# DEVELOPING SEVERITY CLASSIFICATION OF CLEFT LIP NOSE ANATOMICAL DEFORMITY IN MALAYSIAN POPULATION. A MULTICENTER STUDY

*BY*

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## TABLE OF CONTENTS

**CHAPTER 4: STUDY PROTOCOL**



**CHAPTER 5: APPENDICES**

**ABSTRAK**

**Pengenalan:**

Keterukan kecacatan sumbing bibir dan hidung unilateral primer dihipotesiskan mempunyai kesan yang ketara ke atas komplikasi selepas pembedahan, hasil kosmetik, dan keperluan untuk pembedahan tambahan. Masih belum ada sistem yang mapan dan diiktiraf lagi untuk mengklasifikasikan keterukan kecacatan sumbing bibir dan hidung unilateral primer. Matlamat kajian ini adalah untuk mengesahkan Skala Penilaian Kecacatan Hidung yang dicipta adalah alat objektif yang boleh dipercayai untuk menilai kecacatan sumbing bibir dan hidung unilateral primer praoperasi dan hasil pembaikan terhadap pesakit bibir sumbing oleh kedua-dua pakar bedah dan pegawai perubatan.

**Metodologi:**

Sistem penarafan berdasarkan tiga pembolehubah kecacatan hidung yang merangkumi nisbah simetri muka alar, nisbah lebar lubang hidung dan sudut kolumel telah dicipta oleh kami. Kami menambah hasil pengukuran individu ke dalam jumlah skor minimum 3 dan maksimum 9. Skor keterukan dikelaskan kepada ringan, sederhana dan teruk, manakala pesakit pasca operatif dikelaskan kepada cemerlang, baik dan sederhana.

Enam peserta (3 pakar bedah plastik perunding dan 3 pegawai perubatan pembedahan plastik) telah menilai 50 set gambar dua dan tiga dimensi (2D dan 3D) piawai praoperasi bagi pesakit yang mengalami kecacatan sumbing bibir dan hidung unilateral primer. Setiap peserta telah diambil ukuran beza ketinggian lekuk alar-fascial, panjang hidung, lebar lubang hidung dan sudut kolumel. Berdasarkan ukuran, nisbah simetri muka alar, nisbah lebar lubang hidung dan sudut kolumel dikira dan diberi skor pada skala 1–3

menggunakan Skala Penilaian Kecacatan Hidung. Pekali korelasi intrakelas digunakan untuk mengukur kebolehpercayaan “interrater” pakar bedah dan pegawai perubatan. Keputusan perbandingan nisbah antara pakar bedah dan pengawai perubatan untuk penilaian pra operasi dan pasca operasi telah dianalisis.

**Keputusan:**

Kebolehpercayaan interrater untuk semua pembolehubah dikelaskan sebagai "baik" yang ditentukan oleh nilai pekali korelasi intrakelas berjulat dari 0.64 (baik) hingga 0.79 (cemerlang) untuk semua peserta dan kedua-dua gambar khusus 2D dan 3D ($p<0.05$). Penemuan ini menunjukkan tahap interrater yang tinggi antara pakar bedah dan pengawai perubatan dan kedua-duanya boleh menilai keterukan sumbing dengan pasti menggunakan Skala Penilaian Kecacatan Hidung.

**Kesimpulan:**

Kajian ini menunjukkan Skala Penilaian Kecacatan Hidung sebagai alat objektif yang teguh untuk menilai tahap keterukan praoperasi kecacatan anatomi bibir sumbing dan hidung pada individu mengalami kecacatan sumbing bibir dan hidung unilateral primer. Oleh itu, Skala Penilaian Kecacatan Hidung ini boleh digunakan untuk mengklasifikasikan individu yang mengalami kecacatan sumbing bibir dan hidung unilateral primer dan untuk mengkategorikan mereka untuk hasil kajian masa hadapan.

## ABSTRACT

### Introduction

The primary unilateral cleft lip/nose (UCL/N) anatomical deformity severity is hypothesized to have a significant impact on post-surgical complications, cosmetic outcome, and the necessity for additional surgery. There is no established and commonly recognized system for classifying the severity of primary UCL/N anatomical deformity. The goal of this study is to verify the Nasal Deformity Rating Scale created is a reliable objective tool for assessing preoperative UCL/N anatomical deformity and repair outcome in cleft lip patients by both surgeons and plastic surgery residents.

### Method

A rating system based on three variables of nasal deformity, which includes alar facial symmetry ratio, nostril width ratio, and columellar angle, is developed. We add the individual measurement results into a total score of minimum 3 and maximum 9. Severity score is classified into mild, moderate, and severe, while postoperative patients are classified into excellent, good, and fair. Six participants (3 consultant plastic surgeons and 3 plastic surgery residents) had assessed 50 sets of preoperative standardized two- and three-dimensional photographs of UCL/N patients. Each participant had been taken measurements of difference of the alar facial grooves, nasal length, nostril widths, and columellar angle. Based on the measurement, the alar facial symmetry ratio, nostril width ratio, and columellar angle were calculated and scored on a scale of 1–3 using the Nasal Deformity Rating Scale developed. The intraclass correlation coefficient was used to measure the interrater reliability of surgeons and residents. The results of ratio comparisons between surgeons and residents for preoperative and postoperative

assessments were analyzed.

**Results**

Interrater reliability for all variable was classified as "good" determined by intraclass correlation coefficients value ranged from 0.64 (good) to 0.79 (excellent) for all participants and both 2D and 3D specific photographs ($p<0.05$). These findings demonstrate a high degree of interrater between surgeons and residents and that both can reliably grade cleft lip nasal anatomical severity using the Nasal Deformity Rating Scale.

**Conclusion**

This study establishes the Nasal Deformity Rating Scale as a robust objective tool for assessing the degree of preoperative severity of cleft lip and nose anatomical deformity in individuals with UCL/N. Thus, the Nasal Deformity Rating Scale can be used to classify individuals with primary UCL/N deformity and to categorize them for future outcome studies.

# CHAPTER 1

# INTRODUCTION

## 1.1 INTRODUCTION

Cleft lip and palate are one of the most frequently occurring congenital craniofacial defects. It has a prevalence rate of 1:700 (1). In less than 20% of patients, it is an isolated cleft lip, whereas 50% have a combined cleft lip and palate (2). This deformity occurs in a very conspicuous part of the body, necessitating adequate aesthetic as well as functional outcome after surgery (3). The various anatomical anomaly and unesthetic postoperative deformity may cause psychosocial problems and discrimination when not treated adequately (4). Even after surgical intervention, patients' appearances may remain unsatisfactory due to scarring, insufficient correction, and other factors (4).

Human judgement is a reliable method for evaluating facial aesthetics. Numerous studies have been conducted to produce aesthetic scales for evaluating appearance that have been agreed upon by persons of varying ages, genders, and cultures (5). The Visual Analogue Scale, a five-point ordinal scale, a standard clinical assessment, a photograph assessment, and three-dimensional imaging are all instances of subjective evaluation techniques (3, 4, 6, 7). Numerous researches have been conducted to evaluate face landmarks derived using an electromagnetic digitizer (8). However, methods for objective evaluation remain restricted. Therefore, we developed a nasal deformity grading scale to provide a simple and accurate tool for assessing the severity of deformity and repair outcome in individuals with cleft lip.

The primary purpose of correcting craniofacial defects, including cleft lip and palate, is to enhance the patient's facial aesthetic appearance and hence his or her acceptability in society (5). As the most prominent feature of the face, the nose's appearance is a critical

factor in determining anatomical deformity and surgical result. The ultimate goal of cleft surgery is to minimize the deformities caused by the cleft. This deformity is the primary source of stigma for patients and the most noted aspect by society (6). The severity and prognosis of cleft lip and palate patients are substantially connected with attractiveness ratings (5). There is currently no universal agreement on a system for evaluating cleft aesthetics. Future rating systems should include a significant number of patients to provide sufficient evidence, as well as age, race, gender, and cleft type matching. There should be sufficient inter- and intrarater reliability, repeatability, and reproducibility, similar between assessors (lay vs professional), allowing comparison of cleft units, and maybe a patient-reported result for a thorough aesthetic evaluation (9).

Postoperative result should also be evaluated by taking preoperative anatomical deformity into account. This necessitates the development of a standardized procedure for assessing pre- and postoperative clinical appearance. This enables us to determine if the abnormalities are the result of the malformation, iatrogenic events, or inadequate repair (10).

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# CHAPTER 2

# OBJECTIVE OF STUDY

## 2.1 GENERAL OBJECTIVE

To provide an objective assessment tool to evaluate the deformity severity and surgical outcome of cleft lip nasal area.

## 2.2 SPECIFIC OBJECTIVE

2.2.1 To compare a preoperative assessment of alar facial symmetry, nostril width and columellar angle on cleft lip patients measured by plastic surgeons and plastic surgery residents.

2.2.2 To compare a post-operative assessment of alar facial symmetry, nostril width and columellar angle on cleft lip patients measured by plastic surgeons and plastic surgery residents.

2.2.3 To compare the good interrater agreement between plastic surgery residents and consultants in evaluating cleft lip nasal deformity using the Nasal Deformity Rating Scale on 2D and 3D photograph

# CHAPTER 3

## MANUSCRIPT

## (THE CLEFT PALATE-CRANIOFACIAL JOURNAL)

## 3.1 TITLE PAGE

# DEVELOPING SEVERITY CLASSIFICATION OF CLEFT LIP NOSE ANATOMICAL DEFORMITY IN MALAYSIAN POPULATION. A MULTICENTER STUDY

**Selected journal:**

The Cleft Palate-Craniofacial Journal

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Keywords: cleft lip; cleft lip nasal deformity; severity classification of cleft lip; unilateral cleft lip

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## 3.2 ABSTRACT


### Introduction

The primary unilateral cleft lip/nose (UCL/N) anatomical deformity severity is hypothesized to have a significant impact on post-surgical complications, cosmetic outcome, and the necessity for additional surgery. There is no established and commonly recognized system for classifying the anatomical severity of primary UCL/N. The goal of this study is to verify the Nasal Deformity Rating Scale created is a reliable objective tool for assessing preoperative UCL/N anatomical deformity and repair outcome in cleft lip patients by both surgeons and plastic surgery residents.

### Method

A rating system based on three variables of nasal deformity, which includes alar facial symmetry ratio, nostril width ratio, and columellar angle, was developed. We add the individual measurement results into a total score of minimum 3 and maximum 9. Severity score is classified into mild, moderate, and severe, while postoperative patients are classified into excellent, good, and fair. Six participants (3 consultant plastic surgeons and 3 plastic surgery residents) assessed 50 sets of preoperative standardized two- and three-dimensional photographs of UCL/N patients. Each participant took measurements of difference of the alar facial grooves, nasal length, nostril widths, and columellar angle. Based on the measurement, the alar facial symmetry ratio, nostril width ratio, and columellar angle are calculated and scored on a scale of 1–3 using the Nasal Deformity Rating Scale. The intraclass correlation coefficient was used to measure the interrater reliability of surgeons and residents. The results of ratio comparisons between surgeons and residents for preoperative and postoperative assessments were analyzed.

**Results**

There was no significant mean difference of ratio measurements for 2D and 3D pictures rated by the surgeons and residents for both preoperative and postoperative assessments ($p > 0.05$). Interrater reliability for all variable was classified as "good" determined by intraclass correlation coefficients value ranged from 0.64 (good) to 0.79 (excellent) for all participants and both 2D and 3D specific photographs ($p < 0.05$). These findings demonstrate a high degree of interrater between surgeons and residents and that both can reliably grade cleft anatomical severity using the Nasal Deformity Rating Scale.

**Conclusion**

This study establishes the Nasal Deformity Rating Scale as a robust objective instrument for assessing the degree of preoperative severity of cleft lip and nose anatomical deformity in individuals with UCL/N. Thus, the Nasal Deformity Rating Scale can be used to classify individuals with primary UCL/N deformity and to categorize them for future outcome studies.

Keywords: Cleft lip / Cleft lip severity classification/ cleft lip nose deformity/ primary cleft lip classification.

## 3.3 INTRODUCTION

It has been proven that the eventual success of cleft lip surgery is impacted by the surgeon's expertise, patient load, and service organization (1). The severity of the primary unilateral cleft lip nasal anatomical deformity has also been regarded as a significant predictor of the final look of the lip and nose following correction, as well as a vital factor in postoperative outcomes such as aesthetic result, complications, and the need for additional surgery. Fisher notes in his exquisite paper on the correlation of objective measures and the severity of the cleft lip deformity, "The eventual look of the lip and nose is governed by a variety of factors; nevertheless, the key determinant is the degree of the primary abnormality." Thus, any outcome research requires a permanent record of the initial anatomical abnormality.

While categorization methods exist to describe the degree of cleft involvement, there is no universally acknowledged standard for determining the initial anatomical severity of the cleft and standard measurement to categorize the outcome of surgical repair. Numerous publications in the literature try to define the gradual phenotypic manifestation of cleft deformity, but there has been no widely recognized classification method for grading preoperative anatomical severity, and no recognized classification scheme is appropriate for examining outcomes (2-5).

The development of a standardized objective tool would enable multicenter collaboration and outcome comparison. Although several attempts have been made to develop a standardized evaluation tool, the approaches offered to date have varied significantly in terms of research design, patient demographic, treatment stage, kind of cleft, evaluators'

expertise, and familiarity with the patients and approaches. As a result, a large number of these tools have failed to provide reproducible results or high levels of inter-rater reliability. Thus, the effect of initial cleft severity on end outcomes is mainly unknown.

A scoring system for nasal deformity is established based on three variables: alar facial symmetry ratio, nostril width ratio, and columellar angle. These three variables are employed because they are readily available and easy to test on a patient, either directly or indirectly via photographs of the patient. Due to the varying distances from which the photographs were taken, we use ratios rather than direct measurements for the first and second variables. We aggregate the findings of each measurement to arrive at a total score of between 3 and 9. Initial anatomical severity score is classified into mild, moderate, and severe, while postoperative patients are classified into excellent, good, and fair (Table 1).

Table 1. Nasal Deformity Rating Scale. Total score ranges from 3 to 9.

| **Variable** | **Score** |
|---|---|
| Alar facial symmetry ratio | Mild (0.01-0.05) = 3<br>Moderate (0.05-0.10) = 2<br>Severe (>0.10) = 1 |
| Nostril width ratio | Mild (0.90-1.10) = 3<br>Moderate (0.60-0.89; 1.11-1.40) = 2<br>Severe (<0.60; >1.40) = 1 |
| Columellar angle | Mild (1-15) = 3<br>Moderate (16-30) = 2<br>Severe (>30) = 1 |

The goal of this blinded, prospective study was to verify the Nasal deformity rating scale as a credible tool in providing an objective assessment tool to evaluate the deformity severity and surgical outcome of cleft lip nasal area through 3 specific aims:

1. To determine if experienced plastic surgeons can use the Nasal Deformity Rating Scale to reliably grade the degree of cleft lip anatomical deformity.
2. To determine if plastic surgery residents can use the Nasal Deformity Rating Scale to reliably grade the degree of cleft lip anatomical deformity.
3. To determine the degree to which surgeons and medical residents grade cleft lip nasal anatomical deformity equally while utilizing the Nasal Deformity Rating Scale.

## 3.4 MATERIALS AND METHOD

### Subjects

All study subjects were recruited from patients admitted for primary cheiloplasty between 2014 and 2022 at Pusat Pengajian Sains Perubatan, Health Campus, Universiti Sains Malaysia, Hospital Raja Perempuan Zainab II, Kelantan, and Hospital Kuala Lumpur, Malaysia. All patients' parents or guardians signed an informed permission form authorizing the research team to use their medical records and images. The institutional review board approved all required paperwork and signatures. This study is registered with Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM), study protocol code USM / JEPeM / 20070388.

One full-time photographer captured standardized basal and frontal presurgical and post-operative photographs with a Huawei digital phone camera for 2D photographs and Occipital's Structure Sensor Mark II for 3D photographs. Patients with unilateral cleft lip with or without associated alveolar or palate cleft were included. Patient with prior surgeries, known congenital syndromes, or other craniofacial abnormalities were excluded as exclusion criteria. From this group, 50 sets of 2D pre- and post-operative photographs, as well as 50 pre- (5 excluded) and 30 post-operative (3 excluded) 3D photographs, were randomly selected and deidentified. Photographs were cropped according to the standard nasal view: superior margin above the eyebrows and inferior margin at the upper lip or the junction between closed lips to eliminate the portion of the face or body that was not affected by the cleft (Figure 1 and 2). Each photograph was cropped to a consistent length and width. Due to poor quality, eight 3D photographs were eliminated. All photographs were color printed on standard A4 paper.

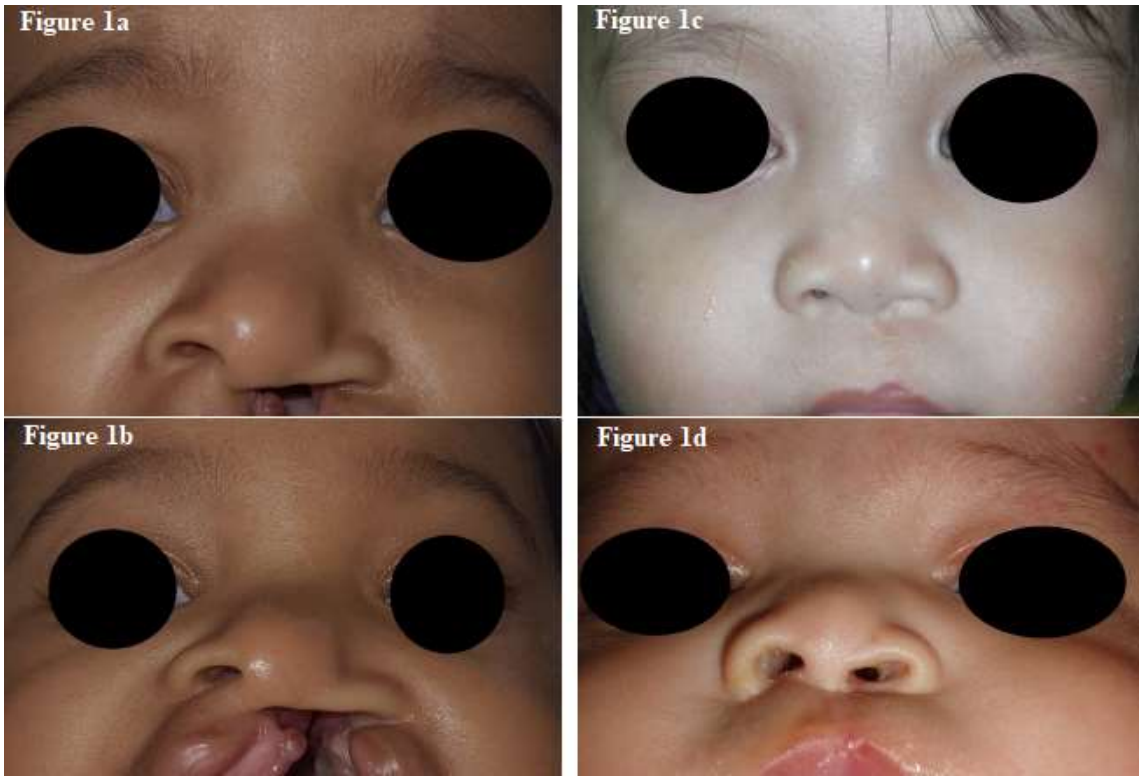

Figure 1: 2D Preoperative (1a and 1b) and postoperative (1c and 1d) photograph

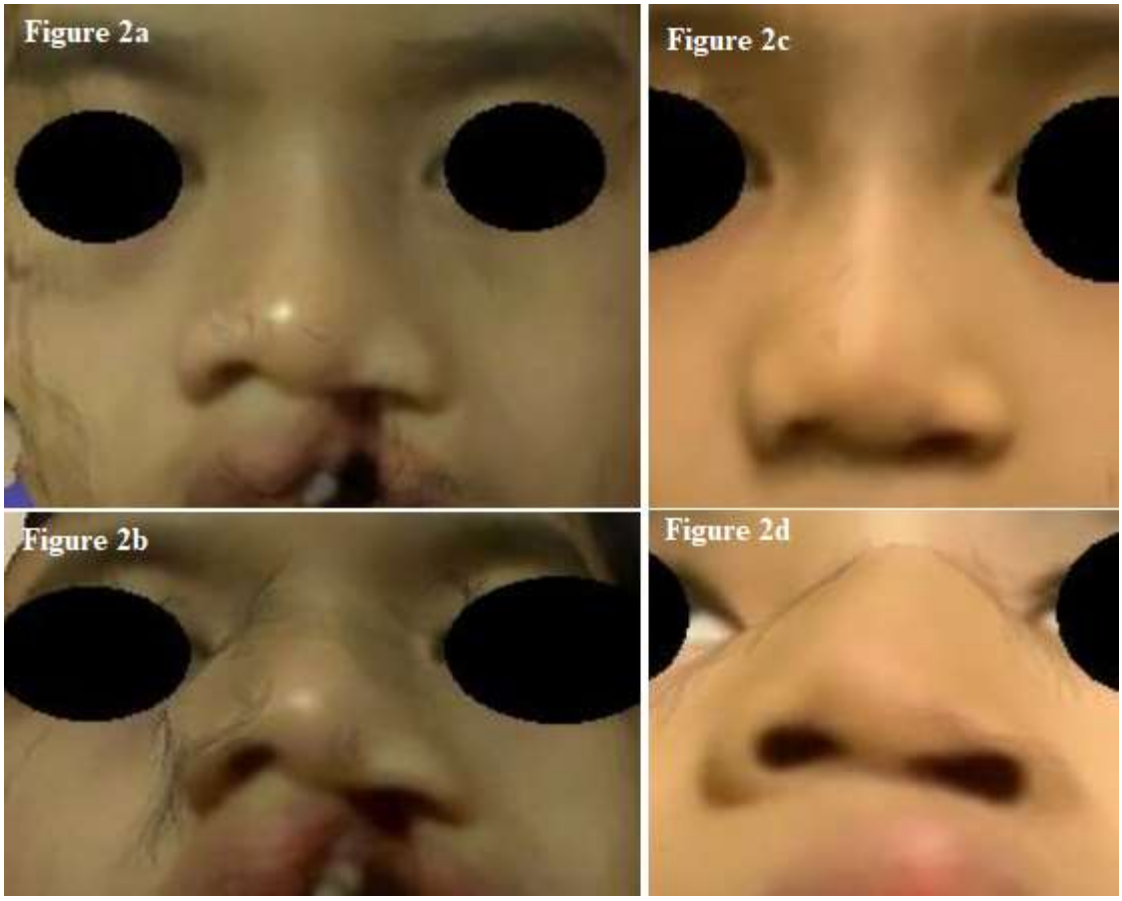

Figure 2: 3D Preoperative (2a and 2b) and postoperative (2c and 2d) photograph

**Assessors**

Two sets of assessors from each centre; Pusat Pengajian Sains Perubatan, Health Campus, Universiti Sains Malaysia, Hospital Raja Perempuan Zainab II, Kelantan, and Hospital Kuala Lumpur, Malaysia were recruited to participate in the study. Assessors were between the ages of 30 and 60. The first group comprised of three very skilled plastic surgeons. All surgeons are board certified in plastic surgery and have substantial experience with cleft lip and palate correction. The second group consist of three plastic surgery residents in their third semester or higher and have assisted on at least five cleft lip repair surgeries.

**Assessment**

All participants were given sets of standardized photographs, textual and video instructions on variable measurements, and operational definitions. Participants measured the pre- and postoperative vertical gap of alar facial grooves, nasal length, right and left nostril width and columella angle on each set of photographs using the instructions and the operational definition, and they recorded their findings in the data collection form adjacent to each set of photographs (Figure 3a and 3b). (Refer Appendix A for data collection form).

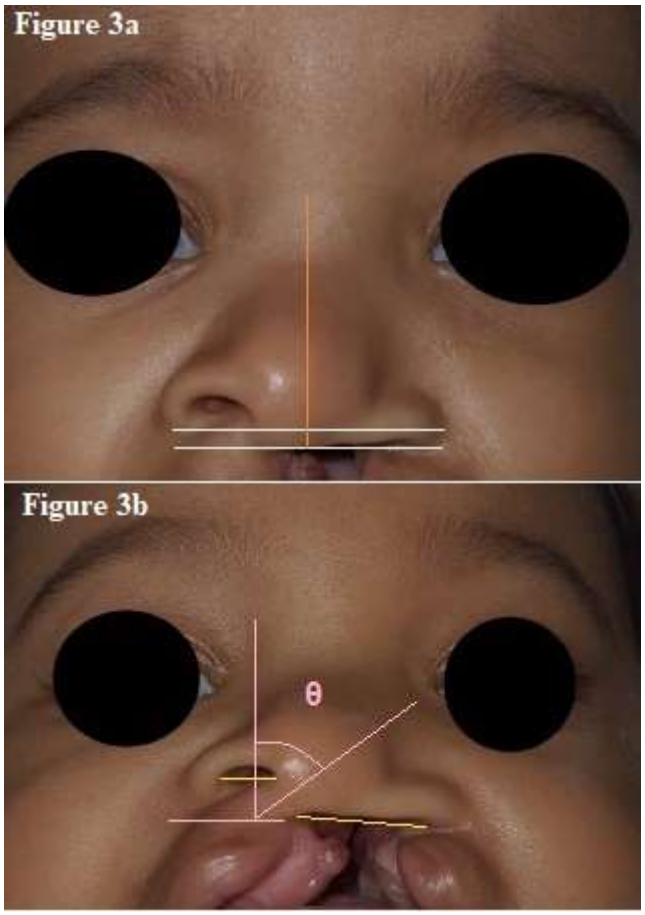


Figure 3a and 3b: The vertical gap of alar facial grooves is the vertical distance between the shown white lines, nasal length is the length of vertical line connecting the horizontal line which crosses the lower alar base to the nasion shown as orange line in the frontal view photograph, right and left nostril width is distance between the most medial and lateral border of the nostril measured on submental view (yellow lines) and columella angle (θ) is measured on the submental view shown in pink lines.

The data were kept strictly confidential and strictly stored in a secure location that is only accessible by the research team and will not be shared with any regulatory body.

**Statistical Analysis**

All statistical analyses were performed using the SPSS version 24 (SPSS 24, SPSS, Inc., USA). Statistical significance was defined as $P < 0.05$. Comparison ratio measurements between surgeon and residents for preoperative and postoperative assessments were analyzed. Interrater reliability was determined by calculating the intraclass correlation coefficients (ICCs) for both groups combined for each variables measured. This show whether the rating scale have good, moderate, poor interrater reliability.

ICCs were then evaluated using the scale developed by Cicchetti (1994)(7), which categorizes ICCs of <0.40 as poor, 0.40-0.59 as fair, 0.60-0.74 as good and 0.75-1.00 as excellent strength of agreement (Table No. 2).

Table No. 2: ICC value interpretation according to Cicchetti (1994).

| ICC Value | Strength of Agreement |
|---|---|
| < 0.40 | Poor |
| 0.40-0.59 | Fair |
| 0.60-0.74 | Good |
| 0.75-1.00 | Excellent |

The criteria for validation of the ICC value were by the number of sample size. According to Bujang (6), using the following formula:

$$n = 1 + \frac{2\,(Z_\alpha + Z_\beta)^2 k}{(\ell n\, C_0)^2 (k-1)}$$

$$C_0 = \frac{1 + k\theta_0}{1 + k\theta_1}$$

$$\theta_0 = \frac{R_0}{1 - R_0} \quad ; \quad \theta_1 = \frac{R_1}{1 - R_1}$$

The number of rater is denoted as (k), and it can range between 2 to 10. Six assessors would give good ICC value with the power=80% and 90% (Table 3). Statistical significance was determined using P value < 0.05.

Table No. 3. Six assessors would give good ICC value with the power =80% and 90%

| Observation per Subject | ICC | Number of subjects (power=80%) | Number of subjects (power=90%) |
|---|---|---|---|
| 6 | 0.6 | 4 | 6 |
| | 0.7 | 4 | 5 |
| | 0.8 | 3 | 4 |
| | 0.9 | 3 | 3 |

## 3.5 RESULTS

Plastic surgeons and residents used the Nasal Deformity Rating Scale to rate the anatomical severity of cleft lip deformities in this study. ICCs are used to measure interrater reliability, or the degree of agreement between assessors when evaluating a subject.

A total of 6 assessors (3 residents and 3 surgeons) were recruited for this study. The data obtained was expressed as mean and standard deviation (SD) for numerical variables as tabulated in Table 4.

Table 4: Descriptive statistics of preoperative and postoperative measurements by the assessors expressed as the mean (standard deviation)

| Variables | Surgeon Mean (SD) | Resident Mean (SD) | p-value |
|---|---|---|---|
| Vertical gap of alar facial grooves (preoperative) | 2.85(1.54) | 3.10(1.73) | 0.271 |
| Nasal length (preoperative) | 44.10(9.18) | 43.76(9.15) | 0.827 |
| Right nostril width (preoperative) | 12.45(6.44) | 13.01(5.48) | 0.511 |
| Left nostril width (preoperative) | 17.46(8.44) | 17.80(7.84) | 0.769 |
| Columella angle (preoperative) | 34.34(10.74) | 35.19(13.24) | 0.624 |
| Vertical gap of alar facial grooves (postoperative) | 1.28(0.81) | 1.63(0.97) | 0.014 |
| Nasal length (postoperative) | 53.31(8.90) | 53.28(8.85) | >0.950 |
| Right nostril width (postoperative) | 12.11(2.93) | 12.91(3.34) | 0.111 |
| Left nostril width (postoperative) | 13.74(3.70) | 14.40(3.91) | 0.277 |
| Columella angle (postoperative) | 12.13(7.75) | 14.67(8.15) | 0.046 |

The result revealed that there was no significant mean difference of related variables between the surgeons and residents except for postoperative vertical gap of alar facial grooves (p=0.014) and columella angle (p=0.046). Residents have higher mean of both variables compared to surgeon. However, there was no significant mean difference of ratio measurements for 2D and 3D pictures rated by the surgeons and residents for both preoperative and postoperative assessments (p >0.05). This shows that the ratings were similar between the rater involved (Table 5 and 6).

Table 5: Comparison ratio measurements between surgeon and residents for preoperative assessments result.

| Dimension | Variables | P Surgeon Mean(SD) | P Resident Mean (SD) | Mean difference (95% CI) | P value |
|---|---|---|---|---|---|
| 2D | Ratio A/B | 2.34(0.63) | 2.28(0.64) | 0.06(-0.19,0.31) | 0.637 |
| | Ratio C/D | 1.18(0.39) | 1.36(0.56) | -0.18(-0.37,0.01) | 0.066 |
| | Columella angle | 1.44(0.64) | 1.50(0.71) | -0.06(-0.33,0.21) | 0.658 |
| 3D | Ratio A/B | 2.04(0.72) | 1.96(0.75) | 0.09(-0.22,0.39) | 0.576 |
| | Ratio C/D | 1.26(0.44) | 1.30(0.51) | -0.04(-0.24,0.15) | 0.665 |
| | Columella angle | 1.40(0.54) | 1.45(0.65) | -0.04(-0.29,0.20) | 0.731 |

Table 6: Comparison ratio measurements between surgeon and residents for postoperative assessment result.

| Dimension | Variables | P Surgeon Mean (SD) | P Resident Mean (SD) | Mean difference (95% CI) | P value |
|---|---|---|---|---|---|
| 2D | Ratio A/B | 2.92(0.27) | 2.90(0.30) | 0.02(-0.09,0.13) | 0.730 |
| | Ratio C/D | 2.26(0.56) | 2.20(0.49) | 0.06(-0.15,0.27) | 0.573 |
| | Columella angle | 2.76(0.43) | 2.66(0.48) | 0.10(-0.08,0.28) | 0.275 |
| 3D | Ratio A/B | 2.87(0.35) | 2.72(0.45) | 0.14(-0.07,0.35) | 0.180 |
| | Ratio C/D | 2.07(0.53) | 2.10(0.72) | -0.03(-0.37,0.30) | 0.837 |
| | Columella angle | 2.57(0.73) | 2.52(0.74) | 0.05(-0.33,0.43) | 0.797 |

There was significant agreement found between the surgeons and residents in both overall result and for each 2D and 3D specific pictures ($p<0.05$). All the agreement value ranged from 0.64 (good) to 0.79 (excellent) (Table 7).

Table 7: Intraclass correlation (ICC) for each variables measured.

| Dimension | Variables | ICC (95% CI) | P value |
|---|---|---|---|
| Overall | Ratio A/B | 0.73(0.40,0.71) | <0.001 |
| | Ratio C/D | 0.72(0.56,0.82) | <0.001 |
| | Columella Angle | 0.74(0.59,0.84) | <0.001 |
| 2D | Ratio A/B | 0.64(0.36,0.79) | <0.001 |
| | Ratio C/D | 0.69(0.44,0.83) | <0.001 |
| | Columella Angle | 0.72(0.50,0.84) | <0.001 |
| 3D | Ratio A/B | 0.79(0.37,0.82) | <0.001 |
| | Ratio C/D | 0.75(0.46,0.88) | <0.001 |
| | Columella Angle | 0.77(0.50,0.89) | <0.001 |

Three plastic surgeons and three residents evaluated two-dimensional photographs of 50 clefts, 45 preoperative three-dimensional photographs, and 27 postoperative three-dimensional photographs with varied degrees of anatomical severity. Overall ICC was 0.72-0.74. (Table 7). All agreement values ranged between 0.64 (good) to 0.79. (excellent). As previously stated, an ICC of 0.60-0.74 was regarded as good value, while an ICC of 0.75-1.00 was considered excellent value. Because the ICCs for all groups were greater than 0.60, our results showed that both residents and surgeons can accurately assess the anatomical severity of cleft lips nasal deformity preoperatively and postoperatively using the Nasal Deformity Rating Scale.

## 3.6 DISCUSSION

The World Health Organization (WHO) reports that orofacial cleft is the most frequent craniofacial birth deformity in the world, with a prevalence ranging from 3.4 to 22.9 per 10,000 births (8,9). Oral clefts are classified into three types: cleft lip alone (CL), cleft lip with or without cleft palate (CL/P), and cleft palate alone (CP). Shah et al. reported that unilateral CL/P was the most prevalent kind of orofacial cleft in Malaysia, accounting for 88.6 percent of Malays, 8.7 percent Chinese, 2.5 percent Indian, and 0.2 percent others (10). In contrast to other authors who found frequent occurrences on the left side, the right-side cleft was more prevalent in the Malaysian population.

Cleft surgery has been and continues to be the most significant and ongoing humanitarian surgical effort on a worldwide scale. The initial evaluation and documentation of primary anatomical deformity are very critical in determining the surgical result. The final result of a surgical correction is important in defining success. Moreover, monitoring and comparing outcomes is vital in developing best practices.

The aesthetic look of the lip and nose after cleft lip surgery is a critical component of the overall outcome. Numerous factors influence surgical results following cleft lip repair, and many debate that the severity of the primary deformity is the most crucial. Thus, surgical outcomes should be assessed taking the primary deformity into account. Unfortunately, to-date there is no universally accepted classification of cleft lip nasal anatomical severity, which makes comparisons of postoperative outcomes with preoperative anatomical deformity a difficult task. Hence, the creation of a standardized objective tool for assessing preoperative cleft severity is required to enable result

comparisons among surgeons, techniques, and institutions. A reliable objective assessment tool for the primary anatomical severity of cleft lip nasal deformity would aid in the proper assessment of postoperative results, and evaluate whether deformities are caused by the malformation itself, iatrogenic events, or insufficient repair as well as in refining techniques and providing better care to patients.

Human judgement is a reliable method for evaluating facial aesthetics. Numerous research has been conducted in order to develop aesthetic scales for rating looks that have been agreed upon by people of different ages, genders, and cultures (11). Subjective evaluation procedures include the Visual Analogue Scale, a five-point ordinal scale, a conventional clinical examination, an image assessment, and three-dimensional imaging (12-15). Numerous studies have been carried out to analyses face landmarks produced from an electromagnetic digitizer (16). Several publications in the literature attempt to characterize the gradual phenotypic manifestation of cleft deformity, but there is no commonly accepted measure of primary cleft severity and no well-established classification scheme for evaluating outcomes.

Millard noted the "classification challenge" of cleft lip, stating that "many systems have been offered but none have been universally accepted caused by language differences, inaccuracies, omissions, and lack of simplicity." (17) As a result, the potential impact of primary cleft severity on end outcomes is unmeasured and mostly unreported. Similarly, the degree of deformity has been proposed to play a role in surgical complications, albeit this is debatable and not supported by the literature. (18)

**The Nasal Deformity Rating Scale**

An ideal categorization system for severity of cleft lip and nose anatomical deformity would accurately describe the degree of the deformity in a way that is simple, reproducible, practical, and surgically applicable. Additionally, such a method would enable pertinent investigation of findings and outcomes by comparing various techniques on similar patient sample groups. It would also enable the creation of an analytical approach to correction, utilizing a series of operations tailored to the anatomic irregularities associated with given deformities.

In unilateral cleft lip patients, variable degrees of lip, nose, and skeletal base displacement and hypoplasia result in a progressive severity of dysmorphology. Increased degrees of deformity and separation of skeletal elements result in gradual malposition of the alar base and septum, leading to progressive nasal deformity caused by flattening and elongation of the nostrils, combined with downward deflection of the alar cartilage.

Fisher offered compelling evidence that expert surgeons can reliably evaluate patients based on their subjective assessments and that these subjective ratings correlate with objective anthropometric measurements. (19) He established the nostril width ratio and demonstrated that it varies linearly with unilateral cleft lip nasal deformity, suggesting that it may serve as an objective and independent indicator of severity. However, prior research comparing the abilities of laypeople and surgeons to serve as evaluators has shown inconsistent results. (20)

The Nasal Deformity Rating Scale is an objective tool that rates the severity of a unilateral cleft lip/nose anatomical deformity quickly and efficiently. It establishes standard rules

for assessing the overall look of the cleft lip nasal anatomical deformity and categorizes individuals UCL/N into three groups based on the anatomical severity of their primary deformity. Cleft lip and nose malformation are classified into mild, moderate and severe based on the anatomical severity of lip and nose involvement.

The ICCs for each group were the most noteworthy findings of this investigation. Scaling cleft nasal anatomical severity is only achievable if people constantly agree on how they rate severity. Significant agreement was observed between the surgeons and residents in both the overall result. Our findings show that there was "good to excellent" interrater reliability, as shown by ICCs ranging from 0.64 to 0.79 across all three groups, and that both surgeons and residents can reliably grade cleft lip nasal anatomical severity when utilizing the Nasal Deformity Rating Scale.

Individually and collectively, the findings of this study demonstrate that surgeons and residents rate photographs equally, demonstrating a high degree of correlation between responders both within and across categories. The ICCs and the comparison between ratio of photographs rated by the surgeons and residents in this study both indicate high levels of interrater reliability between individuals and among groups. This study successfully validates the Nasal Deformity Rating Scale as a valid and reliable objective tool for rating the anatomical severity of cleft lip nasal deformity in patients born with ULC/N. This is especially critical because competent surgeons are frequently unavailable to examine the severity of initial clefts and the post-surgical outcome for research purposes, particularly in resource-limited countries. We have repeatedly learnt this lesson, as dependence on surgeon ratings has been a significant impediment to developing and implementing an effective surgical outcomes system.