LONG-TERM NASOLABIAL OUTCOME AND PATIENT SATISFACTION POST UNILATERAL CLEFT LIP REPAIR IN PATIENTS AGED ABOVE 14 YEARS IN A SINGLE CENTER

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Dr. Muath Mamdouh Mahmod Al-Chalabi

TABLE OF CONTENTS

CHAPTER 3: BODY

CHAPTER 4: APPENDICES

LIST OF TABLES AND FIGURES

LIST OF ABBREVIATIONS

HUSM: Hospital Universiti Sains Malaysia

SPSS: Statistical Package for Social Science

n: Number

CLP: Cleft Lip and Palate

CLA: Cleft Lip and Alveolus

CL: Cleft Lip

SWA: Satisfaction with Appearance Scale

ABSTRAK

Objektif: Menilai hasil jangkamasa panjang penampilan nasolabial dan kepuasan pesakit yang pernah menjalani pembedahan pembaikan bibir dan lelangit sumbing unilateral dibawah unit sains rekonstruktif, dan kini berumur 14 tahun dan ke atas.

Rekabentuk kajian: Kajian keratan rentas secara retrospektif melibatkan data pesakit celah bibir dan lelangit unilateral.

Lokasi: Unit sains rekonstruktif di Hospital Universiti Sains Malaysia (HUSM) yang merupakan pusat pembedahan pembaikan bibir sumbing dan lelangit.

Populasi kajian: Semua pesakit yang menjalani pembedahan pembaikan bibir sumbing dan lelangit unilateral semasa dua tahun pertama kehidupan and kini berumur 14 tahun dan ke atas.

Dapatan Kajian: Sebanyak 50 rekod pesakit melibatkan 13 pesakit lelaki (26%) dan 37 pesakit perempuan (74%) telah dianalisa. Dua puluh lapan peratus pakar bedah dan pesakit berpendapat penampilan nasolabial adalah memuaskan. Tiada pengubahsuaian pembedahan atau komplikasi selepas pembedahan berlaku dalam kalangan pesakit. Terdapat hubungan yang signifikan antara komen pakar bedah dan kepuasan pesakit. Pakar bedah yang menilai penampilan nasolabial memuaskan mempunyai kebarangkalian yang lebih tinggi untuk pesakit melaporkan kepuasan yang sama.

Konklusi: Penilaian jangkamasa panjang penampilan nasolabial dalam individu yang mempunyai sumbing bibir dan lelangit selepas pembedahan akan mempengaruhi kepuasan pesakit. Kepuasan pesakit dicadang menjadi satu ukuran tambahan kepada penilaian pembedahan yang berjaya. Ukuran tambahan ini akan meningkatkan hasil pembedahan dan impak positif kepada psikologi pesakit klef.

ABSTRACT

Objective: To assess long-term nasolabial outcomes and patient satisfaction in patients who underwent unilateral cleft lip and palate repair surgery by reconstructive science unit and whose current age is 14 years or above.

Design: This is a retrospective cross-sectional study among unilateral cleft lip and palate patient data records.

Setting: The reconstructive science unit in the Hospital Universiti Sains Malaysia (HUSM).

Participants: All the patients who underwent unilateral cleft lip and palate repair by the reconstructive science unit within the first two years of their lives and whose current age is 14 years or above. Their data records were accessed and analyzed.

Results: The data records of 50 patients were analyzed, including 13 males (26%) and 37 females (74%). Twenty-eight percent of surgeons and patients opined the nasolabial appearance was satisfactory. There were no surgical modifications or post-operative complications among patients. There was a significant association between the surgeon's comment and the patient's satisfaction. Therefore, a surgeon's comment of acceptable nasolabial appearance has a higher chance of patients reporting satisfaction.

Conclusion: The long term evaluation of the nasolabial appearance in individuals with cleft lip and palate following surgical correction will show how satisfactory the surgical outcome was, thereby influencing patient satisfaction. In this study, we recommended evaluating patient satisfaction as the second measure of surgical success. All of these assessments will contribute to enhancing surgical results and the psychological effects on cleft patients.

CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

The cleft lip and palate is a congenital facial deformity malformation that affects both function and aesthetics due to an absence of union of the palatine processes throughout embryonic life. It is present in 1 in 700-1,100 births in the world[1-3] and is considered to be one of the common craniofacial anomalies.[4,5] However, the prevalence varies according to race/ethnicity, sex, and type of the cleft.[5] Clinically, the clefts can be found unilaterally or bilaterally, with unilateral clefts being the most frequent.[1] Usually, children born with cleft lip and palate undergo a series of corrective surgeries[6-8] within the first 24 months of life,[6] and this may be prolonged over many years.[7]

Typically, recommendations for lip repair were made by the plastic surgeon, and consultations occurred with the orthodontist and oral surgeon concerning the desired aesthetic consequences of the surgery and the need for, and timing of, bone grafting procedures if needed.[9] The Millard rotation advancement repair has remained the most preferred procedure among cleft surgeons ever since it was first described. However, most plastic surgeons use modified techniques.[10] Cleft lip surgery is one of the most dramatic surgical procedures used to revise a disfigured face into a very acceptable one. There is accumulative evidence that the plastic surgeon's skill may be a more important influence on the outcome than the timing or technique used for cleft lip repair.[11]

The most challenging aspect of cleft lip repair is the post-operative results or outcomes, especially in the long term when facial bone growth is complete, which determines the ultimate facial appearance. Consequently, the treatment of clefts involves not only surgical closure of the cleft, but also an aesthetically and functionally perfect result in adulthood.[12]

Facial attraction awareness is complicated and individualized. The main concern for adult patients with cleft lips is still the correction of nasal asymmetry and the appearance of the lip[7,13,14] because those with a visible facial deformity, are also at risk for social rejection, low self-esteem, speech difficulties as well as unrealistic perceptions about their facial appearance and behavior.[15] But unfortunately, cleft lip repair rarely produces a perfect facial appearance.[13] In conclusion, the definitive goal of all cleft surgery is to minimize the visible stigmata of the cleft-related deformity as most psychological impacts depend on the degree of the post-operative cleft deformity.[15] Furthermore, evaluating the nasolabial appearance may give advantages in assessing long-term post-operative outcomes, helping to minimize facial disfigurement by evaluating the results. This will improve patient care quality and allow better outcome prediction[16] and patient satisfaction.

This retrospective study assesses the long-term nasolabial outcome, particularly the nasolabial outcome after the age of 14, since puberty typically begins between 10 to 12 years in females and 12 to 14 years in males. This period is characterized by an enhanced growth rate that peaks approximately two years after the onset of puberty. Mid-facial projection also reaches maturity at 14 years in males and 13 years in females.[17] Generally, the face matures between 12 and 15 years in males and two years earlier in females.[18] Therefore, we used the word (long-term) to emphasize that we are looking for the result after the age of 14, when the facial bone growth is completed, which gives almost the final appearance.

1.2 PROBLEM STATEMENT & STUDY RATIONALE

Why are you conducting this study?

Research shows that cleft lip and cleft palate are the most common among the various craniofacial developmental abnormalities,[5,19-21] The role of physical appearance has shown that a well and healthy physical appearance, regardless of facial or physical characteristics, is considered attractive.[8,19] The facial region where this deformity occurs is a very conspicuous body part. Therefore, the management of cleft lip and palate should offer both decent aesthetic and functional results.[22]

As the modern treatments and surgical attempts still aiming to keep the number and impact of scars associated with the surgical intervention low, and the outcome of surgeries best as surgeon can, to reach the patient's satisfaction, this study conducted in the same track to achieve good evaluation of long-term lip repair surgeries outcome, particularly nasolabial appearance and patient's satisfaction with the result.

What is the importance of your study finding(s)?

This study aims to research the long-term lip repair surgery outcome of the operations performed by reconstructive science units, particularly the nasolabial appearance as a long term outcome, and address any contributing factors that may affect this outcome. At the end of this study, it is hoped that we will be able to point out the results which can improve the performance of these surgeries.

1.3 RESEARCH QUESTIONS

Did the long term outcomes -particularly nasolabial appearance- is acceptable and the patients are satisfied with the result in patients underwent unilateral cleft lip repair surgery by the reconstructive science unit, at the almost completion of their facial bone growth?

1.4 OBJECTIVES

1.4.1 General objective

- To assess long-term nasolabial outcomes and patient's satisfaction in patients underwent unilateral cleft lip repair surgery by the reconstructive science unit, at the completion of facial growth.

1.4.2 Specific objectives

- To assess long-term scar appearance in patients underwent unilateral cleft lip repair surgery performed by reconstructive science unit.
- To determine any postoperative complications affect the nasolabial outcome of unilateral cleft lip repair surgery.
- To assess patient's satisfaction with the long-term nasolabial appearance and surgeons comments.

1.5 LITERATURE REVIEW

Cleft lip and palate malformations belong to the most common congenital anomalies.[23] The principal aims of managing patients presenting with a cleft lip and/or palate are to establish a balanced, symmetrical face with harmonious proportions by correcting the deformity,[24] to improve their food intake, speech, and hearing, and to significantly improve their facial appearance to decrease the psychological impact on the patients and their families. One of the largely cosmetic issues is cleft lip and palate. The surgical outcome is highly concerning, particularly the long term outcome as the patient gets his or her final facial appearance after complete facial bone growth. Perhaps life-long social and psychological consequences arise from the facial abnormality itself and unfavorably affect the insight of facial attractiveness.[3,8]

Usually, cleft repair surgery outcomes research has focused on objective tools like anatomic measurements, clinical photos, morbidity, and mortality.[25] Patients with repaired complete clefts of the lip and palate always appear with some degree of alteration in the lip, nose, and dentation. Surgical repair of the lip and palate results in a series of well-recognized secondary growth disturbances, comprising anomalies in nasal form, nasal asymmetry, and distortion of the upper lip. There is distinguishable scarring of the philtral area with a contracted or lacking philtral groove.[8]

Assessing surgical outcomes is a cornerstone in estimating the success of cleft management. Multiple potential outcomes have been identified for comparing cleft lip and palate treatments, including facial appearance, dento-facial growth and development, speech, nasal breathing, hearing, patient satisfaction, and quality of life. However, there is no consensus among the numerous professionals in cleft care over which of these outcome measures is the most important.[26]

The literature describes facial appearance as an essential outcome of cleft treatment. Patients with clefts and their parents most typically anticipate improvements to the appearance of the lip and nose as a result of further treatment. Several reports have proposed that the central role played by facial appearance in developing a reliable rating for assessment of nasolabial appearance was a challenge in many studies. The premise that facial appearance is subjective, complicated, and variable has been acknowledged. Various methods for assessing facial beauty have been described, and they are based on facial profile, nasolabial appearance, or dental arch connection.[26]

Al-Omari et al.[15] conducted a literature search in 2005 to find all studies that evaluated the cleft-related malformation qualitatively and quantitatively, and they scanned the period between 1966 and 2003 to identify 40 publications belonging to various categories in assessing the outcome of cleft lip and palate surgeries.

In a recent systematic review of the facial aesthetics outcomes in cleft lip and palate surgery, Sharma et al.[27] shortlisted 53 articles published in the last 30 years. These researches indicated that studies on the facial appearance of the cleft deformity and facial aesthetics have either employed rating systems or simply ranked the patients to differentiate the degree of cleft deformity. Asher-McDade et al.[8] established a standardized process to evaluate the nasolabial appearance of patients with unilateral cleft lip and palate. Standard frontal and lateral photos were masked, leaving only the midface with nose and lips visible to reduce the influence of surrounding facial features on evaluating cleft-related malformation. Assessment is performed by using a 5-point ordinal scale as follows: 1 = very good appearance; 2 = good appearance; 3 = fair appearance; 4 = poor appearance; and 5 = very poor

appearance. The features assessed by the 5-point scale are nasal form, nose symmetry, the shape of vermilion, and nasal profile, including the upper lip.[8]

Recent development in computerized image analysis and digital photography has facilitated the direct evaluation of digital photos on-screen.[15] Kuijpers-Jagtman et al.[28] rightly observed that Asher-McDade derived assessment scale had been validly employed in many studies, as well they used the Asher-McDade scale in assessing the outcome in 42 children of Caucasian origin, with a repaired complete unilateral cleft lip, alveolus, and palate.

Mani et al.[13] conducted a study about nasolabial appearance in adults assessed by the professional judgement by using the Asher-McDade assessment 5-point scale for 109 patients. The study confirmed that the procedure of judgment described by Asher-McDade et al.[8] for the rating of nasolabial appearance, which was used in several previous studies, is a reasonably reliable and reproducible way of evaluating nasolabial appearance.

Sharma et al.[27] mention in a systemic review regarding outcomes in facial aesthetics in cleft lip and palate surgery that the Asher-McDade system has been validated in a large multi-center study looking at cleft lip and palate surgery outcomes.

Mosmuller et al.[29] compared the Asher-McDade aesthetic index to two other methods for evaluating the appearance of the nasolabial region in patients with a complete cleft lip and palate. Retrospective analysis of post-operative pictures of 55 children with cleft lip and palate was performed. For the scoring system by Prahl et al., reliability ranged from 0.43 to 0.53, for the 5-point scale from 0.45 to 0.57, and the scoring system by Asher-McDade et al., reliability was from 0.52 to 0.66. Mosmuller et al.[29] concluded that the Asher-McDade aesthetic index is still superior

to the other scoring systems.[29] In 2017, Mosmuller et al.[2] developed a Cleft Aesthetic Rating Scale as a new rating scale for the assessment of nasolabial appearance in complete unilateral cleft lip and palate patients based on the Asher-McDade assessment 5-point scale. The new scale can assess cropped photographs in which surrounding features are excluded. In addition, this photographic scale can be utilized as a sliding scale, allowing for the creation of many faces. The study concludes that the inter-observer reliability and internal consistency of this new rating scale are both adequate. When three or more observers use the scale, its dependability is excellent. The key advantage is that it is simple to use and requires less time than existing scoring systems, making it an ideal instrument for assessing a large number of patients.

In recent years, numerous studies on patient satisfaction and quality of life after treatment for cleft lip and palate have been conducted, taking into account issues beyond the correction of functional abnormalities alone. These studies typically involve questionnaires and scales to examine personal attitudes such as patient satisfaction.[12]

Generally, in daily life, the judgement of cleft lip repair appearance by the affected patients or their surrounding community is based on a subjective impression. However, in a review by Al-Omari et al.,[15] it was concluded that: “it seems that assessment of facial appearance using a panel of assessors provides a valid and reliable rating of facial attractiveness”.

Regarding satisfaction, Kappen et al.[30] indicate that self-acceptance and satisfaction with treatment outcomes are distinct concepts. It appears that a person can accept their cleft while remaining dissatisfied with the treatment outcome. Chen et al.[31] found that patients with bilateral cleft lip and palate had the lowest scores for satisfaction, but they found no association between satisfaction with the facial appearance or quality of life and gender, while some other researchers reported that women's judgements of their mouth and profile were much lower than men's, indicating that female patients, particularly adolescents, may have more stressors and anxieties about their looks and undergo more cosmetic modifications due to social and internalized pressure.

CHAPTER 2

STUDY PROTOCOL

2.1 STUDY PROTOCOL

RESEARCH PROPOSAL

Research title:

LONG TERM NASOLABIAL OUTCOME AND PATIENT SATISFACTION POST UNILATERAL CLEFT LIP REPAIR IN PATIENTS AGED ABOVE 14 YEARS IN A SINGLE CENTER

Principal investigator:

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Co-researchers:

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Introduction:

The cleft lip and palate is a congenital facial deformity malformation that affects both functions and aesthetics due to an absence of union of the palatine processes throughout embryonic life. It is present in 1 in 700-1,100 births in the world [1-3], to be one of the common craniofacial anomalies [4, 5]. The prevalence varies according to race/ethnicity, sex, and type of the cleft [5]. Clinically the clefts can be found unilaterally or bilaterally, with unilateral clefts being the most frequent [1]. Usually, child born with cleft lip and palate undergoing into a series of corrective surgeries [6-8] within the first 24 months of live [6], and may prolonged over many years [7].

Normally, recommendations for lip repair were made by the plastic surgeon, and consultations occurred with the orthodontist and oral surgeon concerning the desired aesthetic consequences of the surgery as well as the need for, and timing of, bone grafting procedures if needed [9]. The Millard rotation advancement repair started developing soon after its description and since remains the most popular technique among cleft surgeons. But, practically most of the plastic surgeons use a modified techniques [10]. In fact cleft lip surgery is one of the most dramatic surgical procedures used to revise a disfigured face into a very acceptable one. There is accumulative evidence proof that the skill of the plastic surgeon may be a more important influence on the outcome than the timing or technique used for cleft lip repair [11]. The most challenging aspect of the cleft lip repair is the post-operative results or outcomes, particularly in long term after the completion of facial bone

growth which gives final facial appearance. Therapy of clefts does not only comprise surgical closure of the cleft, but rather aims at an aesthetically and functionally optimal result at adult age [12].

The awareness of facial attraction is complex and individual, nevertheless still the primary concern for adult patients with cleft lip is correction of nasal asymmetry and the appearance of the lip [7, 13, 14], because those with a visible facial impairment are also at risk for social rejection, low self-esteem, speech difficulties as well as unrealistic perceptions about their facial appearance and behaviour [15], but unfortunately cleft lip repair is rarely produces perfect facial appearance [13]. In conclusion the definitive aim of all cleft surgery is to minimalize the visible stigmata of the cleft-related deformity, as the most of the psychological impacts depend on the degree of the post-operative cleft deformity [15]. The evaluation of the nasolabial appearance may give advantages to assess post-operative long term outcome, helping to minimize facial disfigurement by evaluating the results and this will result in improvement of the quality of care for patients, better prediction of outcomes [16] and patient's satisfaction.

This retrospective study is to assess the long term nasolabial outcome, and to be more specific to assess the nasolabial outcome after age of 14 years, because puberty generally occurs around age 10 to 12 years in females, and age 12 to 14 years in males; this time period is marked by an increased growth velocity that peaks about two years after onset. Mid-facial projection also reaches maturity at 14 years in males and 13 years in females [17]. In general, the face matured between 12 and 15 years in males and 2 years earlier in females [18]. Therefore we used "long term" to ensure that we are looking for the result after the age of 14 when the facial bone growth completed which gives almost the final appearance.

Problem statement & Study rationale:

Why are you conducting this study?

Injury, disease, or operations outcome that alters the face appearance is a difficult task. It is moreover challenging for children with congenital craniofacial disorders and their parents to adjust. Researches show, among the various craniofacial developmental abnormalities, cleft lip and cleft palate occurs most common [5, 19-21]. The role of physical appearance has

showed that a well and healthy physical appearance, regardless of facial or physical characteristics, is considered attractive [8, 19]. The facial region where this deformity occurs is a very conspicuous part of the body. Therefore management of cleft lip and palate should offer both decent aesthetic and functional results [22].

As the modern treatments and surgical attempts still aiming to keep the number and impact of scars associated with the surgical intervention low, and the outcome of surgeries best as surgeon can, to reach the patient's satisfaction, this study conducted in the same track to achieve good evaluation of long term lip repair surgeries outcome, particularly nasolabial appearance and patient's satisfaction with the result.

What is the importance of your study finding(s)?

This study is aimed at researching the long term lip repair surgery outcome, of the operations performed by plastic and reconstructive unit, particularly the nasolabial appearance as a long term outcome, and to address any contributing factors may affect this outcome. At the end of this study, it is hoped that we will be able to point out the results which can improve the performance of these surgeries.

Research Question:

Did the long term outcomes -particularly nasolabial appearance- is acceptable and the patients are satisfied with the result in patients underwent unilateral cleft lip repair surgery under plastic and reconstructive science unit, after the almost of their facial bone growth completed?

Objectives:

A. General:

To assess long term nasolabial outcomes and patient's satisfaction in patients underwent unilateral cleft lip repair surgery under plastic and reconstructive science unit, and currently his/her age is 14 years or above.

B. Specific:

- To assess long term scar appearance in patients underwent unilateral cleft lip repair surgery performed by plastic and reconstructive science unit.

- To figure out any postoperative complications affect the nasolabial outcome of unilateral cleft lip repair surgery.
- To assess patient's satisfaction with the long term nasolabial appearance.

Literature review:

The cleft lip and palate malformations belong to the most common congenital anomalies [23]. The principal aims of treatment of the patients presenting with a clefted lip and/or palate are to achieve an acceptable end result, in which defect is corrected to produce a balanced, symmetrical face with harmonic proportions [24], and to improve their food intake, speech and hearing, and to significantly improvement the face appearance to decrease the psychological impact on the patients and their families. One of largely a cosmetic issue is cleft lip and palate, and the surgical outcome is highly concerned particularly the long term outcome as the patient got his/her final facial appearance after fully facial bone growth. Perhaps life-long social and psychological consequences arise from the facial abnormality itself and unfavorably effect the insight of facial attractiveness [3, 8].

Usually, the focus of results research for cleft repair surgery has been on objective instruments such as anatomic measures, clinical photographs, morbidity, and mortality [25]. Patients with repaired complete clefts of the lip and palate always appear with some degree of distortion of the lip, the nose, and dentation. Surgical repair of the lip and palate result in series of well-recognized secondary growth disturbances, comprising anomalies in nasal form, nasal asymmetry, and distortion of the upper lip. There is distinguishable scarring of the philtral area with a contracted or lacking philtral groove [8]. Assessing surgical outcomes is a corner stone in estimating the success of cleft management. Numerous potential outcomes for comparing cleft lip and palate treatment have been reported, including dento-facial growth and development, facial appearance, speech, hearing, nasal breathing, quality of life, and patient satisfaction. But, there is no agreement among the many specialists in cleft care about which one of these outcome measures is most significant [26]. Facial appearance has been described in literature to be a significant outcome of cleft treatment by the patient. Perfections in the appearance of the lip and nose are the most often anticipated aspects for additional management by patients with clefts and their parents. Several reports have proposed the central role played by facial appearance in developing a reliable rating for assessment of nasolabial appearance was a challenge in many

studies. This has been recognized to the concept that facial appearance is subjective, complex, and multivariate. Various approaches of facial aesthetics assessment have been reported, and they are based on nasolabial appearance, facial profile, or dental arch relationship [26].

Al-Omari et al. [15] conducted a literature search in 2005 to identify all publications that assessed the cleft-related deformity both qualitatively and quantitatively, and they scanned the period between 1966 to 2003, to confined 40 publications belonging to various categories, in assessing the outcome of cleft lip and palate surgeries. In a recent systematic review of the outcomes in facial aesthetics in cleft lip and palate surgery, Sharma *et al.* [27] shortlisted 53 articles published in the last 30 years. These researches indicated that studies on the facial appearance of the cleft deformity and facial aesthetics have either used rating scales or simply ranked the subjects as means of differentiating the degree of cleft deformity. Asher-McDade et al. [8] established a standardized process to evaluate the nasolabial appearance of patients with unilateral cleft lip and palate. Standard frontal and lateral photographs were masked, leaving only the midface with nose and lips visible to lessen the influence of the surrounding facial features on assessment of the deformity related to cleft. Assessment is performed by using a 5-point ordinal scale as follows: 1= very good appearance; 2= good appearance; 3= fair appearance; 4= poor appearance; and 5= very poor appearance. The features assessed by 5-point scale are: nasal form, nose symmetry shape of vermilion and nasal profile including upper lip [8]. Lately, changes in digital photography and computerized image analysis have simplified direct assessment from on-screen digital images [15]. Kuijpers-Jagtman et al. [28] rightly observed that Asher-McDade derived assessment scale had been validly employed in many studies, as well they used the Asher-McDade scale in assessing the outcome in 42 children of Caucasian origin, with a repaired complete unilateral cleft lip, alveolus, and palate. Mani et al. [13] in 2010 conducted a study in about nasolabial appearance in adult assessed by professional judgment by using Asher-McDade assessment 5-point scale for 109 patients. The study confirmed that procedure of judgement described by Asher-McDade et al. for the rating of nasolabial appearance, which was used in several previous studies, is a reasonably reliable and reproducible way of evaluating nasolabial appearance. Sharma et al. [27] in 2012 mention in a systemic review regarding outcomes in facial aesthetics in cleft lip and palate surgery that Asher-McDade system has been validated in a large multi-center studies

looking at cleft lip and palate surgery outcomes. Mosmuller et al. [29] in 2015 compare the Asher-McDade aesthetic index with 2 systems used to score the appearance of the nasolabial area in patients with a complete cleft lip and palate. Retrospective analysis of post-operative pictures of 55-child with cleft lip and palate was performed. For the scoring system of Prahl et al, reliability about 0.43 to 0.53, for the 5-point scale between 0.45 and 0.57, and for the scoring system by Asher-McDade et al these varied between 0.52 and 0.66. Mosmuller et al. concluded that the Asher-McDade aesthetic index is still superior to the other scoring systems [29]. In 2017 Mosmuller et al. [2] developed a Cleft Aesthetic Rating Scale as a new rating scale for the assessment of nasolabial appearance in complete unilateral cleft lip and palate patients based on Asher-McDade assessment 5-point scale. The new scale can be used to assess photographs cropping in which surrounding features are excluded. The reference photographic scale can be used as a sliding scale, and in this way different faces can be created. The study concludes that this new rating scale has a satisfactory level of inter-observer reliability and an excellent level of internal consistency. The scale achieves good reliability when used by three or more observers. The main advantage is easy to use and is less time-consuming in comparison with existing scoring systems, making it a perfect tool for assessing large number of patients.

Numerous studies on life quality and patient satisfaction after therapy of cleft lip and palate have been conducted in recent years and have thus taken account of aspects reaching beyond the correction of functional disorders only. Normally, these studies employed questionnaires and used scales for measurement of personal attitudes like patient satisfaction [12].

Generally, in daily life the judgement of cleft lip repair appearance by the affected patients or their surrounding community is based on subjective impression. In a review by Al-Omari et al. in 2005 [15] it was concluded that: “it seems that assessment of facial appearance using a panel of assessors provides a valid and reliable rating of facial attractiveness”. Regarding the satisfaction Kappen et al. [30] suggest that the satisfaction with treatment outcome and self-acceptance are two different entities. It appears to be possible for a participant to be accepting of his/her cleft, while still dissatisfied with the end result of treatment. Chen et al. [31] found that patients with bilateral cleft lip and palate had the lowest scores for satisfaction, but they found no association between satisfaction with facial appearance or quality of life and gender, while some other researches have been shown that women’s

ratings of their mouth and profile were significantly lower than those of men, suggesting that female patients, particularly adolescents, may have more psychosocial issues of and concerns about appearance and undergo more facial corrections as a result of social and internalized pressure.

Research design:

This will be a retrospective cross-sectional study among the patient's data record who had unilateral cleft lip repair performed by plastic reconstructive science unit to determine the long term nasolabial outcome and patient's satisfaction.

Study area

Hospital Universiti Sains Malaysia

Study population

The study population include all patients who underwent unilateral cleft lip repair under plastic reconstructive science unit, within first two years of their lives and currently his/her age is 14 years or above.

Subject criteria

Inclusion criteria:

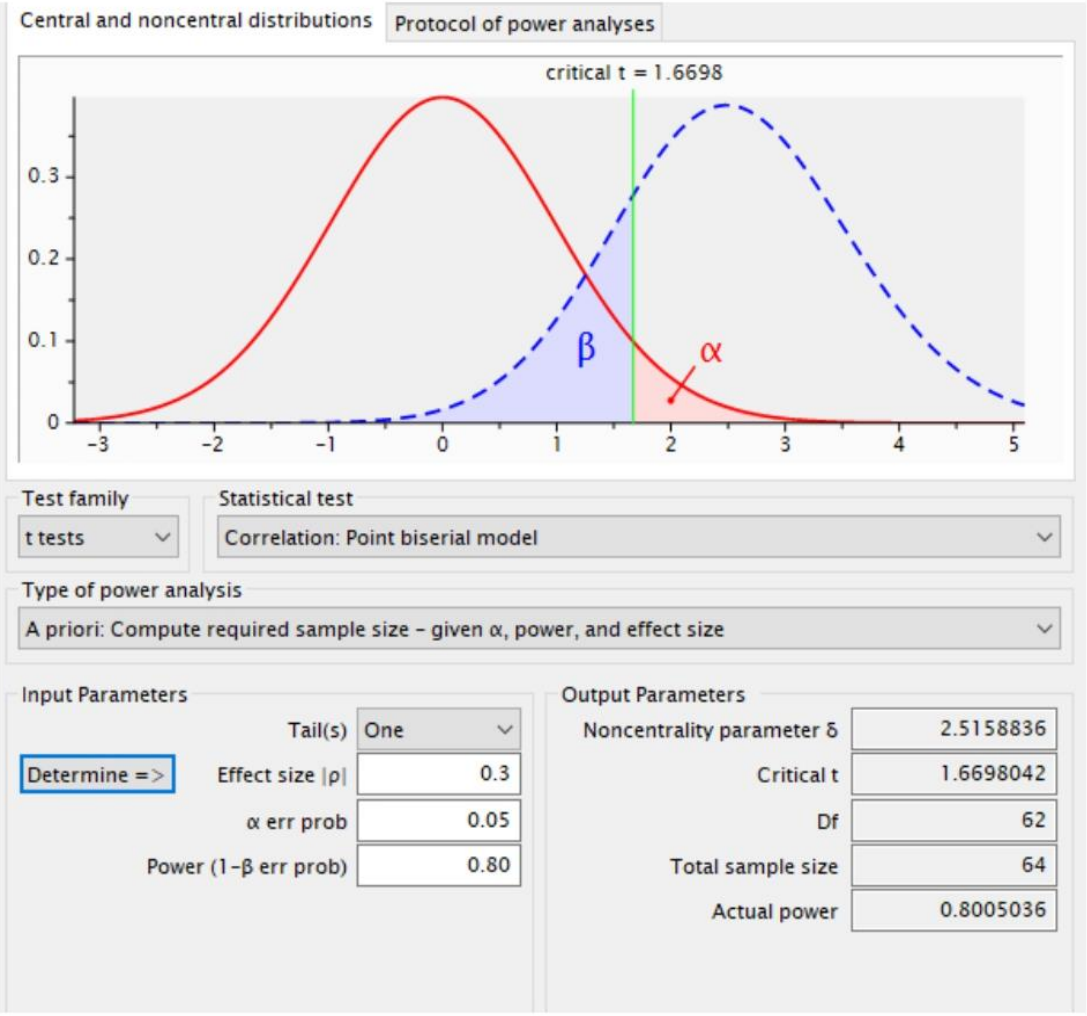
1. All non-syndromic patients who underwent unilateral cleft lip repair by plastic reconstructive science unit
2. Currently his/her age is 14 years or above.
3. Surgery should be done within the first 2 years of life.

Exclusion criteria:

1. Incomplete data records.
2. Patient who underwent lip repair in another center & currently follow up with our unit.

Sample size estimation

Sample size is estimated based on previous studies [32]. By taking α error=0.05, power of study =80%, effect size medium ρ=0.3 standard deviation (σ=0.3), by using G power software version 3.1 to calculate sample size, the minimum sample size will be 64.



Sampling method and subject recruitment

Convenience sampling method will be employed throughout the course of this study due to the limited time constraints. In patients who meet the inclusion criteria, their medical records will be revised to fill-up the proforma. Only the case note from archive will be revised and proforma will be filled accordingly.

Research tool

The following Proforma of Long Term Outcomes of Unilateral Cleft Lip Repair will be used

Proforma of Long Term Outcomes of Unilateral Cleft Lip Repair

PERSONAL DETAILS:

Patient's tag:

Age at Operation: **Current Age:**

Comorbidities: ☐ Syndromic ☐ Non-syndromic **Gender:** ☐ Male ☐ Female

Type of Cleft:

Family History of Cleft: ☐ No ☐ Yes

CLEFT LIP REPAIR:

Surgeon Experience: Trainee <5 years ☐ Specialist >10 years ☐ Consultant >10 years ☐

Type of Repair:

Any Surgical Modification:

Post-Operative Complication:

Diagnosis of Secondary Deformity:

Revision Surgery: ☐ No ☐ Yes **If Yes:**

At Which Age: **Surgeon Experience:**

LONG TERM FOLLOW UP:

Date of Last Follow up:

Age at Last Follow up:

Remarks of Last Follow up:

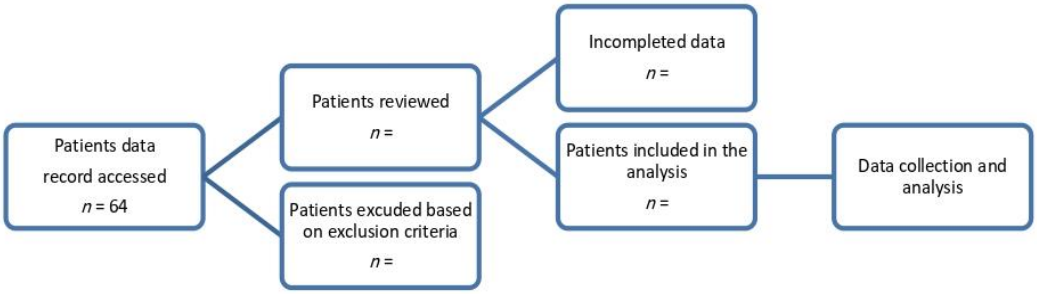
Outcomes:

Satisfaction:

Data collection method

Case notes will be recruited from HUSM archive database based on the inclusion criteria. Data will be filled in the proforma after obtain it from medical records.

Study flowchart



Data analysis

Data will be analyzed using Statistical Package for Social Science (SPSS) software version 24. Continuous data will be summarised using descriptive and inferential statistics.

Expected result(s)

Table 1: Patients demographics

Variables		N (%)
Gender	Male	
	Female	
Comorbidities	Syndromic	
	Non-Syndromic	
Side of Cleft	Right	
	Left	
Type of Cleft	Complete	
	Incomplete	
	Microform	
Family History	Yes	
	No	

Table 2: Cleft lip repair

Type of Repair	N (%)
Millard's Rotation Advancement	
Millard's Rotation Advancement + McCoombe's nasal repair	

Table 3: Post-operative complications and surgical revision

Variable		N (%)
Complications	Yes	
	No	
Surgical Revision	Yes	
	No	

Table 4: Patient's satisfaction

Patient's Satisfaction	N (%)
Satisfied with both lip & nose appearance	
Satisfied with lip but unsatisfied with nose appearance	
Satisfied with nose but unsatisfied with lip appearance	
Unsatisfied with both lip & nose appearance	

Gantt chart & milestone

Research activity	Oct. 2021 – Dec. 2021	Dec. 2021 – Feb. 2022	Feb. 2021 – Apr. 2022	Apr. 2022 – Jun. 2022
Data Collection				
Data Analysis				
Manuscript Preparation & Write-up				
Presentation & Publication				

Ethical consideration(s):

1. **Subject vulnerability**

   Only medical recorded data in the case note will be accessed, the proforma will be filled accordingly. No physical participants.

2. **Declaration of absence of conflict of interest**

   There is no conflict of interest in this study

3. **Privacy and confidentiality**

   All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.

4. **Community sensitivities and benefits**

   This study will benefit the plastic surgeons and trainees in plastic and reconstructive unit as it evaluates the long term nasolabial appearance after lip repair which performed by plastic and reconstructive science unit in HUSM. Such researches can improve the outcome of lip repair surgeries by addressing outcome and figuring out the contributing factors that may affect long term result.

5. **Honorarium and incentives**

   No research funding is needed and no participant in this study.

6. **Other ethical review board approval [Not applicable]**

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