Anthropometric and Physiologic Parameters in Cleft Neonates: A Hospital-Based Study

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Abstract: The oro-facial morphology is greatly affected in neonates with a cleft lip and palate. The initial evaluation of neonate’s body and maxillary arch dimensions is important for treatment planning and predicting growth in cleft patients. The objective of this study was comparative evaluation of the anthropometric and physiologic parameters of cleft and non-cleft neonates in a hospital-based set up. This cross sectional study was conducted on 88 cleft and non-cleft neonates (n = 44 in each group) aged between 0 and 30 days after obtaining approval from the institutional ethics committee and positive written informed consent from their parents. Neonates’ body weight, body length, head length, head circumference, and maxillary arch dimensions were measured. Maxillary arch dimensions were measured on dental casts with digital sliding calipers. Statistical analyses performed using the independent t-test and one-way ANOVA analysis were followed by Bonferroni correction for post-hoc comparison. The results showed statistically significant differences in birth weight (p < 0.0001), head length (p < 0.01), head circumference (p < 0.007), and maxillary arch dimensions (p < 0.0001) between cleft and non-cleft neonates. These findings suggest that cleft neonates had significant anthropometric and physiologic variations than non-cleft neonates.

Keywords: cleft lip and/or palate; neonates; birth weight; birth length; head length; head circumference; maxillary arch dimensions; cleft impression technique; BCLP; UCLP

1. Introduction

The cleft lip and/or palate (CL/P) is one of the most common congenital craniofacial abnormality in neonates. The incidence of CL/P is 1.7 per 1000 live births with ethnic and geographical variation worldwide [1]. In India, neonates born with craniofacial anomalies comprise about 1.10 per 1000 live births [2]. Mossey et al. reported the incidence of 0.93 per 1000 live births [3]. Another study, in south India, reported the incidence of 1.09 per 1000 live births [4]. The CL/P has a multifactorial etiology that includes both genetic and environmental factors. These environmental risk factors include exposure to tobacco, alcohol, inadequate nutrition intake, infections, and teratogens during 6th to 13th week of intrauterine life [1].

The treatment approach of CL/P in neonates is multidisciplinary. The assessment, diagnosis, and treatment plan starts immediately just after birth. Treatment plan varies...
from parental psychological support to naso-alveolar molding, cheiloplasty, palatoplasty, orthodontic therapy, and multiple revision surgeries at different stages till adulthood. Correct surgical and non-surgical treatments at the right times are critical for the greatest functional and aesthetic results. In an attempt to assess the general health, as well as the surgical outcome and growth of a cleft neonate at different stages, it is important to determine and maintain the anthropometric and physiological parameters since birth in the first place. For initial evaluation of a neonate’s body, the dimensions of maxillary arch is a crucial factor for treatment planning and growth prediction in cleft patients. To the best of our knowledge, there is a paucity in the literature regarding evaluation of the anthropometric and physiologic parameters of cleft and non-cleft neonates at our tertiary care center. The present cross sectional study was designed as per STROBE guidelines [5] with an objective of comparative evaluation of the anthropometric and physiologic parameters of cleft and non-cleft neonates in a hospital based set up.

2. Materials and Methods

2.1. Participants

This cross-sectional, hospital-based study was conducted among 88 neonates, 44 with a cleft Lip and/or palate and 44 without (both male and female), aged between 0 and 30 days. Approval from the Institutional Ethics Committee was obtained prior to the initiation of the study (IEC Number: 31 April 2014). The neonates included in the study were divided into two groups: Group I—neonates with a cleft lip and/or palate (experimental group); Group II—age-matched healthy neonates (control group). A positive written informed consent from the parents was taken prior to including neonates for the study. The inclusion criteria of the cleft group included non-syndromic cleft lip and/or palate (unilateral, bilateral, and isolated) neonates aged between birth to 30 days reported to the Department of Orthodontics, Government Dental College, Civil Hospital, Ahmedabad, Gujarat, India between the duration of April 2014 to April 2015. Only neonates with parents who provided written informed consent were considered. The inclusion criteria of the control group were age-matched healthy neonates selected from Department of Paediatrics, Civil Hospital, Ahmedabad, Gujarat, India. The exclusion criteria for both the groups were neonates with preterm birth, systemic abnormality, and associated syndrome, or neonates older 30 days. All 88 neonates in the study were of Gujarati origin. This might be due to the population’s predominance in this geographical area of the country where the study was conducted.

A total of 47 cleft neonates reported at the hospital, 3 of which were excluded from the study due to the presence of associated syndrome. Group I was further divided into three sub groups: Subgroup I—neonates with a unilateral cleft lip and palate (UCLP) \((n = 22)\), Subgroup II—neonates with an isolated cleft palate (ICP) \((n = 10)\), and Subgroup III—neonates with a bilateral cleft lip and palate (BCLP) \((n = 12)\).

2.2. Measures

The physiological and anthropometric measurements, such as birth weight, birth length, head circumference, head length, and maxillary gum pad dental models (Figure S1), were recorded by an trained and experienced examiner within 48 h of birth, as suggested by Jennson et al. and Cheikh Smile et al. [6,7]. The birth weight (Figure S2) was measured using an electronic digital scale with an accuracy of \(\pm 10\) gm. Birth length was measured by horizontal infant stadiometer to the nearest 0.5 cm (Figure 1a,b). Head length (Figure 2a) and circumference (Figure 2b) were measured in supported upright position with a non-extendable flat measuring tape (Table 1).
For taking maxillary arch anthropometric measurements, impression of the neonate’s maxillary gum pad was made within 48 h of birth. Primary impression was taken using impression compound with the neonate in upright position, with back supported in mother’s lap. The cast was poured using a dental plaster, after which a wax spacer was adapted over the plaster model. The next step was to fabricate a perforated, size-compatible special tray using self-cure acrylic material. The final impression was made with elastomeric impression material (putty wash impression) sequentially using heavy body and light body material. The final cast obtained with good details was taken to record linear anthropometric measurements with more accuracy [8,9]. The putty wash impression ensured the good-quality study model [10]. Any residual impression material left in oral cavity was checked by running the pulp of the finger throughout the vestibule and cleft area. The oral cavity was cleaned with sterilized wet gauze piece.

The final impression was poured with dental stone. The dental casts with good anatomic details were obtained using this method [9,11]. In the past, materials such as alginate and impression compound were used and their lack of ability to record finer details of cleft were observed, but the chances of tearing and the overflow of material are high [10]. All clinical steps from obtaining cast model of maxillary gum pad till taking the measurements were performed by a single, well-trained, and experienced orthodontist. Airway patency was maintained with caution, overloading of impression material was avoided, and an empathic atmosphere for the parents and guardians was maintained for safety and emotional support. The impression was taken in the clinical setting area that was prepared to handle any inadvertent emergency. The maxillary anthropometric
measurements were: inter canine width, inter tuberosity width, arch length, and arch circumference. These were measured as landmarks \cite{12,13}, as described in Table 1 using digital sliding calipers measurable to the nearest 0.01 mm. (Figure 3).

**Table 1.** Landmarks for variables in the present study \cite{6,7,12}.

| S. No. | Variables       | Units | Definition                                                                 |
|--------|-----------------|-------|-----------------------------------------------------------------------------|
| 1      | Head Length (HL) | cm    | The maximum length of the head in sagittal plane; measured from glabella, anteriorly to the most prominent point of the head posteriorly. |
| 2      | Head Circumference (HC) | cm    | The distance recorded from glabella, anteriorly to the most prominent point of the head posteriorly in transverse plane where the measuring tape is anchored and loop around head transversely. |
| 3      | Inter-canine width (ICW) | mm    | The canine point is the landmark at intersection of the groove of the lateral labial frenum and the crest of the ridge. (C-C') |
| 4      | Inter-tuberosity width (ITW) | mm    | The distance between the tuberosity points T-T'. |
| 5      | Arch Length (AL) | mm    | A compound measurement. (I-TT') |
| 6      | Arch Circumference (AC) | mm    | For UCLP: T-C-I-P+ L-C'-T'  |
|        |                  |       | For BCLP: T-C-L + P-I-P' + L'-C'-T'  |
|        |                  |       | For ICP and Controls: T-C-I-C'-T' |

**Figure 3.** Landmarks for the neonatal cleft maxillary arch, as described by Seckel et al. (1995) \cite{12}. I = incisal point, on the crest of the ridge on the line drawn from the labial frenulum to the incisive papilla; (a) C,C' = canine points, where the lateral sulcus crosses the crest of the ridge; (b) T-T' = tuberosity points, at the junction of crest of the ridge with the outline of the tuberosity; L,L' = lateral segment margin of cleft, on continuation of the line marking the crest of the ridge; P,P' = premaxillary margin of cleft, on the continuation of the line marking the crest of the ridge; (c) I-TT' = the perpendicular distance from the incisal point to the T-T' plane. *= denotes the left side (in case of paired landmarks).

2.3. Data Analysis

The study data were summarized using descriptive statistics; continuous measurements were given as mean and standard deviation while all categorical data were presented as n (%). Summarized data were presented using Tables. The Shapiro–Wilk test was used to check the normality of the data. As the data were found to be normally distributed, bivariate analyses were performed using independent t-test and one-way ANOVA analysis, followed by Bonferroni correction for post-hoc comparisons. The level of statistical significance was set at 5% and was denoted as * . Intra-examiner correlation coefficients were assessed using the Kappa co-efficient. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS) version 21, IBM Inc.
3. Results
3.1. Sample Demographics

The intra-examiner variability was checked by performing repeat examination on 10% of randomly selected neonates, and then an intra-examiner Kappa coefficient value was found to be 0.82. The mean age of the neonates with cleft were found to be 48 ± 1.17 h and among neonates without cleft it was found to be 36 ± 2.89 h. The descriptive statistics of study sample are shown in Table 2.

Table 2. Descriptive Statistics of Study Sample. Age, Sex, Origin.

| Variables                  | Cleft Neonates       | Non Cleft Neonates |
|----------------------------|----------------------|--------------------|
| Age Mean ± SD              | 21 ± 1.34            | 36 ± 2.89          |
| Sex Female                 | 11 (52.4%)           | 22 (50%)           |
| Sex Male                   | 11 (47.8%)           | 22 (50%)           |
| Origin Gujarati            | 22 (50.0%)           | 44 (100%)          |
| Origin Others              | 0                    | -                  |

3.2. Comparison among Cleft and Non-Cleft Neonates

Significant differences were seen in the birth weight, head length, and head circumference of the neonates with and without clefts, i.e., birth weight, head length and head circumference were found greater among neonates without clefts as \( p < 0.05 \), whereas birth length did not vary among neonates with or without clefts as \( p = 0.337 \). Inter-canine width, inter-tuberosity width, and arch length were found to be significantly increased among neonates with cleft as \( p < 0.05 \), whereas arch circumference was found to be significantly higher among neonates without cleft (Table 3).

Table 3. Comparison of birth weight, length, head length, head circumference, and maxillary arch dimensions among cleft and non-cleft neonates.

| Variables                  | Group      | N  | Mean   | Std. Deviation | Std. Error Mean | \( p \) Value |
|----------------------------|------------|----|--------|----------------|-----------------|--------------|
| Birth Weight kg            | Cleft      | 44 | 2.4693 | 0.53060        | 0.07999         | 0.0001 *     |
|                           | Non-Cleft  | 44 | 2.9355 | 0.41032        | 0.06186         | 0.337        |
| Birth Length cm            | Cleft      | 44 | 45.080 | 6.1351         | 0.9249          | 0.011 *      |
|                           | Non-Cleft  | 44 | 46.029 | 2.2322         | 0.3365          | 0.007 *      |
| Head Length cm             | Cleft      | 44 | 19.148 | 4.5820         | 0.6908          | <0.0001 *    |
|                           | Non-Cleft  | 44 | 20.988 | 1.0134         | 0.1528          | <0.0001 *    |
| Head Circumference cm      | Cleft      | 44 | 30.848 | 5.0974         | 0.7685          | <0.0001 *    |
|                           | Non-Cleft  | 44 | 33.042 | 1.4385         | 0.2169          | <0.0001 *    |
| ICW mm                     | Cleft      | 44 | 28.6534 | 4.97135        | 0.74946         | <0.0001 *    |
|                           | Non-Cleft  | 44 | 31.0927 | 4.86118        | 0.73285         | <0.0001 *    |
| ITW mm                     | Cleft      | 44 | 31.0927 | 4.86118        | 0.73285         | <0.0001 *    |
|                           | Non-Cleft  | 44 | 32.8466 | 1.21610        | 0.18333         | <0.0001 *    |
| Arch Length mm             | Cleft      | 44 | 27.4307 | 7.12700        | 1.07444         | <0.0001 *    |
|                           | Non-Cleft  | 44 | 18.9145 | 0.66602        | 0.10041         | <0.0001 *    |
| Arch Circumference mm      | Cleft      | 44 | 63.273 | 13.0836        | 1.9724          | <0.0001 *    |
|                           | Non-Cleft  | 44 | 68.023 | 1.6352         | 0.2465          | <0.0001 *    |

ICW, Inter-canine width; ITW, Inter-tuberosity width; * Statistical Significance, \( p < 0.05 \).
3.3. Comparison of Each Type of Cleft

Among the 44 neonates with a cleft lip and palate, the prevalence of BCLP, ICP, and UCLP was found to be 27.3%, 22.7%, and 50%, respectively (Table 2). No significant differences were seen in the prevalence of BCLP, ICP, and UCLP among males and females ($p > 0.439$) (Table 2). The birth length of the neonates were found to be significantly higher among neonates with BCLP as compared to neonates having ICP and UCLP ($p = 0.018$) whereas the birth weight was found to be almost similar among neonates with ICP, UCLP, and BCLP (Table 4).

Table 4. Comparison of birth weight, length, head length, head circumference, and maxillary arch dimensions among different cleft type.

| Variable            | Cleft Type | N  | Mean   | Std. Deviation | Std. Error | 95% Confidence Interval for Mean | Minimum | Maximum | $p$ Value | POST HOC |
|---------------------|------------|----|--------|----------------|------------|---------------------------------|---------|---------|-----------|----------|
| Birth Weight kg     | UCLP       | 22 | 2.4295 | 0.54416       | 0.11602    | 2.1883 - 2.6708                  | 1.40    | 3.50    | 0.525     | -        |
|                     | ICP        | 10 | 2.3800 | 0.66466       | 0.21019    | 1.9045 - 2.8555                  | 1.40    | 3.50    | 0.408     |          |
|                     | BCLP       | 12 | 2.6167 | 0.37576       | 0.10790    | 2.3792 - 2.8541                  | 2.30    | 3.40    | 0.408     |          |
| Birth Length cm     | UCLP       | 22 | 43.000 | 6.8522        | 1.4609     | 39.962 - 46.038                  | 20.00   | 54.00   | 0.018     | 3 > 1, 2 |
|                     | ICP        | 10 | 44.850 | 4.3910        | 1.3885     | 41.709 - 47.991                  | 38.00   | 53.00   | 0.019     | 2 > 1, 3 |
|                     | BCLP       | 12 | 49.083 | 3.9418        | 1.1379     | 46.579 - 51.588                  | 44.00   | 55.00   | 0.019     |          |
| Head Length cm      | UCLP       | 22 | 17.705 | 2.5850        | 0.5511     | 16.558 - 18.851                  | 9.00    | 24.00   | 0.019     | 2 > 1, 3 |
|                     | ICP        | 10 | 22.500 | 7.7172        | 2.4404     | 16.979 - 28.021                  | 15.00   | 33.50   | 0.038     | 2 < 3, 1 |
|                     | BCLP       | 12 | 19.000 | 2.4863        | 0.7177     | 17.420 - 20.580                  | 17.00   | 24.00   | 0.038     |          |
| Head circumference cm| UCLP       | 22 | 31.695 | 4.3515        | 0.9277     | 29.766 - 33.625                  | 14.00   | 36.00   | 0.038     | 1 > 3 > 2 |
|                     | ICP        | 10 | 27.300 | 6.9290        | 2.1911     | 22.343 - 32.257                  | 16.00   | 32.00   | 0.038     |          |
|                     | BCLP       | 12 | 32.250 | 3.3337        | 0.9624     | 30.132 - 34.368                  | 26.00   | 36.00   | 0.038     |          |
| ICW mm              | UCLP       | 22 | 30.8782| 5.44867       | 1.16166    | 28.4624 - 33.2940                | 18.00   | 38.00   | <0.001    | 1 > 3 > 2 |
|                     | ICP        | 10 | 23.6920| 2.12724       | 0.67269    | 22.1703 - 25.2137                | 20.88   | 26.00   | <0.001    |          |
|                     | BCLP       | 12 | 28.7092| 1.98762       | 0.53738    | 27.4463 - 29.9720                | 25.07   | 32.52   | <0.001    |          |
| ITW mm              | UCLP       | 22 | 32.0845| 5.56885       | 1.18728    | 29.6155 - 34.5536                | 20.00   | 41.60   | <0.001    | 3, 1 > 2 |
|                     | ICP        | 10 | 26.5050| 1.72657       | 0.54599    | 25.2699 - 27.7401                | 24.00   | 29.00   | <0.001    |          |
|                     | BCLP       | 12 | 33.0975| 2.29046       | 0.66120    | 31.6422 - 34.5528                | 27.82   | 35.68   | <0.001    |          |
| Arch Length mm      | UCLP       | 22 | 24.6123| 2.61028       | 0.55651    | 23.4549 - 25.7696                | 18.00   | 30.00   | <0.001    | 3, 1 > 2 |
|                     | ICP        | 10 | 21.7470| 2.71107       | 0.85732    | 19.8076 - 23.6864                | 18.00   | 28.00   | <0.001    |          |
|                     | BCLP       | 12 | 37.3342| 5.22381       | 1.50798    | 34.0151 - 40.6532                | 33.00   | 48.27   | <0.001    |          |
| Arch Circumference mm| UCLP       | 22 | 56.545 | 8.3264        | 1.7859     | 54.832 - 62.259                  | 47.00   | 77.00   | <0.001    | 1, 2 > 3 |
|                     | ICP        | 10 | 53.300 | 6.7931        | 2.1450     | 48.448 - 58.152                  | 46.00   | 68.00   | <0.001    |          |
|                     | BCLP       | 12 | 60.750 | 0.9653        | 0.2787     | 60.137 - 61.363                  | 60.00   | 62.00   | <0.001    |          |

ICW, Inter-canine width; ITW, Inter-tuberosity width; * Statistical Significance, $p < 0.05$.

The head length was found to be significantly higher among neonates with ICP as compared to the ones with UCLP and BCLP ($p = 0.019$), whereas the head circumference was found to be maximum among neonates with BCLP, marking a significant difference as compared to neonates with ICP ($p = 0.038$). The inter-canine width was found to be significantly greater among neonates with UCLP whereas intertuberosity width, arch length, and arch circumference was seen the highest among neonates with BCLP ($p < 0.050$) (Table 4).

4. Discussion

A hospital-based study was conducted on 88 neonates with cleft and non-cleft neonates aged between 0 to 30 days. Neonate’s anthropometric and physiological parameters, birth weight, birth length, head circumference, head length, along with maxillary arch dimensions on dental model were analysed. The standardized methods were followed to record the variables by an experienced operator. Significant differences were seen in the birth weight, head length, and head circumference of the clefts and non-clefts neonates.
Birth weight, head length, and head circumference were found to be larger among non-cleft neonates whereas birth length did not vary among the two groups. All recorded maxillary arch anthropometric parameters were found to be statistically significant between the cleft and non-cleft group.

The birth weight is an important physiologic parameter in neonates which reflects the general health of the newly born child. Villar et al. reported that the average birth weight (2.9 ± 0.4 kg) among healthy neonates in India was less than their counterparts in other races, which is in good agreement with our study for non-cleft neonates [14]. Birth weight (2.4 ± 0.5 kg), head length (19.1 ± 4.5 cm) and head circumference (30.8 ± 5 cm) were found significantly decreased in cleft neonates. These findings coincides with the studies by Marques et al., Bowers et al., Felix et al., and Cunningham et al. [15–18]. Although the fact that Seth and Maxwell demonstrated was that there were no differences between the two groups [19]. No statistically significant differences were found for the birth length (Clefts- 45.0 ± 6.1 cm; Non Clefts 46.02 ± 2.2 cm). This finding is consistent with those of Jensen et al., Duncan et al., Rudman et al., and Ranalli and Mazaheri [6,20–22]. Marques et al. found that there is a strong significant correlation between the birth weight, length, and head circumference, and he reported that it was most compromised in cleft neonates in order of birth weight followed by birth length and head circumference [15], which are consistent with our results except for birth length. The etiological factors of the smaller body stature at birth in cleft neonates were proposed by various authors previously [23,24]. These multiple factors can be due to the reduction in sex gonadotropin, anterior pituitary gland function, birth trauma, as well as in genetic, congenital, systematic, and reduced growth hormone prenatally [23,24].

The maxillary arch dimensions recorded in this study between the cleft and non-cleft were inter-canine width, inter-tuberosity width, arch length, and arch circumference. On performing statistical analyses, all of these maxillary arch variables were found significantly different between cleft and non-cleft neonates. Inter-canine width, inter-tuberosity width, and arch length were found to be significantly larger among cleft neonates whereas arch circumference was found to be significantly higher among non-cleft neonates.

The prenatal development of maxilla involves a closely integrated facial and perioral muscle attachment to the underline bone and leads to the formation of complex morphology of the complete palate. Any disruption in the development of the perioral and facial muscle attachment along with the associated skeletal component ultimately affects the dento-alveolar segment morphology. In a complete cleft lip and palate, there is a unilateral or bilateral non-union of palatal process with nasal septum at the prenatal age between 4 to 7 weeks which leads to the development of complete UCLP and BCLP, respectively. ICP is developed between the intrauterine ages of 8 to 12 weeks to non-union of the secondary palate. This creates an imbalance between the perioral musculature. There is an imbalance of forces due to discontinuity in the nasolabialis insertion, lateral buccinator pull, and other perioral groups of muscles. As result, the anteromedial rotation of the lesser segment and abnormal lateral pull of the greater segment occurs in UCLP. In BCLP, there is an anteromedial collapse of segments bilaterally with protruding the premaxillary complex. Collectively, this leads to increased transverse and anteroposterior dimensions of the maxillary gum pad in CLP neonates [25]. Our findings correlate favorably with the description stated by Markus et al. [25], also confirmed in previous findings by Mello et al. [26], Harila et al. [27], Lo et al. [28], and Honda et al. [14]. The present study is consistent with findings of da Silva et al. [29], who found that maxillary arch dimensions and morphology are distorted by the presence of the cleft.

In this study, the prevalence of BCLP, ICP, and UCLP was found to be 27.3%, 22.7%, and 50%, respectively, within the cleft neonates. Birth length was found to be significantly larger among BCLP neonates as compared to neonates with ICP and UCLP, whereas birth weight was found to be almost similar among three cleft subgroups (Table 4). The head length was found to be significantly larger among ICP neonates as compared to UCLP and BCLP neonates. The head circumference was found to be highest among BCLP neonates,
displaying a significant difference with ICP neonates. Inter-canine width was found to be significantly larger among neonates with UCLP (30.8 ± 5.4 mm) followed by BCLP (28.70 ± 1.9 mm) and ICP (23.69 ± 2.1 mm) neonates. These values are in good agreement with Mello et al. [26], Harila et al. [27], and Lo et al. [28], who all stated similar findings. The inter-tuberosity width, arch length, and arch circumference were the largest among neonates with BCLP within the cleft group. This concurs well with Lo et al. [28], and Honda et al. [14]. The dimensions of ICP were closer to the non-cleft group in this study (ICP; ICW 23.69 ± 2.1 mm; ITW 26.50 ± 1.7 mm; AC 53.30 ± 6.7 mm; AL 21.74 ± 2.7 mm).

4.1. Clinical Implication

Increased transverse width signifies the lateral displacement and divergence of the palatal shelves in cleft neonates. It may be attributed due to imbalanced forces in the perioral area [28]. The maxillary arch dimensions signifies the amount of tissue deficiency present in cleft neonates. In the present study, larger tissue deficiency was found in UCLP and BCLP. The similar findings in Asian population were suggested previously by Honda et al. [14]. These findings suggest that initial documentation of tissue deficiency may help in the sequential management to minimize scar formation and to provide a positive environment for the growth of maxilla. Although it is multifactorial, the iatrogenic factors can be limited cautiously with the knowledge of these dimensions. The amount of deformity and tissue deficiency helps in treatment planning and decision making to cleft team clinicians. The larger the defect, the more caution that is required for the stability of interventions, such as cheiloplasty, palatoplasty, etc., at different age groups, to plan long-term rehabilitation accordingly. Mutuality and reciprocity between surgeon, clinicians, and health care workers is recommended for good collaboration.

A simple impression technique can provide a true replica of cleft deformity in toto. It is a crucial advantage for maxillary arch assessment at birth in our study [14,30–32]. It is cost-effective for the maintenance of initial records for collaborative and decision-making purposes at cleft centers. The other alternatives of dental plaster models used were two dimensional photographs [33] scanned digital models [34,35] and, most recently, intraoral scanners [36,37]. The digital models are beneficial but there is always the added cost of sophisticated desktop and intraoral scanners. A manual measurement of maxillary cast by experienced and trained operators is a viable option to record maintenance in developing countries with poor resources.

4.2. Limitation

There are two limitations of our study. The first one is that it was a hospital-based study, and only the cleft neonates who reported to our hospital were recruited in this study. It may not include the neonates who were referred to some other cleft center. However, this center is a centralized tertiary care center so the majority of cleft neonates are referred here for the needful management. The other limitation was the sample size of the cleft subgroups; however, it was a secondary finding of this study. Furthermore, from the results of these subgroups, a clear pattern has emerged regarding the neonates reported to a hospital; this would help in tailoring the individualized presurgical orthopaedic and surgical management with long-term follow-up. In addition, the collected records would help in establishing the baseline data for disease burden and pattern. This could be utilized for hospital administrative purposes by administrators for an efficient regional cleft care program.

5. Conclusions

Cleft neonates, compared to non-cleft neonates, had significant anthropometric and physiologic variations.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/children8100893/s1, Figure S1: Maxillary Arch Study model. (A) Non-cleft; (B) Unilateral
cleft lip and/or palate; (C) Isolated cleft palate; and (D) Bilateral cleft lip and/or palate. Figure S2: Diagrammatic representation of birth weight measurement in neonates.

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**Institutional Review Board Statement:** The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of GOVERNMENT DENTAL COLLEGE AND HOSPITAL, AHMEDABAD (APRIL2014/31).

**Informed Consent Statement:** Informed consent was obtained from all parents of minor subjects involved in the study.

**Data Availability Statement:** Anonymized data are available on request from the corresponding author with permission of the participants in the study. The data presented in this study are not publicly available due to ethical reasons (to protect the privacy of participants).

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