Assessment of complete unilateral cleft lip and palate treatment outcome using EUROCRAN index and associated factors

Anas Imran Arshad [a], Mohammad Khursheed Alam [b, *], Mohd Fadhli Khamis [c]

[a] School of Dental Sciences, Universiti Sains Malaysia, Malaysia
[b] Orthodontic Department, College of Dentistry, Al Jouf University, Sakaka, Saudi Arabia
[c] Forensic Dentistry Unit, School of Dental Sciences, Universiti Sains Malaysia, Malaysia

A B S T R A C T

Objectives: Assessment of treatment outcome is the only non-invasive approach to identify the effects of cleft lip and palate repair and modify management accordingly. Here the aim is to assess the outcome of complete unilateral cleft lip and palate (CUCLP) patients using EUROCRAN index and to check whether there are any factors associated with the treatment outcome.
Materials and methods: It is a retrospective cross sectional study. Dental models were collected from archives of two cleft referral centers in Pakistan. Five blinded examiners scored 101 models twice at two week interval. The primary outcome was mean EUROCRAN scores based on dental arch relationships and palatal surface morphology.
Results: A mean(SD) score of 2.72 (0.76) and 2.20 (0.73) was determined based on dental arch relationships and palatal surface morphology, respectively. According to the final logistic regression model, modified Millard technique (cheiloplasty) and Veau-Wardill-Kilners' method (palatoplasty) had higher odds of producing unfavorable treatment outcome.
Conclusions: Present study determined a fair and a fair to poor treatment outcome based on dental arch relationships and palatal surface morphology, respectively. Our study suggests a significant association between treatment outcome and primary surgical techniques for lip and palate. These findings could warrant a modification of management protocols to ensure improvement in future cleft outcomes.

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1. Introduction

Globally, an estimate of 1.43 per 1000 live births have some form of cleft lip and palate (CLP) [1]. In Pakistan, one in every 523 live births is affected by it [2]. Although a multidisciplinary approach for treating cleft lip and palate patients has been greatly emphasized [3], a traditional decentralized approach with poor accountability is a common trend in developing countries. It is mandatory for every sufferer to undergo primary surgical repair, which led to the development of a vast variety of techniques to achieve the primary structure and function. However, the ideal technique for cheiloplasty and palatoplasty is yet to be identified or developed by evidence based research [3]. In order to improve and develop ideal technique it is necessary to assess the effects of treatment that is currently provided. Different indices based on dental arch relationships have been commonly used to assess treatment outcomes.

GOSLON index is still widely used for outcome assessment [4], however, its ability to assess the transverse discrepancy has been limited. The Huddart/Bodenham scoring system was initially modified to assess bilateral cleft lip and palate patients but, since then, efforts for its use in unilateral cleft lip and palate patients have been made [5,6]. However, it focuses mainly on the transverse dental arch relationships by scoring individual inter-arch occlusal relations. By the commencement of Eurocleft project, efforts were made to establish an index which included two different scorings [7,8]. Dental arch relationship scoring to assess anteroposterior and vertical plane and palatal morphology scoring to assess in transverse plane, contemporaneously reporting palatal surface morphology. Apart from the effect of post-natal repair, pre-natal factors like sexual disparities, family history of CLP, and cleft occurrence side have also been considered important [9]. Assessment of treatment outcome of the existing approaches plays a pivotal role in documenting the precision and effectiveness of

* Corresponding author.
E-mail address: dralam@gmail.com (M.K. Alam).

available techniques. Outcome assessment is imperative to justify modifications in treatment strategies like technique and timing of primary surgeries [10].

The aim of this retrospective study is to assess the treatment outcome of complete unilateral cleft lip and palate (CUCLP) patients using EUROCRAN index and to test the hypothesis that there is an association between the pre-postnatal factors and treatment outcome.

2. Material and methods

This observational study was approved by Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (USM/JEPeM/ 15050166). Sample size was calculated using an estimated prevalence of population proportion. Population proportion was considered unlikely to exceed 31.7% ($p = 0.317$) from previous publications involving the largest sample of other Asian population with the level of significance set at 5% [11]. To calculate a 95% confidence interval ($Z = 1.96$) for P with a margin of error (d) no more than 0.09, $n = \left(Z/d\right)^2 \times P(1-P)$ [12]. Where, n, the required sample size was 102 [13]. Both cleft care centers granted prior authorization for collection of data. One hundred and one dental study models of consecutively treated non-syndromic CUCLP children and corresponding history charts were retrieved from two regional cleft centers archives located in Punjab, Pakistan. The selection criteria were based on current literature [14], (1) age range from 7 to 10, (2) non syndromic CUCLP, (3) primary lip (cheiloplasty) and palate (palatoplasty) repair has been performed, (4) no orthodontic, functional orthopedic treatment or bone augmentation has been performed, and (5) complete availability of required information in patient history charts (see Fig. 1 for selection process). Study models of other types of CLP, gross surface porosities,

and inadequate information were excluded. Random numbers were assigned to dental models by a non-examiner individual to ensure examiner blinding. After delivering calibration courses, 101 pairs of dental models were rated twice by five examiners for two different gradings ($101 \times 2 \times 5 \times 2 = 2020$ observations). There was a two-week interval between first and second observation to eliminate memory bias.

A mean (SD) age of 8.05 (0.79) was calculated. According to EUROCRAN index, dental models are scored from grade 1 (having very good outcome and requiring minimal orthodontic intervention) to grade 4 (having poor outcome and necessity of orthognathic corrective surgery), based on dental arch relationship scoring and 1 to 3 based on palatal surface morphology [7]. Based on literature, the four dental arch relationship grades are dichotomized as, favorable (grade 1 and 2) and unfavorable (grade 3 and 4) treatment outcomes. Primary dependent variable of interest was the treatment outcome. It was categorized as favorable or unfavorable. Independent variables included prenatal (sex, family history of CLP, and cleft occurrence side), and postnatal (cheiloplasty and palatoplasty technique) factors. Two techniques of both cheiloplasty and palatoplasty were common choice in both cleft centers. Multiple numbers of operating surgeons was involved, but standard protocols of operating techniques were followed. In Pakistan, timing of cheiloplasty is traditionally six to ten months of age, whereas, one-stage palatoplasty is usually carried out between 12 and 18 months of age.

Descriptive statistics were conducted to quantify distribution of sample characteristic. Kappa statistics were used to assess reliability and reproducibility of intraobserver and interobserver agreements. Chi square tests were used to compare proportions of each characteristic variable with the bivariate treatment outcome grouping. Association between individual risk factors and treatment outcome were evaluated using bivariate logistic regression.
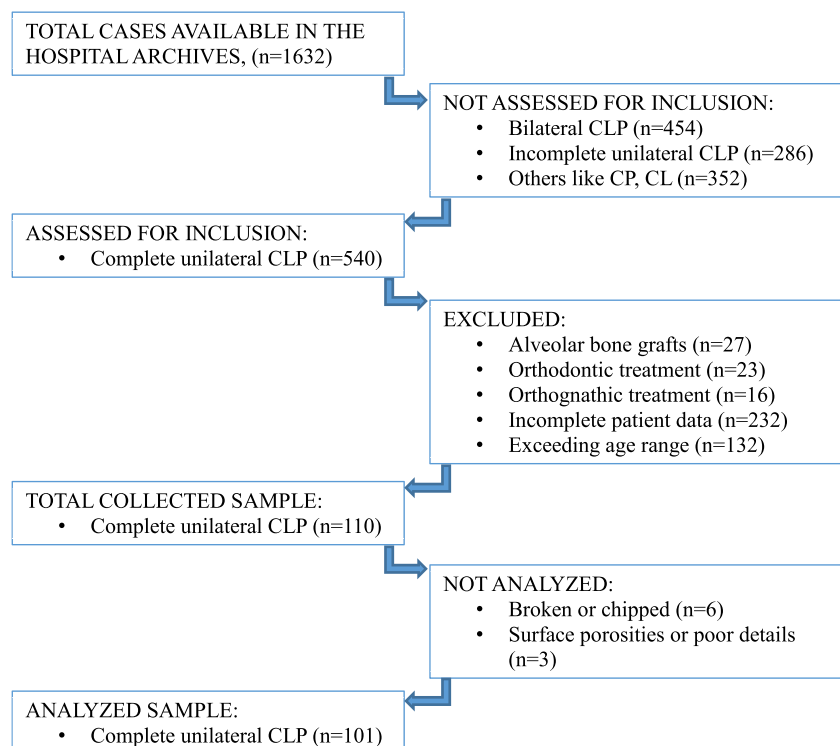

Fig. 1. Flow Diagram for sample inclusion.