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Occlusal Outcome of Orthodontic Treatment for Patients With Complete Cleft Lip and Palate

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Abstract

Aim: To assess occlusal outcomes of orthodontic treatment for patients with complete cleft lip and palate.

Design: Retrospective assessment using the Peer Assessment Rating (PAR) index.

Setting: Consecutive patients treated by one consultant orthodontist at a tertiary care cleft center.

Participants: One hundred twenty-seven patients with either complete unilateral cleft lip and palate (UCLP) or bilateral cleft lip and palate (BCLP) consecutively treated with fixed appliances.

Intervention: Fixed orthodontic appliance treatment and orthognathic surgery when required.

Outcomes: The PAR index assessment was carried out by a calibrated-independent assessor. Treatment duration, the number of patient visits, and data on dental anomalies were drawn from patient records and radiographs.

Results: One hundred two patients' study models were assessed after exclusions. Mean start PAR score for UCLP (n = 71) was 43.9 (95% CI, 41.2-46.6, SD 11.5), with a mean score reduction of 84.3% (95% CI, 81.9-86.7, SD 10.1). The UCLP mean treatment time was 23.7 months with 20.1 appointments. Mean start PAR score for BCLP (n = 31) was 43.4 (95% CI, 39.2-47.6, SD 11.4), with a mean score reduction of 80.9% (95% CI, 76.3-85.5, SD 12.5). The BCLP mean treatment time was 27.8 months with 20.5 appointments.

Conclusion: These results compare well with other outcome reports, including those for patients without a cleft, and reflect the standard of care provided by an experienced cleft orthodontist. As with high-volume surgeons, orthodontic treatment for this high need group is favorable when provided by a high-volume orthodontist. These findings may be used for comparative audit with similar units providing cleft care.

Keywords

dental occlusion, orthodontics, dental anomalies

Introduction

Cleft lip and/or palate (CL/P) has an incidence of around 1:700 live births, making it the most common craniofacial anomaly in humans (Fraser, 1970). The treatment pathway for patients with a cleft is multidisciplinary, with orthodontists being core members of the cleft team. Various outcome measures have been described for this patient group (Jones et al., 2014), but it was primarily the result of clinical studies into comparative treatment outcomes using measures such as the GOSLON Yardstick (Mars et al., 1987; Mars et al., 1992; Semb et al., 2005) that eventually lead to the UK Clinical Standards

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Advisory Group report into cleft care (Sandy et al., 1998). This highlighted the relatively poor outcomes for patients with a cleft in the United Kingdom compared to some Northern European teams and drove the restructuring and centralization of cleft services. Recommendations from this report also included the need for regular audit of treatment results, with high-volume centers thought to provide better training and predictable outcomes (Bearn et al., 2001).

Quality of treatment outcomes for patients with a cleft can vary significantly, with treatment requiring multiple stages and specialty input. Optimization of the factors that can impact upon outcome, including technique and timing of primary surgery, subsequent revisions, alveolar bone grafting, and presurgical or postsurgical orthodontics, will help improve the quality of care for these patients. Orthodontic treatment outcome can be assessed in terms of effectiveness and efficiency, whereby effectiveness can be measured as the average amount of improvement or the proportion of patients deemed to have outstanding, good, and poor results (Zahran et al., 2018). Efficiency can be measured in terms of material benefits in relation to the costs of treatment, such as duration and number of appointments (Ackerman, 2004). The use of validated and reliable outcome measures is, therefore, necessary to obtain data on the efficacy of treatment (DeGuzman et al., 1995).

The Peer Assessment Rating (PAR) index can provide a single standardized score for all of the occlusal anomalies, which may be found in a patient's malocclusion (Richmond et al., 1992a). It can be used to measure deviation from accepted occlusal norms, while the difference in pretreatment and post-treatment scores reflects the degree of improvement and success of treatment. The individual components of the PAR index have been weighted based upon British orthodontic opinion and have been used extensively to provide valuable information on the outcomes of orthodontic treatment. The evaluation of the success of treatment is made either from the percentage reduction in the PAR score or using a nomogram. Great improvement is considered to be a PAR score reduction $\geq$22, while improvement (<22% and $\geq$30%) and worse/no improvement (<22% and $\leq$30%) can also be categorized (Richmond et al., 1992b). The starting PAR score can be used to gauge the severity of the malocclusion and likely treatment difficulty. A post-treatment score of 10 or less would generally be deemed an acceptable result, with a score less than 5 being an almost ideal result for alignment and occlusion (Richmond et al., 1992a). The current suggested UK standard for patients with unilateral cleft lip and palate (UCLP) treated with fixed orthodontic appliances is a 69% reduction in PAR score, with 7.5% of cases being deemed worse or no different (Deacon et al., 2007). There are no published standards for those born with bilateral cleft lip and palate (BCLP). An earlier study into outcomes in patients without a cleft treated by consultant orthodontists suggested 75% of cases should exhibit a reduction in PAR score greater than 70%, with 3% being worse or no different (McMullan et al., 2003).

Modified PAR weightings have been proposed for patients with UCLP, as the treatment aims can differ from standard orthodontics (Kasem, 2003). Dental anomalies are more common in these patients, such as a missing or supernumerary lateral incisor on the side of the cleft (Ranta, 1986). Depending on the goals of treatment, such as space opening or closure, idealized outcomes like centerline correction and class I molar relationships may be challenging to achieve, particularly on the side of the cleft (Deacon et al., 2007). However, changing the weightings would make comparison with patients without a cleft more difficult. Different weightings have not been validated and may be necessary for each of the different cleft types, something which may develop in the future (Jones et al., 2014). Currently, the PAR index is still used for patients with a cleft in the United Kingdom as the only valid measure of cleft-related orthodontic treatment outcome. There are also no recognized standards for alternative measures of treatment efficiency, such as duration or number of appointments. These factors are likely to be closely associated with the starting complexity of the malocclusion and the individual orthodontist's choice of mechanics (Turbill et al., 2001).

The aim of this study was to evaluate the occlusal outcome of orthodontic treatment provided by one consultant orthodontist at a UK tertiary care cleft center. This outcome was measured using the PAR index. Additional outcome measures including number of appointments and duration of treatment were also recorded.

Material and Methods

Population

A convenience sample comprising of 127 patients with complete cleft lip and palate consecutively treated with fixed appliances, including those where orthognathic surgery was undertaken. Exclusions were made for syndromic patients, those held on the orthognathic waiting list, declined orthognathic surgery, showed poor compliance, or had incomplete records to enable outcome assessment. Poor compliance was defined as the premature removal of an orthodontic appliance due to poor oral hygiene and dental health concerns.

Setting

All treatment was carried out at Royal Manchester Children's Hospital that acts as a regional tertiary care cleft center. Care was funded by the UK National Health Service. All orthodontic treatment was provided by one subspecialty cleft consultant orthodontist. The study period included patients who completed treatment from March 2010 until May 2018 and covered the latter years of the orthodontist's clinical service prior to retirement.

Intervention

No patients underwent presurgical orthopedic treatment. When expansion was necessary prior to alveolar bone grafting, this was completed with a quad helix appliance in combination with a fixed appliance if required for alignment. Definitive orthodontic treatment was provided with preadjusted edgewise fixed

appliances of MBT prescription, 0.022- × 0.025-inch brackets with mostly thermal nickel–titanium wires of 0.014, 0.018, and 0.019- × 0.025-inch dimensions. Standard retention protocol included vacuum-formed polypropylene retainers and a lower canine-to-canine bonded retainer. An upper bonded retainer was used if significant rotations were corrected in the upper labial segment.

Outcomes

Orthodontic study models were scored by an external assessor (A.A.) who had undergone training and calibration in the use of the PAR index with models taken pretreatment and at debonding of appliances. Patient records, including radiographs and clinical notes, were assessed retrospectively for dental anomalies as well as the total number of appointments and duration of treatment in fixed appliances. Treatment time was calculated from the date of orthodontic bond up until removal of the fixed appliance and did not include time spent with sectional fixed or expansion appliances if required prior to bone grafting. Findings of dental anomalies were recorded by a single author (D.S.S.) and duplicated to confirm accuracy by a second author (J.M.).

Data Management

Data collection was completed using a prepiloted Microsoft Excel spreadsheet to facilitate analysis and graphical output. All patient data were recorded anonymously and presented in aggregate. Data analyses were carried out by an author independent of the treatment process (D.S.S.).

Ethical Approval

This project was primarily undertaken for audit and quality improvement purposes using existing patient records. Ethical approval was, therefore, not sought, but registration was completed with the local clinical audit team.

Statistical Analysis

Repeatability of the PAR score was carried out by random rescoring of 30 sets of study models assessed 1 month later by the calibrated outcome assessor. The intra-rater reliability was assessed by calculating the intraclass correlation coefficient (ICC) using a 2-way mixed-effect, single-measure, absolute agreement model. Statistical significance was at the .05 level.

Results

Baseline Characteristics

From the convenience sample of 127 consecutive patients with complete cleft lip and palate treated with fixed appliances, 25 (19.7%) were excluded, most commonly due to them still awaiting orthognathic surgical correction (n = 15, Table 1).

Table 1. Reasons for Patient Exclusion.

	UCLP		BCLP	
Exclusions	N	(%)	N	(%)
Orthognathic waiting list	9	65	6	55
Declined orthognathic surgery	1	7	1	9
Syndromic	1	7	2	18
Poor compliance	1	7	1	9
Incomplete records/transferred hospital	2	14	1	9
Total	**14**		**11**	

Abbreviations: BCLP, bilateral cleft lip and palate; UCLP, unilateral cleft lip and palate.

Table 2. PAR Index Scores by Type of Cleft.

		UCLP, n = 71 (70%)			BCLP, n = 31 (30%)		
PAR score		Pre	Post	% reduction	Pre	Post	% reduction
Mean		43.9	6.6	84.3	43.4	8.4	80.9
95% CI	Lower Bound	41.2	5.5	81.9	39.2	6.2	76.3
	Upper Bound	46.6	7.7	86.7	47.6	10.6	85.5
SD		11.5	4.6	10.1	11.4	6.0	12.5

Abbreviations: BCLP, bilateral cleft lip and palate; UCLP, unilateral cleft lip and palate; PAR, Peer Assessment Rating.

The total number of cases assessed with the PAR index was 102, of which 71 (70%) cases were patients with UCLP and 31 (30%) with BCLP. Seventy-two (71%) patients were male (UCLP n = 46, BCLP n = 26) and 30 (29%) were female (UCLP n = 25, BCLP n = 5). All patients had undergone alveolar bone grafting at the site of the cleft, with 38 (30%) of the starting sample requiring prior expansion with presurgical orthodontics. There were 17 (23.9%) patients with UCLP and 8 (25.8%) patients with BCLP who underwent joint-orthognathic treatment.

Reliability

Intra-rater reliability was good (ICC 0.840), but this must be interpreted with caution due to the wide 95% CI (0.231-0.981). F Test with true value 0 was statistically significant, $F_{1,\ 4} = 13.069$, $P = .014$. Cronbach α was also good at .923. The PAR scores are summarized by cleft type in Table 2.

Outcomes for Patients With UCLP

The mean starting PAR score was 43.9 (95% CI, 41.2-46.6, SD 11.5). The mean end of treatment PAR score was 6.6 (95% CI, 5.5-7.7, SD 4.6). The mean reduction in PAR score was 84.3% (95% CI, 81.9-86.7, SD 10.1), with 91.5% (n = 65) of cases being greatly improved and 8.5% (n = 6) improved. The percentage of cases where the score was worse or no different was

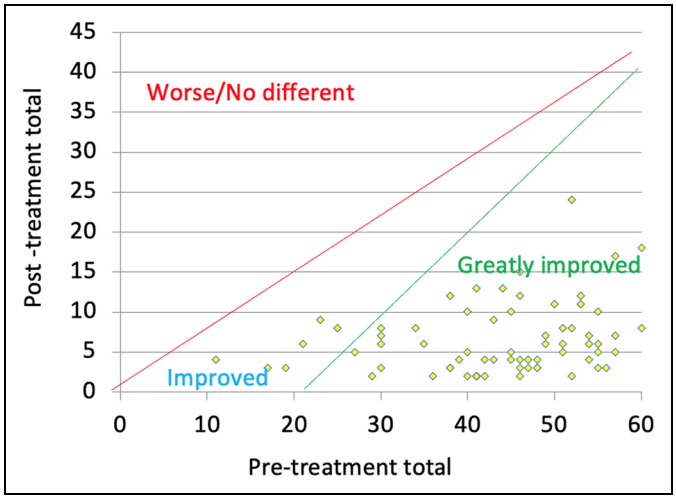

Figure 1. Assessment of improvement in Peer Assessment Rating score total for patients with unilateral cleft lip and palate.*

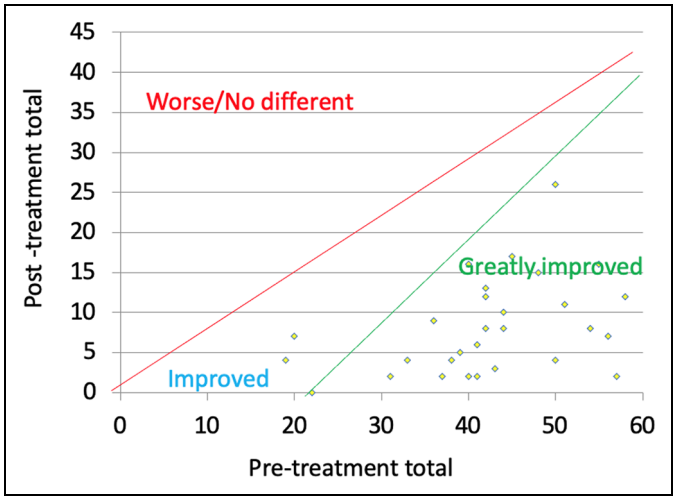

Figure 2. Assessment of improvement in Peer Assessment Rating score total for patients with bilateral cleft lip and palate.*

0%, as demonstrated in the nomogram in Figure 1. The mean treatment time in fixed appliances was 23.7 months (95% CI, 20.9-26.6, SD 10.9), with a mean number of 20.1 (95% CI, 17.9-22.2, SD 8.5) orthodontic appointments. The median PAR efficiency factor (reduction in PAR score divided by treatment time in months) was 1.94.

Outcomes for Patients With BCLP

For patients with BCLP, the mean starting PAR score was 43.4 (95% CI, 39.2-47.6, SD 11.4). The mean end of treatment PAR score was 8.4 (95% CI, 6.2-10.6, SD 6.0). The mean reduction in PAR score was 80.9% (95% CI, 76.3-85.5, SD 12.3), with 93.5% (n = 29) of cases being greatly improved and 6.5% (n = 2) improved. The percentage of cases where the score was worse or no different was 0%, as demonstrated in the nomogram in Figure 2. The mean treatment time in fixed appliances was 27.8 months (95% CI, 22.7-32.9, SD 13.5), with a mean number of 20.5 (95% CI, 17.1-23.9, SD 8.9) appointments. The median PAR efficiency factor was 1.66.

Outcomes of Joint-Surgical Treatment

When looking at outcomes for patients undergoing either orthodontics-only or joint-orthognathic treatment, comparable reductions in PAR score and duration of treatment were seen for both patients with UCLP and BCLP. However, orthognathic surgical correction did result in greater PAR score reduction and a shorter mean time in fixed appliances overall, as demonstrated in Table 3.

Dental Features

As part of orthodontic treatment, 25% (n = 18) of patients with UCLP underwent dental extractions, while for patients with BCLP, this figure was 35.5% (n = 11). Where a maxillary lateral incisor tooth was congenitally missing at the site of the cleft, space closure was attempted for the majority of both patients with UCLP (91.5%, n = 65) and BCLP (87%, n = 27), with space opening being less favored. Multiple dental anomalies were identified from radiographic and clinical records, the incidences of which are presented in Table 4 for patients with UCLP and BCLP.

Discussion

Clinical audit has been defined as "the systematic critical analysis of the quality of care including procedures for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient" (Long, 1996). Clinical audit of PAR score outcomes presented in this study compared favorably with those reported nationally in the United Kingdom for patients with UCLP (Deacon et al., 2007) and for patients without a cleft (McMullan et al., 2003). The high pretreatment PAR scores reflect the severity of the malocclusions treated, likely due to the inclusion of both bilateral and only complete clefts in this sample. These patients present with a higher incidence of dental anomalies compared to patients without a cleft. The starting PAR scores and sample size in this study are also comparable to similar outcome reports (Deacon et al., 2007).

Outcome Comparisons

Patients with cleft lip and palate are a heterogeneous population and vary greatly in their complexity and resultant deviation from orthodontic occlusal norms. This can make this patient group more difficult to treat to idealized standards. Mean PAR outcomes also do not account for this individual variation and may explain some of the differences in reported outcomes depending on the population from which the sample was drawn. A recent retrospective study of occlusal outcomes in 18 patients with CL/P found a mean reduction in PAR score of

Table 3. PAR Index Scores and Mean Duration of Fixed Appliance Treatment for Patients by Type of Cleft and Orthognathic Surgery.

	UCLP			BCLP		
			% reduction			% reduction
PAR score	Pre	Post	95% CI	Pre	Post	95% CI
Orthodontics only	43.9	7.5	82.4 79.5-85.0	43.2	9.4	78.8 73.0-84.6
Orthognathic surgery	44.0	3.7	90.6 83.5-96.0	44.0	5.8	86.9 80.9-92.9
All	43.9	6.6	84.3 81.2-86.3	43.4	8.4	80.9 76.3-85.5
	UCLP			**BCLP**		
Duration (months)	**Mean**		**95% CI**	**Mean**		**95% CI**
Orthodontics only	25.4		22.2-28.6	28.8		23.2-34.5
Orthognathic surgery	16.9		12.0-21.8	24.1		11.3-36.9
All	23.7		20.9-26.5	27.6		22.6-32.6

Abbreviations: BCLP, bilateral cleft lip and palate; UCLP, unilateral cleft lip and palate; PAR, Peer Assessment Rating.

Table 4. Incidence of Dental Anomalies for Patients With Complete Cleft Lip and Palate.

	UCLP		BCLP	
Dental anomalies	N	(%)	N	(%)
Congenitally missing cleft lateral incisor	43	60.6	22	71
Ectopic teeth	4	5.6	5	16
Supernumerary teeth	10	14	2	6.5
Diminutive right lateral incisor	7	9.9	5	16
Diminutive left lateral incisor	16	22.5	6	19.3
Hypoplastic right central incisor	6	8.5	13	42
Hypoplastic left central incisor	5	7	13	42

Abbreviations: BCLP, bilateral cleft lip and palate; UCLP, unilateral cleft lip and palate.

29.33; however, this was higher in patients who underwent joint-orthognathic treatment, with a reduction of 32 (Trimetsuntorn et al., 2020). A similar study of 34 patients with UCLP found a mean PAR score reduction of 29.59, but a greater reduction of 37.43 for patients who underwent orthognathic correction (Manosudprasit et al., 2011). Both of these studies examined comparatively small samples and included patients with incomplete clefts and isolated cleft palate; however, a greater reduction in PAR score was similarly seen in our cohort of patients undergoing cleft orthognathic treatment (n = 25) as opposed to those who underwent orthodontics alone (n = 77). Orthognathic surgery allows for even greater correction of dentoalveolar relationships in more severe cases of maxillary hypoplasia that are beyond the scope of orthodontic camouflage. It is noted that interpretation of the reduced mean treatment duration for patients with UCLP undergoing joint-orthognathic correction in this study should be viewed with caution. Data are likely to have been skewed by several patients only requiring simple orthodontic alignment prior to surgery.

Heterogeneity in the definition of treatment duration is challenging when making a comparison with the published literature. A UK national study examining UCLP occlusal outcomes reported a mean orthodontic treatment duration of 27 months over 18 patient visits (Deacon et al., 2007). Within this study, data report a shorter mean treatment duration for the UCLP sample at 23.7 months, but with a greater number of mean patient visits (n = 20.1). The increased complexity of bilateral clefting may account for the longer mean treatment duration found for patients with BCLP at 27.8 months over a similar mean number of appointments (n = 20.5). This may also be attributed to the time taken to align the often more severely ectopic maxillary canines and higher incidence of dental anomalies in patients with BCLP compared to UCLP.

The incidence of dental anomalies was comparable to a large sample of 425 patients with UCLP in the Scandcleft trials (Rizell et al., 2020), which found the cleft lateral incisor to be missing in 43.8% of cases. This trial also identified supernumerary teeth in 16.9% and ectopic eruption in 14.6% of these patients. The sample of patients with UCLP in our study shows a greater incidence of a missing cleft lateral incisor (60.6%) and lesser incidence of ectopic teeth (5.6%). The incidences for patients with BCLP are greater for both of these anomalies in tooth number and position. Space closure for a missing maxillary lateral incisor was the overwhelming treatment preference for this cohort of patients (90%, n = 92). This is higher than the 61% reported by Deacon et al. (2007), but the restorative burden of space opening for a prosthesis is likely to have influenced the choice of treatment mechanics (Josefsson & Lindsten, 2019).

Limitations

As this was a retrospective evaluation, some outcomes were missing, including incomplete records for patients who

transferred hospitals or those still awaiting orthognathic surgery. The threshold for exclusion of patients based on poor compliance (n = 2) was high so as to ensure that the treatment outcomes reported were a true reflection of the cleft orthodontic service. These exclusions are in line with recommendations from an international consensus paper on minimum data set and core outcome measures for cleft care appraisal (Allori et al., 2017). Patients were excluded if they chose to decline orthognathic surgery and accept a compromised occlusion against the recommendation of the multidisciplinary team.

The PAR index was the main outcome measure used. Post-treatment PAR scoring was carried out on study models taken at the time of debonding the appliance and so do not indicate the long-term stability of these outcomes in the retention period and beyond. We also reported treatment time in fixed appliances and number of appointments, including emergency visits. We did not explore additional factors such as adverse treatment effects or measures of health resource utilization, which may have provided more evidence on the efficiency and cost–benefits of orthodontic treatment for patients with a cleft. A study on the orthodontic burden of care for 42 patients with CL/P reported a mean total orthodontic treatment duration of 3.4 years over 44 appointments (Hameed et al., 2019), including the duration of presurgical orthodontics if required prior to secondary alveolar bone grafting. Although we did not include this measure in our evaluation, our yet unpublished data on presurgical orthodontic expansion have found an expected mean duration of 10.8 months (SD 4.55) over a mean of 9.8 visits (SD 3.34). When total orthodontic treatment duration is compared, it is likely that the figures we report are comparable with those findings by Hameed et al. (2019).

Future Research

Patient-reported outcome measures (PROMs) are increasingly important in the evaluation of quality in health care, including orthodontics (Ryan & Cunningham, 2018). CLEFT-Q is one such PROM that has been developed for use in cleft care (Wong Riff et al., 2017), and validated measures of self-esteem or health-related quality of life could provide a more complete assessment of the efficacy and value of orthodontic treatment in patients with CL/P. Incorporating these multifaceted measures of patient care into the development of a core set of outcomes will help support comparison and the continual appraisal of treatment results in prospective research to further improve the standard of care for these patients (Allori et al., 2017; Tsichlaki et al., 2017).

Conclusions

The mean percentage PAR score reduction for both patients with UCLP (84.3%) and BCLP (80.9%) in this study compared well with other outcome reports, including those for patients without a cleft. These results reflect the standard of care provided by an experienced cleft orthodontist and suggest that, as with high-volume surgeons, orthodontic treatment for this complex and high needs patient group is favorable when provided by a high-volume orthodontist. These findings may also be used for comparative audit with similar units providing cleft care.

Declaration of Conflicting Interests

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