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# Assessment of complete unilateral cleft lip and palate patients: Determination of factors effecting dental arch relationships

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## ABSTRACT

**Objectives:** The purpose of the current study was to assess the treatment outcome of non-syndromic patients having complete unilateral cleft lip and palate (CUCLP) by using GOSLON index and to determine any association of pre and/or postnatal factors with the treatment outcome.

**Materials and methods:** One hundred and one sets of dental models of patients having CUCLP were assessed in this retrospective study. Five examiners that were blinded to case-specific information scored the dental models at two instances with an interval of two weeks to ensure memory bias elimination ( $5 \times 101 \times 2 = 1010$  observations). Calibration courses were conducted prior to scoring and each examiner was provided with scoring sheets, pictures of GOSLON reference models and flowcharts explaining the scoring method.

**Results:** According to GOSLON index, a mean (SD) GOSLON score of 3.04 (1.25) was determined. Based on treatment outcome groups, 62 patients had favorable (grade 1, 2, and 3) and 39 cases had unfavorable (grade 4 and 5) treatment outcome. Chi-square tests revealed a significant association of gender ( $P = 0.002$ ), cheiloplasty ( $P = 0.001$ ) and palatoplasty ( $P < 0.001$ ) with the treatment outcome. These associations were further explored by entering five independent variables in the logistic regression models.

**Conclusions:** The current study found an intermediate treatment outcome of CUCLP cases using GOSLON index. Final logistic model showed that gender, cheiloplasty, and palatoplasty had significantly higher odds of influencing outcomes. Identification of these factors provides us an evidence of traditional and outdated surgical methods and encourages clinicians to adopt current techniques to improve treatment outcomes. This implementation will facilitate comparison between the traditional and current techniques of primary surgical repair.

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## 1. Introduction

An overall incidence of one orofacial cleft per 700 live births has been documented [1,2]. According to an unprecedented epidemiological study in Pakistan, one in every 523 live births is affected by some type of orofacial clefting [3]. Surgical management of the cleft defect is necessary for affected cases. Numerous studies have been conducted to assess and evaluate the most suitable primary surgical techniques to manage such cases [4]. However, the objective in developing countries is the provision of surgical management

rather than the choice of surgical techniques, which has led to the traditional use of similar techniques for all cases regardless of clinical variations and choice of available techniques [4,5]. It is imperative to assess the techniques that are being traditionally practiced to determine their outcome and to identify their shortcomings. Dentoalveolar relationships have been most frequently used to assess the treatment outcome of cleft cases [6].

GOSLON index has been accepted and used widely to assess the treatment outcome based on dental arch relationships [4,7,8]. We used GOSLON index for its simplicity, precision, reliability. Though initially developed to assess ten years old cases, its versatility has been assessed in previous studies [9,10]. It will also facilitate a comparison of cross-center studies. This study aims identification of any associated factors to establish evidence based practice in the

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target population [11,12].

Some prenatal factors like gender, family history of cleft occurrence, and the side of cleft occurrence and postnatal factors like primary lip repair (cheiloplasty) and primary palate repair (palatoplasty) have been previously assessed [11,13]. However, Kajii, Alam, Mikoya, Oyama, Koshikawa-Matsuno, Sugawara-Kato, Sato and Iida [13] involved different cleft phenotypes and therefore lacked homogeneity of data. Whereas, Chan, Hayes, Shusterman, Mulliken and Will [11] assessed only the prenatal factors like gender, age, and sex. Cleft phenotype plays an important role when considering the size and extent of the defect. Therefore, the current study aims to: (1) assess the treatment outcome of non-syndromic patients with only complete unilateral cleft lip and palate (CUCLP) (2) determine an association of pre and postnatal factors with the treatment outcome.

## 2. Methods

### 2.1. Sample setting and collection

Ethical clearance for publishing outcomes of this observational study was obtained from Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM) (USM/JEPeM/15050166). The sample size was determined by estimating prevalence based on proportions of other Asian populations. According to previous studies in the Asian population, with the level of significance set at 5%, population proportion was considered unlikely to exceed 31.7% [14]. The formula used for calculating sample size ( $n$ ) with a 95% confidence interval ( $Z$ ) was [15].

$$n = \left( \frac{Z}{d} \right)^2 \times P(1 - P)$$

where,  $Z = 1.96$ ;  $P = 0.317$ ; with a margin of error ( $d$ )  $\leq 0.09$ .

A sample size of 101 cases was collected and it was considered sufficient to represent the population [14]. Prior approvals for retrieval of dental models were obtained from two cleft centers and one hundred and one dental models were collected from Punjab, Pakistan. Patient information data were also recorded. Selection criteria followed a previous study by Dugas [16] to allow cross center comparison, 7–10 years old, (2) non-syndromic CUCLP, (3) had previously undergone cheiloplasty and palatoplasty procedures, (4) Patients in which orthodontic, functional orthopedic or bone grafting has not been performed, and (5) cases for which records were completely available. Other cleft phenotypes and defected models were not included. Cheiloplasty (at six to ten months of age) and palatoplasty (at twelve to eighteen months of age) procedures were carried out by experienced surgeons who followed standard protocols in both cleft centers. For cheiloplasty, a choice between Millard and modified Millard technique was usually made and for palatoplasty, either Von Langenbeck (VL) or Veau-Wardill-Kilners' pushback (VY) method was traditionally used. Regarding the cheiloplasty, any extension in incision line along the base of the ala of nose or an incision extending deep along the base of columella was considered a modification of the conventional Millard technique.

A non-observing individual, numbered dental models in a random fashion. Calibration courses were conducted twice before scoring the dental models. Examiners were provided scoring sheets, pictures of reference dental models and instructions explaining scoring method in flow charts. Five observers made observations on each pair of the 101 dental models twice at an interval of two weeks to eliminate memory bias ( $5 \times 101 \times 2 = 1010$  observations).

### 2.2. Statistics

According to GOSLON index, each pair of dental models was scored within five groups, from "1 = Excellent" requiring minimal or no treatment to "5 = Very Poor" requiring complex orthognathic intervention [17]. To dichotomize the dependent variable based on treatment outcome, group 1, 2, and 3 were considered favorable and group 4, and 5 were considered unfavorable [11,13]. Intra-examiner and interexaminer agreements were assessed by Kappa statistics. Chi-square analyses were performed to find an association between the favorable/unfavorable treatment outcome groups (independent variable) and gender, family history of cleft occurrence, side of cleft occurrence, cheiloplasty, and palatoplasty (dependent variable). Crude and backward stepwise logistic regression analyses were performed to determine the odds of each dependent variable affecting the treatment outcome [13,14]. Analyses were performed using the statistical package SPSS Version 22.0 (SPSS Inc., Chicago, IL). A value of  $P < 0.05$  was considered to be statistically significant.

## 3. Results

A sample of one hundred and one dental models having non-syndromic CUCLP was included in this study. A mean age of  $8.05 \pm 0.79$  years was calculated. The sample comprised of 58 dental models of male individuals and 43 dental models of female individuals. Distribution of variable characteristics is shown in Table 1. According to Altman [18], there was good to very good intra-examiner agreement between first and second instance ( $\kappa \geq 0.77$ ), and an overall good to very good interobserver agreement ( $\kappa \geq 0.65$ ) at both instances. According to treatment outcome groups, 61.38% had favorable treatment outcome, and 38.62% had unfavorable treatment outcome. Based on GOSLON index, data were distributed among group one to five as 12.8%, 22.7%, 25.7%, 23.7%, and 14.8%, respectively. Mean (SD) of total occlusion score was 3.04 (1.25).

According to Table 1, chi-square tests revealed a statistically significant association of treatment outcome with gender ( $P = 0.002$ ), cheiloplasty ( $P = 0.001$ ), and palatoplasty ( $P = 0.000$ ). Unadjusted logistic regression revealed that the factors associated with increased odds of resulting in unfavorable treatment outcome were female gender, the modified technique for cheiloplasty, and Veau-Wardill-Kilners' pushback method for palatoplasty (Table 2). Exploratory analyses were performed by entering all dependent variables in the adjusted (backward stepwise) logistic regression model. The side of cleft occurrence variable and family history of cleft were eliminated in the first and second step, respectively. The final model predicted that females with CUCLP, modified Millard technique for cheiloplasty, and VY pushback technique had higher odds of producing unfavorable treatment outcome, which was found statistically significant (Table 3).

## 4. Discussion

The present study assessed the treatment outcome of 101 non-syndromic patients having a complete unilateral cleft lip and palate phenotype only. The study focused on identifying the pre and postnatal factors that could affect the treatment outcome.

This study found a frequent incidence of cleft occurrence in males which is in agreement with the findings of the previous epidemiological study in Pakistan and also of other populations [1,3,19]. A frequent cleft occurrence on the left side was found which was also documented in previous studies [20]. Final logistic regression model indicated that females had higher odds of having unfavorable treatment outcome, which is in agreement with a



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