Oral health related quality of life in cleft lip and palate patients rehabilitated with conventional prostheses or dental implants

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Abstract

Objectives: Cleft lip and/or palate (CLP) is the most common congenital craniofacial abnormality, with a prevalence of 9.92 per 10,000 live births. In treating patients with CLP, oral rehabilitation is definitely a very important phase of the treatment in order to improve the patient's oral health related quality of life (OH-QoL). The aim of this retrospective study is to assess the OH-QoL in patients rehabilitated with different prosthetic options, thus comparing the conventional treatments, which include removable partial dentures and fixed partial dentures, with the implant-supported prostheses. **Materials and Methods:** Sixty-three patients were enrolled in this retrospective survey [44 females (69.84%) and 19 males (30.16%)] with a mean age of 34.93 ± 7.04 years (age range 21–53 years). They were all treated for CLP and rehabilitated with a conventional prosthesis or an implant-supported denture. Two different questionnaires were used in the present study to evaluate patients' OH-QoL: The Italian version of the 49-item Oral Health Impact Profile (OHIP-49) and the Italian version of the Cleft Evaluation Profile (CEP). Statistical analysis was performed using analysis of variance (ANOVA) test, with a significant $P < 0,05$. **Results:** Data analysis revealed that patients rehabilitated with implant-supported dentures and fixed partial dentures showed a good level of satisfaction with their prostheses, scoring low values in the OHIP-49 and high values in the CEP, while subjects with removable partial dentures scored the highest values in the OHIP-49 and the lowest values in the CEP, which means an unsatisfactory feeling ($P < 0.05$). **Conclusions:** OH-QoL is a challenging demand for all prosthodontists. Our results show, clearly, that patients rehabilitated with implant-supported dentures are more satisfied compared to subjects with fixed partial dentures and removable partial dentures.

Key words: *Cleft lip and palate, congenital malformation, dental implants, prosthetic rehabilitation, quality of life*

INTRODUCTION

Cleft lip and/or palate (CLP) is the most common congenital craniofacial abnormality, with a prevalence of 9.92 per 10,000 live births.[1,2]

Treatment of CLP requires a multidisciplinary approach: Maxillofacial surgeons, orthodontists, oral surgeons, prosthodontists, otorhinolaryngologists, speech-language pathologists, neurologists, and psychologists are all involved.[2,3]

Oral rehabilitation is an important phase of the treatment, it involves re-establishing esthetics, phonetics, and function, the primary goals of prosthetic rehabilitation, which are directly related to the dysfunctions and alterations determined by malformations.[2-4]

Prosthetic rehabilitation options include either conventional prostheses, such as removable partial dentures (RPDs) and fixed partial dentures (FPDs), or implant-supported prostheses.[4-6]

In recent years, the oral health related quality of life (OH-QoL) of CLP patients has been evaluated using different methods, which include semi-structured interviews and self-administered questionnaires.[7-10]

Patient's satisfaction following CLP treatment, has been investigated extensively, however only few studies focused on oral rehabilitation.[8,10]

The aim of this study is to assess OH-QoL in patients rehabilitated with different prosthetic options, thus comparing the conventional treatments, which include the RPDs and the FPDs, with implant-supported prostheses.

MATERIALS AND METHODS

This retrospective study was conducted at the Department of Oral and Maxillofacial Sciences of the "Sapienza" University of Rome, and approved by the institution review board (ref. no. 3552).

The study was open to all patients who met specific inclusion and exclusion criteria and provided signed informed consent according to the World Medical Association's Declaration of Helsinki.

Sixty-three patients were enrolled in this retrospective survey [44 females (69.84%) and 19 males (30.16%)] with a mean age of 34.93 ± 7.04 years (age range 21–53 years). They were all treated for CLP and rehabilitated with a conventional prosthesis or an implant-supported denture.

Fifty-three (84.12%) subjects were diagnosed with unilateral CLP, while 10 (15.88%) patients had a bilateral cleft lip.

Out of all the patients enrolled in this study, 38 received conventional prosthetic rehabilitation. Of these, 10 had RPDs and the remaining 28 patients received FPDs with dental bridges.

Dental implants were placed in 25 patients: Alveolar bone grafts in the cleft area were performed prior to the implant placement. These grafts were taken from donor sites, which were the iliac crest for 16 subjects and the mandibular ramus and symphysis for the remaining 9 people (7 and 2, respectively).

A total of 29 dental implants were inserted in 25 patients after a mean period of 5 months (range 4–6 months) from the bone graft procedure. Each subject received one implant in the upper lateral incisor area, except in two cases of bilateral cleft where two dental implants were placed for the patient, one in the left and one in the right upper lateral incisor area.

Implant-supported single crowns were realized in a mean time of 4 months after surgery.

After a mean follow-up of 24.25 ± 9.84 months (range 12–56 months), patients were invited to participate in this survey.

Two different questionnaires were used in the present study to evaluate patients' OH-QoL: The Italian version of the 49-item Oral Health Impact Profile (OHIP-49)[11] and the Italian version of the Cleft Evaluation Profile (CEP) proposed by the Royal College of Surgeons Cleft Lip and Palate Audit Group.[12]

Subjects completed the OHIP-49, which focuses on seven impact dimensions (functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with its standard ordinal format ('never', 'hardly ever', 'occasionally', 'often', 'very often') as a self-administered questionnaire.

The answers were recorded using the Likert scale (values from 0 to 4, with 0 representing the best outcome possible and 4 representing the worst).

The OHIP-49 was analyzed through the 'additive method' (OHIP-ADD) by summing the item values for the 49 questions (range 0–196). High OHIP scores indicated poor OH-QoL, while low OHIP scores showed satisfactory and adequate OH-QoL.

Patients completed the CEP also, which consists of an eight-item list (speech, hearing, lip, nose, teeth, bite, breathing, and profile) as a self-administered questionnaire.

For each item in the CEP, subjects were asked to rate their satisfaction on a 7-point Likert scale ranging from very satisfactory (a rank of 1) to very unsatisfactory (a rank of 7), and the mean scores for each answer were recorded.

Statistical analysis

Patients were divided into groups based on their rehabilitation: RPDs (Group 1), FPD (Group 2), and implant-supported dentures (Group 3).

Analysis of variance (ANOVA) test was performed. Primary null hypothesis were verified, finding a proper limit value for each subgroup of the two questionnaires, in order to determine satisfaction with prosthetic rehabilitation [Tables 1 and 2].

A $P < 0.05$ was considered significant. A specific statistical software (IBM SPSS V10 Statistics, IBM, Armonk, NY, USA) was used for data analysis.

RESULTS AND DISCUSSION

Descriptive analysis was used to summarize the data of the two questionnaires. For each macro area and for each subset, the mean and the median values were calculated and illustrated on graphs using charts [Tables 3 and 4, Figures 1 and 2].

In the OHIP-49 questionnaire, four subgroups were considered particularly to evaluate overall satisfaction with prosthetic rehabilitation: FL = Functional limitation, P1 = Physical pain, P2 = Psychological discomfort, and D1 = Physical disability.

In the CEP questionnaire, the scores of four questions were analyzed: Speech, appearance of teeth, appearance of lip, and bite.

Data analysis revealed that patients rehabilitated with implant-supported dentures and FPDs showed a good satisfaction with their prostheses, scoring low values in the OHIP-49 and high values in the CEP, while subjects with RPDs scored lower values in the OHIP-49 and

Table 1: OHIP-49 null hypothesis tested

Subgroup	Hypothesis
FL = Functional limitation	H0=9, H1<9
P1 = Physical disability	P0=9, P1<9
P2 = Psychological discomfort	F0=9, F1<9
D1 = Physical disability	R0=9, R1<9

Table 2: Cleft Evaluation Profile null hypothesis tested

Subgroup	Hypothesis
Speech	B0=3, B1<3
Appearance of the teeth	G0=3, G1<3
Appearance of the lip	M0=3, M1<3
Bite	S0=3, S1<3

Table 3: Descriptive analysis of OHIP-49

Measures	Removable partial dentures	Fixed partial dentures	Implant-supported dentures
FL			
Mean	17.5	7.357143	4.28
Standard error	0.670820	0.338118	0.280000
Median	18	7	4
Mode	18	7	6
Standard deviation	2.121320	1.789150	1.400000
Sample variance	4.500000	3.201058	1.960000
Kurtosis	−0.204586	−0.194465	−1.229396
Skewness	−0.742026	0.376928	−0.149575
Range	6	7	4
P1			
Mean	8.8	5.428571	3.6
Standard error	0.533333	0.301796	0.316228
Median	8	5	4
Mode	8	5	4
Standard deviation	1.686548	1.596955	1.581139
Sample variance	2.844444	2.550265	2.500000
Kurtosis	−0.212272	−0.912328	−1.055494
Skewness	0.910236	−0.065957	0.041247
Range	5	5	5
P2			
Mean	9.8	3.535714	2.32
Standard error	0.592546	0.208815	0.262805
Median	9.5	3.5	2
Mode	8	3	2
Standard deviation	1.873796	1.104943	1.314027
Sample variance	3.511111	1.220899	1.726667
Kurtosis	1.815214	−1.299284	0.902422
Skewness	1.246370	−0.008372	1.025977
Range	6	3	5
D1			
Mean	9	3.214286	2.28
Standard error	0.394405	0.305839	0.273983
Median	9.5	3.5	2
Mode	10	4	1
Standard deviation	1.247219	1.618347	1.369915
Sample variance	1.555556	2.619048	1.876667
Kurtosis	−0.911808	0.202241	0.456252
Skewness	−0.859054	0.698863	0.926939
Range	3	6	5
D2			
Mean	4.4	1.964286	2
Standard error	0.339935	0.188857	0.230940
Median	4	2	2
Mode	4	2	2
Standard deviation	1.074968	0.999338	1.154701
Sample variance	1.155556	0.998677	1.333333
Kurtosis	−0.882027	1.986493	2.245183
Skewness	0.322013	1.274506	1.588498
Range	3	4	4
D3			
Mean	4.3	1.892857	1.8

Contd...

Table 3: Contd...			
Measures	Removable partial dentures	Fixed partial dentures	Implant–supported dentures
Standard error	0.472582	0.207908	0.191485
Median	4	2	2
Mode	4	1	1
Standard deviation	1.494434	1.100144	0.957427
Sample variance	2.233333	1.210317	0.916667
Kurtosis	−0.151800	2.906502	3.948519
Skewness	0.359543	1.663659	1.671971
Range	5	4	4
H			
Mean	3.4	1.571429	1.32
Standard error	0.371184	0.157935	0.111355
Median	3.5	1	1
Mode	2	1	1
Standard deviation	1.173788	0.835711	0.556776
Sample variance	1.377778	0.698413	0.310000
Kurtosis	−1.456630	1.314469	1.841379
Skewness	0.041223	1.397412	1.584456
Range	3	3	2

FL=Functional limitation, P1=Physical disability, P2=Psychological discomfort, D1=Physical disability, D2=Psychological disability, D3=Social disability, H=Handicap
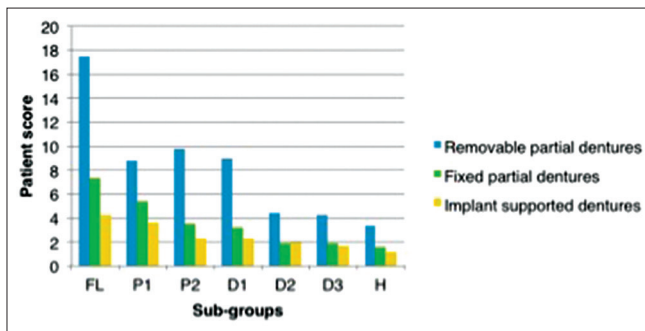

Figure 1: OHIP-49 scores for patient population

higher values in the C, which means an unsatisfactory feeling [Figures 1 and 2].

Data were analyzed by ANOVA test. They were statistically significant for a $P < 0.05$.

Statistical analysis suggested that quality of life in patients rehabilitated with RPDs is lower than in subjects who received FPDs or implant-supported dentures.

The prosthetic rehabilitation of CLP patients is directly related to the dysfunctions and alterations determined by the malformation: Thus re-establishing function, phonetics, and esthetics are the primary goals of oral rehabilitation.[7,8]

Table 4: Descriptive analysis of Cleft Evaluation Profile			
	Removable partial dentures	Fixed partial dentures	Implant–supported dentures
Speech			
Mean	4.5	2.714286	1.92
Standard error	0.521749	0.169477	0.140475
Median	5	3	2
Mode	3	3	2
Standard deviation	1.649916	0.896790	0.702377
Sample variance	2.722222	0.804233	0.493333
Kurtosis	−1.287321	−0.397291	−0.816029
Skewness	−0.092769	−0.372448	0.111674
Range	5	3	2
Hearing			
Mean	1.2	1.285714	1.2
Standard error	0.133333	0.086940	0.081650
Median	1	1	1
Mode	1	1	1
Standard deviation	0.421637	0.460044	0.408248
Sample variance	0.177778	0.211640	0.166667
Kurtosis	1.406250	−1.075846	0.592885
Skewness	1.778781	1.003249	1.597493
Range	1	1	1
Appearance of the teeth			
Mean	4.1	2.500000	1.76
Standard error	0.504425	0.174423	0.132665
Median	4	2	2
Mode	4	2	2
Standard deviation	1.595131	0.922958	0.663325
Sample variance	2.544444	0.851852	0.440000
Kurtosis	−0.132884	−0.702620	−0.612077
Skewness	0.414745	0.304387	0.302405
Range	5	3	2
Appearance of the lip			
Mean	4.9	3.107143	2.08
Standard error	0.458258	0.214175	0.190788
Median	5	3	2
Mode	3	3	2
Standard deviation	1.449138	1.133310	0.953939
Sample variance	2.100000	1.284392	0.910000
Kurtosis	−1.224490	−0.741043	−0.676963
Skewness	−0.334079	−0.059766	0.456277
Range	4	4	3
Appearance of the nose			
Mean	4.6	2.892857	2.2
Standard error	0.498888	0.214175	0.182574
Median	5	3	2
Mode	5	2	2
Standard deviation	1.577621	1.133310	0.912871
Sample variance	2.488889	1.284392	0.833333
Kurtosis	−0.820483	−0.741043	−0.060711
Skewness	−0.229210	0.059766	0.642979
Range	5	4	3

Contd...

| Table 4: Contd...			
	Removable partial dentures	Fixed partial dentures	Implant-supported dentures
Breathing through the nose			
Mean	4.7	2.750000	2.4
Standard error	0.578312	0.209718	0.163299
Median	4.5	2	2
Mode	3	2	2
Standard deviation	1.828782	1.109721	0.816497
Sample variance	3.344444	1.231481	0.666667
Kurtosis	−2.265159	−0.655542	−0.274209
Skewness	0.144424	0.536298	0.099843
Range	4	4	3
Profile of the face			
Mean	4	2.928571	2.64
Standard error	0.471405	0.229611	0.151438
Median	3.5	3	3
Mode	3	2	3
Standard deviation	1.490712	1.214986	0.757188
Sample variance	2.222222	1.476190	0.573333
Kurtosis	−1.333929	−0.972794	−0.262694
Skewness	0.503115	0.145685	0.107163
Range	4	4	3
Bite			
Mean	4.2	2.392857	1.88
Standard error	0.512076	0.157185	0.176257
Median	4.5	2	2
Mode	6	3	2
Standard deviation	1.619328	0.831745	0.881287
Sample variance	2.622222	0.691799	0.776667
Kurtosis	−1.694864	−0.449372	0.928081
Skewness	−0.204102	−0.049337	1.042386
Range	4	3	3
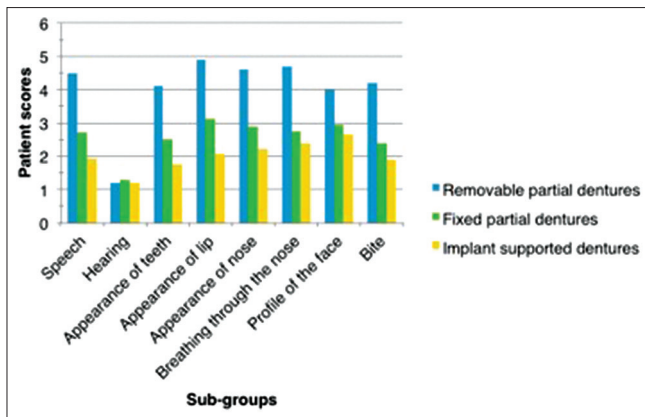
Figure 2: Cleft Evaluation Profile scores for patient population

CLP patients undergo multiple surgical treatments overlapping along a timeline ranging from birth to late teenage years.[13,14]

RPDs are not completely accepted by these patients and should be avoided, and considered as a secondary choice for obtaining a proper restoration that is capable of ensuring esthetic and psychological results.[14]

However, RPDs are recommended in patients presenting tissue deficiency, soft palate dysfunction, numerous palatal fistulas, and high risk of hypernasal speech.

They could bealso used as temporary prostheses prior to implant placement in young patients, who need to complete their surgical treatment or finish their dental and skeletal growth first.[14,15]

According to the authors, their use should be as limited as possible.

FPDs are considered a good option for prosthetic rehabilitation, particularly when alveolar bone grafts fail and implant placement is not possible. A three-unit/six-unit dental bridge is made, preparing the central incisor and the canine as abutments; in case of dental anomalies of teeth, adjacent to the cleft, extension of the bridge may be necessary involving other teeth to ensure a proper relationship between root and crown.[15-17]

However, nowadays, implant-supported prostheses have become the gold standard for prosthetic rehabilitation of CLP patients.[18-20]

According to a systematic review[18] authored by Wermker *et al.*, mean dental implant survival rate after 5 years is 88.6% in these subjects and can be compared to a control population.

Dental implant placement is generally recommended after a mean period of 4–6 months from the alveolar bone graft.[18-21] According to our experience, donor sites from the iliac crest, mandibular ramus, and symphysis can be used with some compliance.

Dental implant insertion achieves good esthetic and functional results, restoring the dental arch and the continuity of bone alveolar defects; patients generally accept implant-supported prostheses very well.[21-23]

Subjects showed a good satisfaction, scoring the highest values in CEP and the lowest in OHIP-49: Functional limitation, physical and psychological disability values were very low, and speech, appearance of teeth/lip, and bite were very high.

CONCLUSIONS

OH-QoL is a challenging demand for prosthodontists to achieve functional and esthetic

results as a way to improve psychological comfort for CLP patients.

The retrospective nature of this study and its relatively small sample may have affected our results. The risk of selection bias is higher and the quality of the data is lower compared to prospective studies.

However, this study is, to the best of the authors' knowledge, and aesthetics results is a way to improve psychological comfort for CLP patients. Our results clearly show that patients rehabilitated with implant-supported dentures are more satisfied, compared to subjects with FPDs and RPDs.

According to the authors, dental implant placement should be considered as the gold standard in prosthetic rehabilitation of CLP patients, in order to ensure achieving the best esthetic and functional results and therefore maximize patient satisfaction with their oral rehabilitation.

Financial support and sponsorship

Conflicts of interest

There are no known conflicts of interest associated with this publication.

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