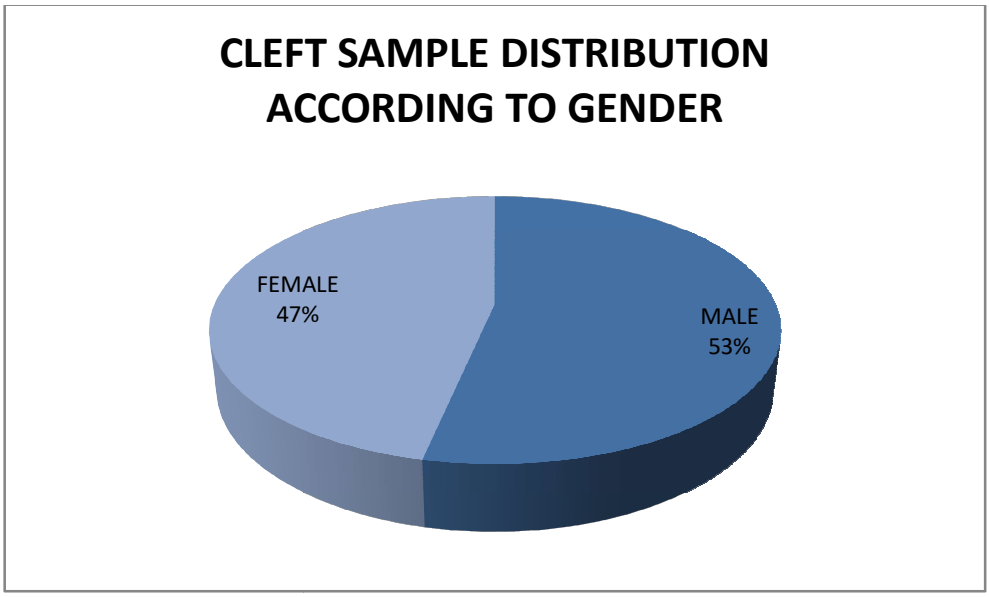
TABLE 12: CLEFT EVALUATION PROFILE FOR CLEFT PARTICIPANTS

	AVERAGE	MEAN	STANDARD DEVIATION
SPEECH	129	2.19	1.48
HEARING	236	3.93	0.36
APPEARANCE OF TEETH	127	2.11	1.26
APPEARANCE OF NOSE	95	1.58	1.18
BREATHING THROUGH NOSE	133	2.21	1.60
APPEARANCE OF LIP	92	1.53	1.26
PROFILE OF FACE	114	1.9	1.37

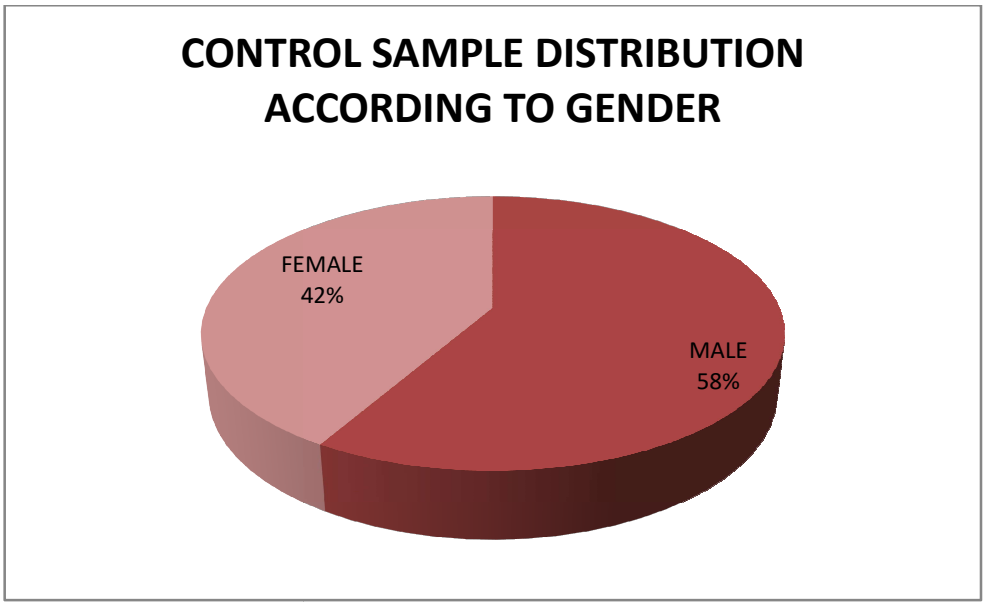
TABLE 13: COMPARISON OF CLEFT EVALUATION PROFILE FOR CLEFT PARTICIPANTS AND CAREGIVER PARTICIPANTS

	CLEFT (n=60)			CAREGIVER (n=60)				
	AVERAGE	MEAN	STANDARD DEVIATION	AVERAGE	MEAN	STANDARD DEVIATION	T VALUE	P VALUE
SPEECH	129	2.19	1.48	145	2.41	1.38	-1.019	.310
HEARING	236	3.93	0.36	239	3.98	0.12	-1.008	.316
APPEARANCE OF TEETH	127	2.11	1.26	147	2.45	1.32	-1.413	.160
APPEARANCE OF NOSE	95	1.58	1.18	113	1.88	1.26	-1.343	.182
BREATHING THROUGH NOSE	133	2.21	1.60	152	2.53	1.46	-1.128	.262
APPEARANCE OF LIP	92	1.53	1.26	101	1.68	1.17	-.673	.502
PROFILE OF FACE	114	1.9	1.37	152	2.05	1.39	-.593	.554

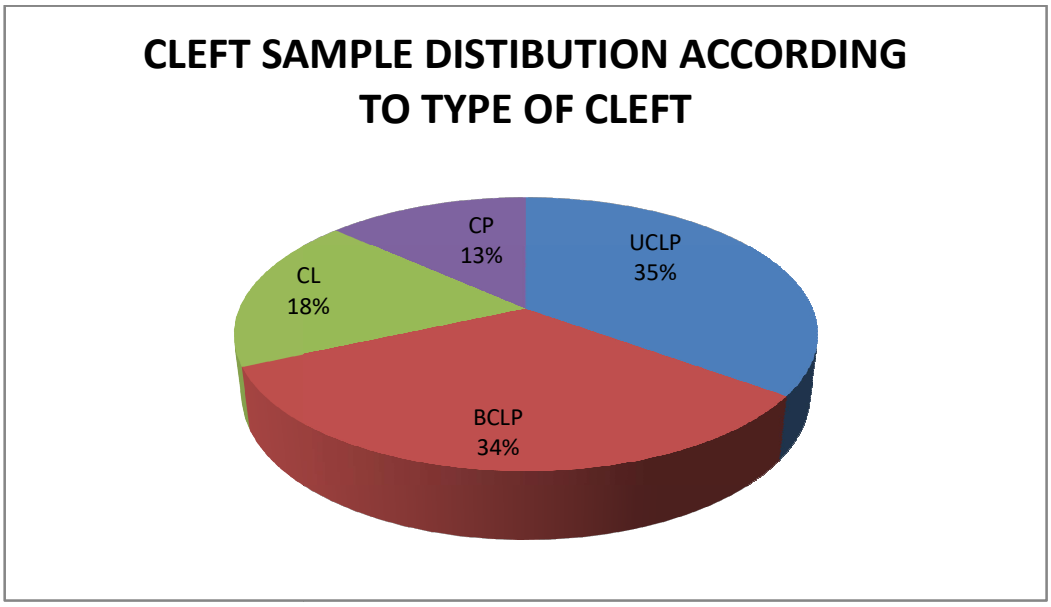
GRAPH 1: GENDER DISTRIBUTION IN CLEFT PARTICIPANTS



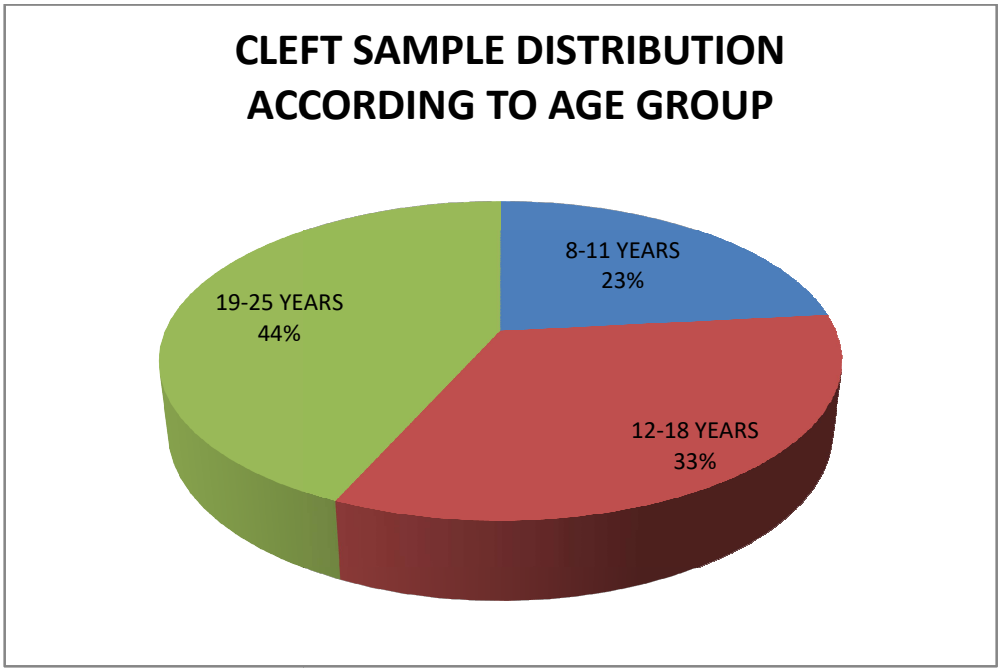
GRAPH 2: GENDER DISTRIBUTION IN CONTROL PARTICIPANTS



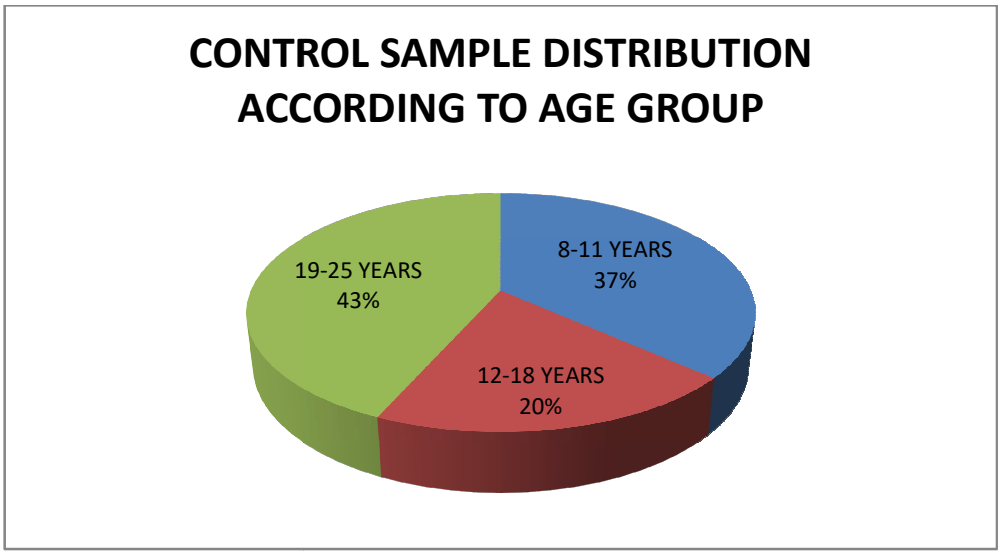
GRAPH 3: TYPE OF CLEFT DISTRIBUTION IN CLEFT PARTICIPANTS



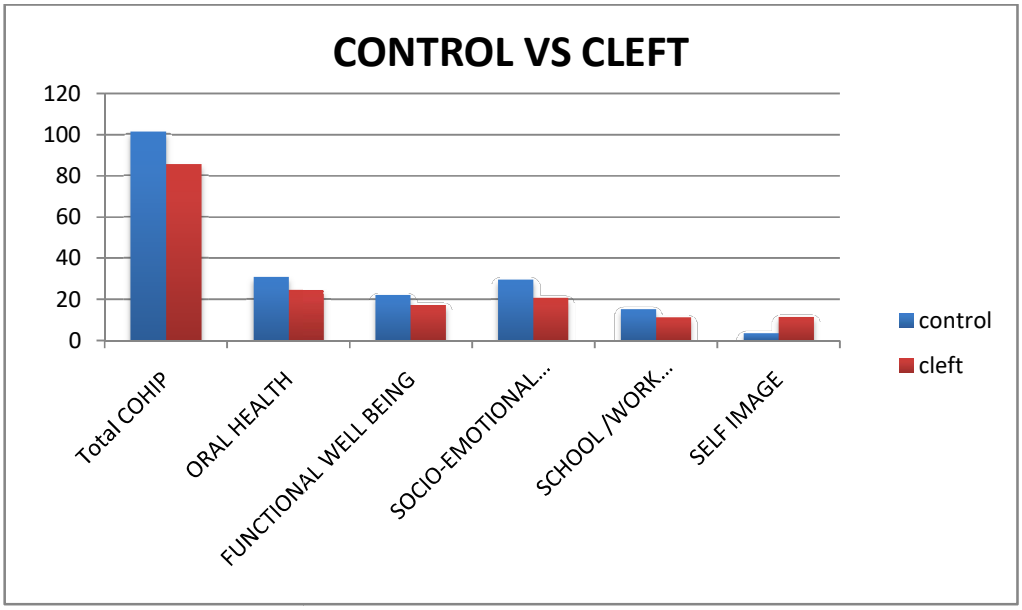
GRAPH 4: AGE DISTRIBUTION IN CLEFT PARTICIPANTS



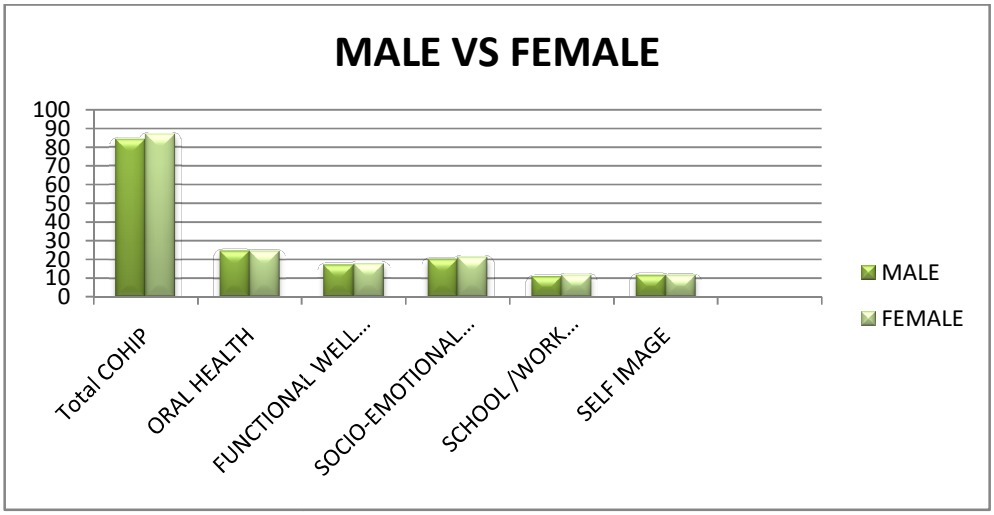
GRAPH 5: AGE DISTRIBUTION IN CONTROL PARTICIPANTS



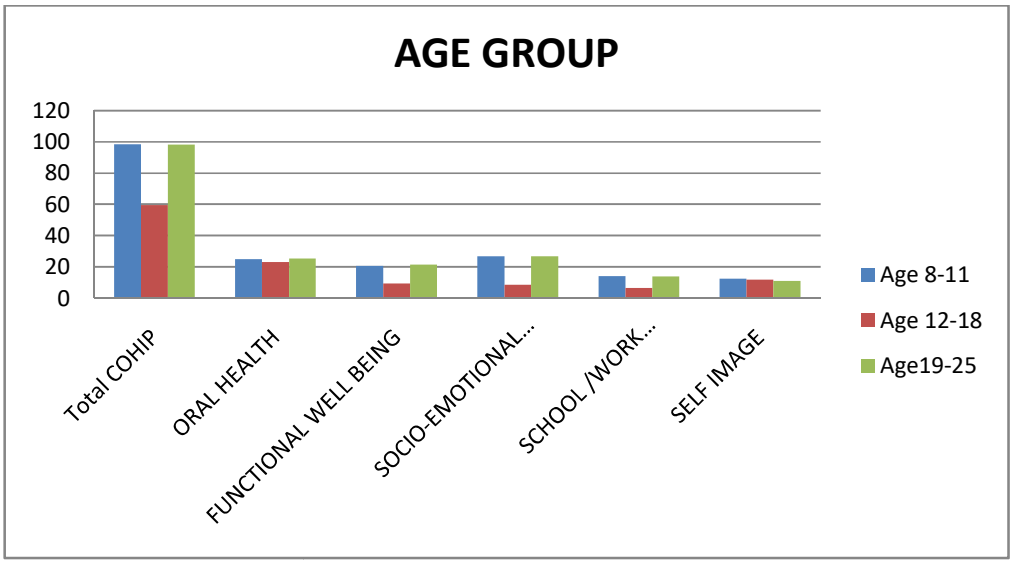
GRAPH6: COMPARISON OF OVERALL AND SUBSCALE SCORES FOR CLEFT PARTICIPANTS AND CONTROL PARTICIPANTS



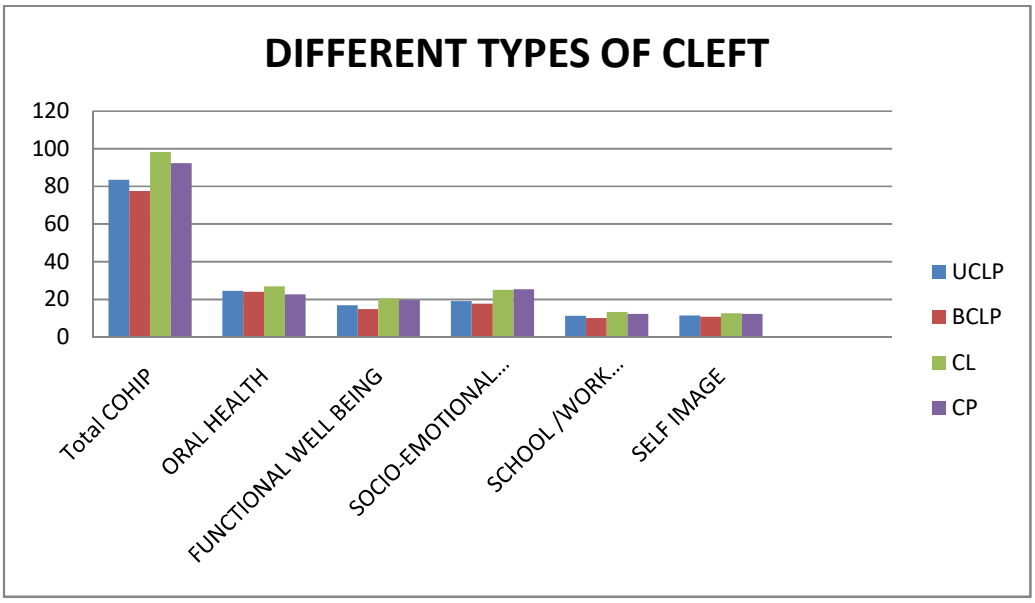
GRAPH 7: COMPARISON OF OVERALL AND SUBSCALE SCORES FOR CLEFT MALE PARTICIPANTS AND CLEFT FEMALE PARTICIPANTS



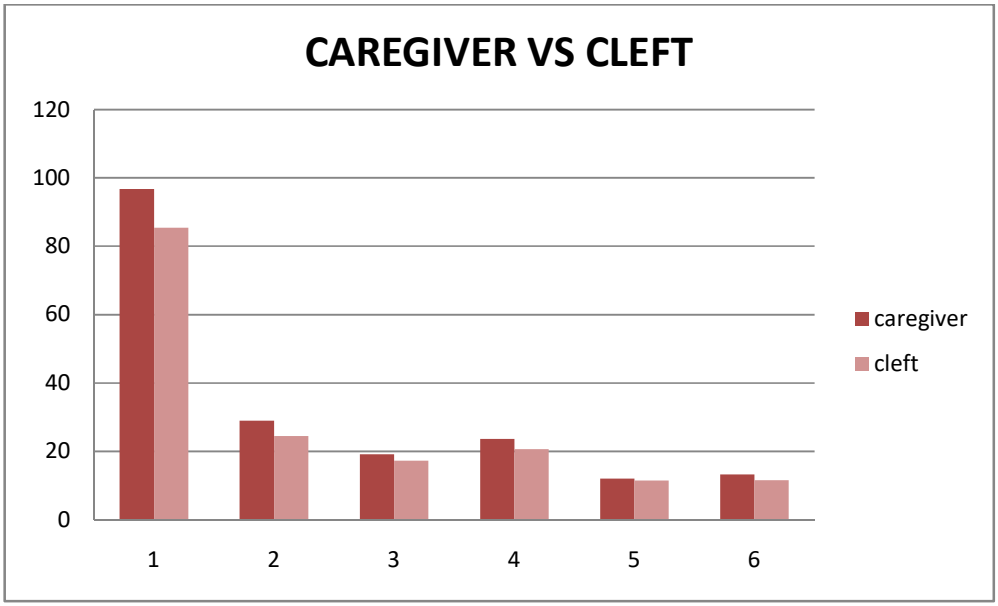
GRAPH 8: COMPARISON OF OVERALL AND SUBSCALE SCORES AMONGDIFFERENT CLEFT AGE GROUP PARTICIPANTS



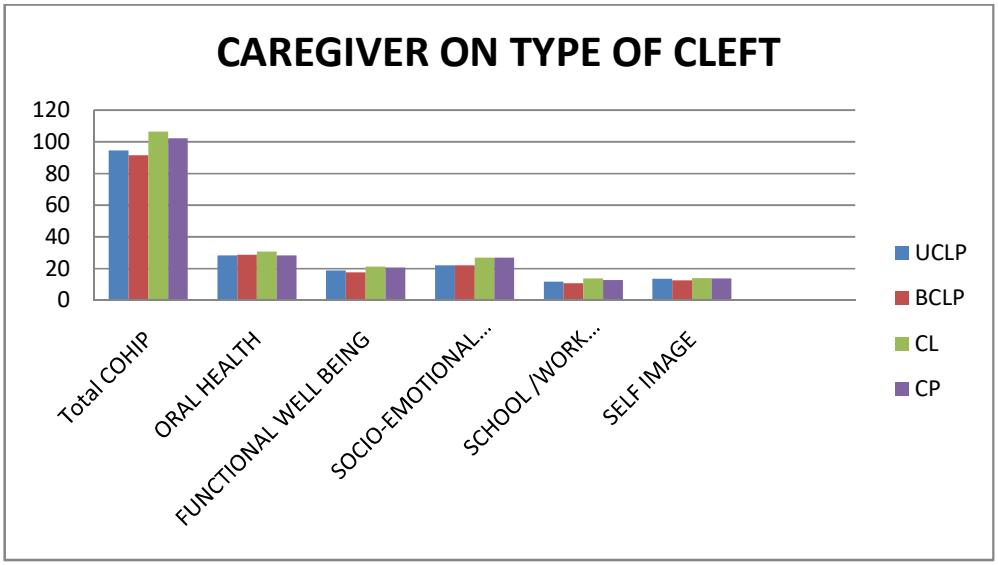
GRAPH 9: COMPARISON OF OVERALL AND SUBSCALE SCORES AMONGDIFFERENT TYPE OF CLEFTGROUP PARTICIPANTS



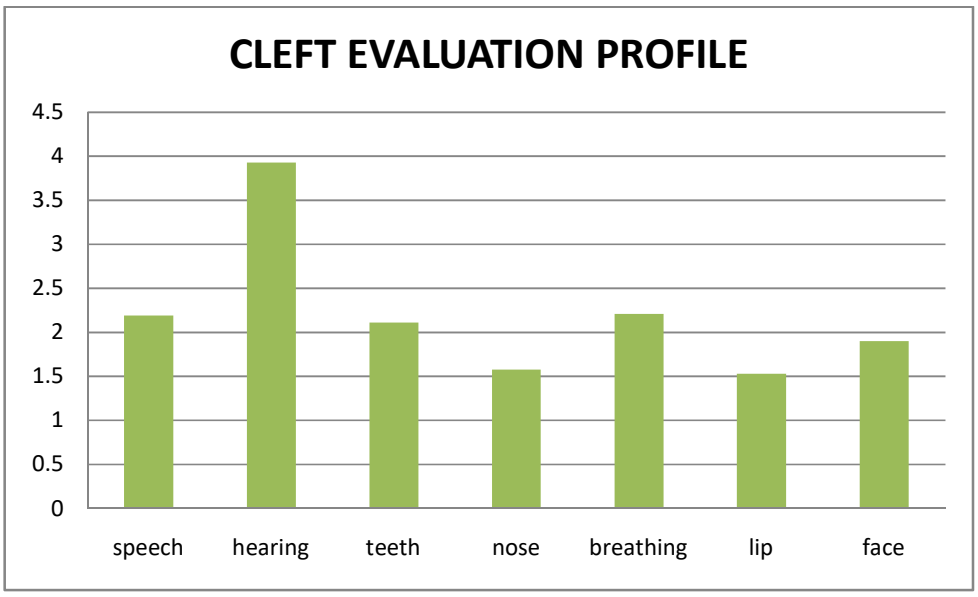
GRAPH 10 : COMPARISON OF OVERALL AND SUBSCALE SCORES FOR CLEFT PARTICIPANTS AND CONTROL PARTICIPANTS



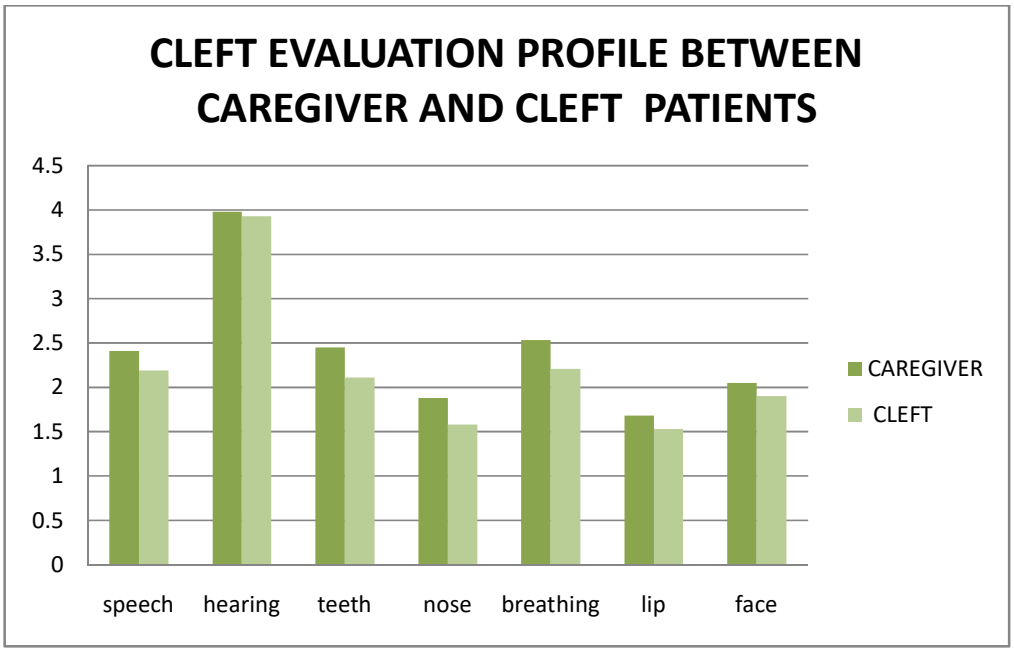
GRAPH 11: COMPARISON OF OVERALL AND SUBSCALE SCORES AMONGDIFFERENT TYPE OF CLEFT BY THE CAREGIVER GROUP



GRAPH 12: CLEFT PARTICIPANTS RESPONSE ON VARIOUS ASPECTS OF FACE



GRAPH 12: COMPARISION BETWEEN CLEFT PARTICIPANTS RESPONSE AND CAREGIVER GROUP RESPONSE ON VARIOUS ASPECTS OF FACE



Discussion

DISCUSSION

Children with cleft lip and palate (CLP) may suffer from impaired functions and facial appearance, and multiple treatments are often required to reconstruct and/or improve the situation. Although psychopathology has not been shown to be an associated feature, for children with CLP, studies[7,48] have reported the prevalence of anxiety, depression, inhibition, low self-esteem, reduced cognitive function and achievement in school, and parental stress.

The impact of CLP on quality of life (QoL) is considerable for affected children. Unfortunately, at the beginning of the millennium there was still an urgent need for QoL measures for patients with craniofacial anomalies such as CLP.[5,49] Several research groups have published[8,50] on the development of QoL instruments, but up until now only one has developed an ‘‘internationally’’ validated instrument for children. As part of a large international research project to measure oral health–related QoL (OHRQoL) in children, the Child Oral Health Impact Questionnaire (COHIP) was designed and developed. Two versions of the COHIP were developed, one for children and one for parents. The COHIP was tested and validated using reports on QoL from normal children and children recruited from paediatric, orthodontic, and craniofacial centers. In addition, concordances between caregiver and child reports were investigated.

Broder and Wilson-Genderson (2007)[48] adapted and validated the Child Oral Health Impact Profile (COHIP) in English to measure quality of life in terms of oral health, functional well-being, social-emotional well-being, school environment, and self-image. This scale presented an excellent test-retest reliability and a high internal consistency, contributing a highly valuable instrument for the assessment of the oral health–related quality of life in cleft lip and palate children (Broder et al., 2014)[49]. The use of the Child Oral Health Impact Profile (COHIP) in children with cleft lip and palate could show the impact of this condition and sequelae after treatment such as speech and esthetic problems, nervousness while speaking at school or in public (Chetpakdeechitetal. ,2009)[50] or shows obvious self-image problems (Berk et al., 2001)[7]; hence, the use of the Child Oral Health Impact Profile (COHIP) at the local and regional level could reveal similar relevant issues to as certain the oral health of cleft population.

The first hypothesis is that the children with cleft do not differ in oral health related quality of life compared with healthy subjects – was rejected. The oral health–related quality of life of children with CLP was poorer than that of their peers in overall and all domains. This result is similar to Terhi Kortelainen, et al (2015)[26] where the oral health–related quality of life of Finnish children with CLP was considerably lower than that of their peers in overall and all dimensions, especially social well-being using Finnish Child Perception Questionnaire.

Pedro C. Aravena, et al (2015)[1] showed the influence of the condition of CL/P was observed in relation to a lower quality-of-life score in some aspects such as functional well-being and school environment compared to the Spanish population where the authors used the Spanish version of COHIP**.** Pasquale Piombino, et al, (2014)[20] did a comparison between scores obtained in the cleft and the control group indicated that Italian patients with CLP have more problems with self-esteem and social skills where the authors used the Quality of Life Adolescent Cleft (QoLAdoCleft) Questionnaire**.** Rosany Larissa et al , (2015)[25] showed that no significant difference was observed in the overall HRQoL score among the 2 groups (cleft: 72.2; control: 72.5) using Mini-Mental State Examination, and the Medical Outcomes Study 36 item Short-Form Health Survey (SF-36) among the Brazilian population.

The second hypothesis could not be rejected, as there is no significant gender differences on the COHIP was found. Our result was similar to the Dutch population where there was no difference on the oral health quality of life found based on male and female cleft patients. The tool that Annemieke Bosa et al (2011)[15] used on the Dutch population is similar to ours which is COHIP to evaluate the Oral health related quality of life of cleft patients. Andreas Naros, et al (2018)[44] found that there is no significant main effect appeared for the tested parameters of health related quality of life on cleft gender. Neda Eslami et al, (2013)[16] used Child Oral Health Impact Profile questionnaire found that Quality of life of girls was more affected by oral

health. A significant difference between boys and girls was found on the subscale ‘‘emotional well-being’’ (P =0.027). Rosany Larissa et al (2015)[25] found that Men had higher averages on the Physical Function (PF) and Mental Health (MH) domains. Women with CLP are less satisfied with their facial appearance and the aesthetic results of surgical repair, have psychologic deficits, particularly in relation to self-concept, and have lower HRQoL using Mini-Mental State Examination, and the Medical Outcomes Study 36 item Short-Form Health Survey (SF-36).According to Shabnam Ajami, et al (2017)[41],a significant difference was seen between boys and girls was found on the subscale ‘‘emotional well-being’’ (P¼0.001)using the DS14 and COHIP questionnaires. The risks for type-D personality and negative affectivity were almost twice in girls among CLP patients.

The third hypothesis that there is no difference between different age group in terms of OHRQoL was not rejected. There is no statically significance between the three age group although the overall mean in different domains is less in the middle age group (11to 18years) compared to the other two age group. Neda Eslami et al(2013)[16] found that the oral health related quality of life of cleft lip and palate patients did not change with patients’ age. . There was no significant difference between 8- to 12-year-old patients and those older than 12 years. Andreas Naros, et al (2018)[44] found that there is no significant main effect of age appeared for the tested parameters of health related quality of life on cleft patients. Shabnam Ajami,

et al (2017)[41] said that there was no significant difference between 2 groups of patients within the range of 8 to 11 years and those older than 11 years. However, a positive significant correlation between ‘‘oral symptoms’’ and age (P¼0.029) was found. Annemieke Bosa et al (2011)[15]found that cleft patients aged 12 years and older scored significantly lower on the ‘Emotional well-being’ and ‘Oral symptoms’ subscales.

The fourth hypothesis was rejected, as there was a significant difference between the different cleft types. The ‘Functional well-being’, the socio-emotional wellbeing and total COHIP score was found to be significantly different between different types of cleft, for which p value is 0.030, 0.050 and 0.020 respectively. The Cleft lip (alveolus) group had the highest scores and the bilateral cleft lip and palate showed the least score. It should be kept in mind that different cleft types require different treatment protocols. Annemieke Bosa et al(2011)[15] found a significant difference between the different cleft types and the ‘Functional well-being’ subscale, for which the Cleft lip (alveolus) group had the highest scores, which is almost similar to the finding in our study. Neda Eslami, et al, (2013)[16] who used Child Oral Health Impact Profile questionnaire revealed that the impact of unilateral and bilateral clefts on Oral health related quality of life was similar. The DS14 and COHIP questionnaires were used by Shabnam Ajami, et al (2017)[41] showed that bilateral and unilateral Cleft lip and palate patients had no significant difference regarding the mean scores of COHIP and its

subscales. Andreas Naroset al(2018)[44] also found that there is no significant main effect appeared for the tested parameters of oral health related quality of life on type of cleft.

The fifth hypothesis that there were no differences in COHIP scores between patients and caregiver was rejected. All domains except school /work environment were found to be significant. This shows that the response of cleft patient and parents are not interchangeable. It is always preferred to get the responses directly from cleft patients themselves rather than their caregivers. Our result is similar to the study of Annemieke Bosa et al(2011)[15] used COHIP showed that children scored significantly higher than their caregivers. Rosany Larissa et al (2015)[25] revealed no significant difference was observed in the overall HRQoL score and it various domains among the 2 groups (cleft: 72.2; family: 70.6;) using Mini-Mental State Examination, and the Medical Outcomes Study 36 item Short-Form Health Survey (SF-36).

The sixth hypothesis that Caregivers' perceptions of their child's oral health related quality of life has no difference between different type of cleft patients- was also rejected. Like the cleft patients, the caregivers responses revealed that the cleft lip (alveolus) has a better oral health related quality of life than the other types of clefts. A significant difference is seen in the 'Functional well-being, the socio-emotional wellbeing and total COHIP score where the p value was .031, .050,.014.

The next part of the study is done using the Cleft Evaluation Profile questionnaire to assess the cleft patient and caregivers satisfaction of various aspects of face. The CEP originated from the Royal College of Surgeons Cleft Lip and Palate Audit Group (Turner et al., 1997)[9] and was used to assess perceived satisfaction for individual features related to cleft care. It consists of an seven-item list: speech, hearing, lip, nose, teeth, breathing, and profile. For each item in the CEP, subjects were asked to rate their satisfaction on a 5-point Likert scale ranging from very satisfactory (a rank of 0) to very unsatisfactory (a rank of 4).

All items in the CEP are related to facial features that play a major role in assessing facial appearance among cleft lip and palate patients and can be used to determine the perceived satisfaction of the patients and their parents with the clinical outcome of cleft treatment. The CEP can be employed to determine any significant differences in the parent and child ratings of the features that were related to facial appearance, namely teeth, lips, nose, and facial profile. These are the features patients and parents felt needed attention and were examined for differences of responses between patients and their parents.

In our study, for the parents, the lowest mean score achieved was for the lip, followed by the nose, teeth, and profile of face. For the patients, the lowest mean score achieved was for the teeth, followed by the lips, speech, and nose. There is no significant difference between the cleft group and the

caregiver group. Lowest score show least satisfaction by patient and caregivers. This does not rejects the last hypothesis of our study It was hypothesized that Caregivers' perceptions of their child's satisfaction between various aspects of face do not differ from those of their children with repaired orofacial clefts.

Dental anomalies can be the target for abuse as the teeth and lip obviously contribute to facial appearance (Shaw et al., 1980). It is important for children with dental anomalies to e treated with a multidisciplinary way and referred to the designated consultants for future treatments. Speech and hearing difficulties occur commonly in cleft lip and/or palate deformities which present a barrier to satisfactory communication. Di Biase and Markus (1998) reported that in cleft lip and palate patients, speech was found to be unintelligible to strangers in 19% of 5-year-olds and 4% of 12-year-olds. Speech in CL/P patients evoked comment in 32% of the 5-year-olds and 15% of the 12-year-olds as they were quite different and were teased about by their peers. Hypernasality (excessive nasal tone) was present in 27% of the 5-year-olds and 31% of the 12-year-olds. Children with cleft palate mentioned that their defect was unnoticeable until they spoke; as people heard the ‘‘broken’’ speech, they tended to withdraw from them. This study supported the findings of Millard and Richman (2001), in which children with cleft palate have more speech problems than do children with other types of cleft. There was also some hearing loss in 21% of the 5-year-olds and 16% of the 12-year-olds. The

children with cleft palate only may show greater problems with depressive symptoms and anxiety and more learning problems than children with cleft lip and palate. This may be explained partially by the relationships identified between self-report of symptoms and speech difficulties that can create problems in both adjustment and learning. It appears that these risk factors (self-reported symptoms like self-perception, anxiety, and depression)are exacerbated by speech difficulties. Children with cleft palate who have significant speech difficulties and learning problems for which they should should receive careful monitoring and aggressive treatment, not just for cleft-related conditions, but also for possible learning and adjustment problems. Based on these findings, children with cleft palate have significantly lower self-esteem, some self-perceived depressive symptoms and anxiety, more speech problems, and more learning problems compared with those with cleft of the lip, either unilateral or bilateral. Different cleft groups may demonstrate different risk factors (e.g., speech, face, adjustment, and learning). Counselling sessions and more closer clinical services are need for the increased reported dissatisfaction with speech and appearance points which will help patients address their problems and speak more.

There is agreement between the parent and child ratings for the four features related to facial appearance (teeth, lips, nose, and profile of the face)Siti Noor Fazliah Mohd Noor et al (2006)[12] This may be explained due to the culture of obedience and high degree of agreeing with their parents in

Asian children .Not only the children but 42% of parents are " very involved " in every decision of treatment planning, even few patients were accompanied by grandparents who had an untreated cleft . Having a cleft in our society is not something that the patients or their parents want for his or her well being, but their beliefs and religion dictate that they accept the cleft condition as a fate from God.

With this belief as a background, it effects the satisfaction with cleft treatment, because they can accept whatever the outcome of the surgical treatment and at the same time not want any treatment to the cleft-affected area. Grandparents or parents who did not want treatment, might influence the child's perception of the need of surgery and further treatment. Further, the education level of their parents also may have influenced the child's feeling of satisfaction with surgical treatment.

The level of education of the parents affects the knowledge in understanding the disease process along with the many treatment alternatives available for the cleft lip and palate children as it will also cause difference in their level of satisfaction . The results of this study differ from those of Turner et al. (1997)[9], who found that two features (teeth and lip) differed significantly between the parents and 15-year-old subjects. This was an important finding for cleft care teams as treatment planning may be based purely on the opinions of the parents if the child's involvement in the discussion is minimal which points to the need to carefully address a child's opinion of his or her clinical

outcome independently from the parents. In contrast to Turner et al. (1997)[9], there were no differences in the current study between the child and parent ratings for features related to facial appearances in all age groups. This may be due to a number of factors, including differences in cultural background (most of our sample still practice traditional values), exposure of the patients to the external environment (many patients still kept their traditional culture and beliefs), the area of residence (most patients were from rural areas far from the main city), and the level of education of subjects in the current sample is low.

Previous work with the CEP administered via individual interviews among children with cleft lip and palate who were 1, 5, 10, 15, and 20 years of age and their parents showed that two features (teeth and lip) showed statistically significant differences between the parents and 15-year-old subjects (Turner et al., 1997)[9]. Differences between parental and child ratings for four features related to facial appearance (teeth, lip, nose, and profile) were analysed.

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Summary and Conclusion

SUMMARY AND CONCLUSION

The study was conducted in the Department of Oral and Maxillofacial Surgery, Ragas dental college & hospital. Patients who were treated for cleft lip and palate from the age of 8 years to 25 years, their caregivers and the corresponding age group control participants were included in our study. All the 3 groups (cleft group, caregiver group, and control group) were interviewed with **Child Oral Health Impact Profile** questionnaire and **Cleft Evaluation Profile** questionnaire. From our study, we conclude that

- The participants with cleft had lower oral health related quality of life compared with healthy participants in all domains
- The oral health related quality of life was found to be similar between male and female cleft patients cleft patients
- Age did not have any impact on the oral health related quality of life of the cleft participants
- The oral health related quality of life was lowest in the bilateral cleft lip and palate participants and highest in the cleft lip (alveolus) participants

- The caregivers' perceptions of their child's oral health related quality of life was higher from those of their children with repaired orofacial clefts.

- The caregivers' perceptions of their child's oral health related quality of life has significant difference between different types of CLP especially in Functional well-being, the socio-emotional wellbeing and overall oral health quality of life

- The caregivers' perceptions of their child's satisfaction between various aspects of face did not differ from those of their children with repaired orofacial clefts

- The least satisfaction on various aspects of face was found to be lip, followed by the nose, teeth, and profile of face.

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Annexures

ANNEXURE - 1

RAGAS DENTAL COLLEGE & HOSPITAL
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TO WHOM SO EVER IT MAY CONCERN

Date: 31/12/2019
Place: Chennai

From
The Institutional Review Board
Ragas Dental College and Hospital
Uthandi, Chennai-119

The Project topic titled **" ORAL – HEALTH RELATED QUALITY OF LIFE AMONG CLEFT LIP AND PALATE PATIENTS – QUESTIONNAIRE"** submitted by **Dr. ALKA MARIAM MATHEW** has been approved by the Institutional Review Board of Ragas Dental College and Hospital.

Dr. N.S. Azhagarasan,MDS

Member Secretary,
The Institutional Review Board
Ragas Dental College and Hospital
Uthandi , Chennai-119

ANNEXURE - 2

URKUND

Urkund Analysis Result

Analysed Document:	Oral health quality of life.docx (D61997256)
Submitted:	1/8/2020 8:39:00 AM
Submitted By:	alkamathew08@gmail.com
Significance:	6 %

Sources included in the report:

NANDINI.pdf (D40344610)
PLAGIARISM DOC -URKUND new.pdf (D49746752)
https://www.researchgate.net/publication/6351981_Assessment_of_Patients'_Level_of_Satisfaction_With_Cleft_Treatment_Using_the_Cleft_Evaluation_Profile

Instances where selected sources appear:

10