GROWTH EVALUATION AND TREATMENT OUTCOME OF UNILATERAL AND BILATERAL CLEFT LIP AND CLEFT PALATE PATIENTS - A RETROSPECTIVE STUDY

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"GROWTH EVALUATION AND TREATMENT OUTCOME OF UNILATERAL AND BILATERAL CLEFT LIP AND CLEFT PALATE PATIENTS - A RETROSPECTIVE STUDY"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. M. VEERABAHU, M.D.S., IBOMS.,** Professor and Head, Department of Oral & Maxillofacial Surgery, Ragas Dental College and Hospital, Chennai.

Date: 30/12/2015

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CERTIFICATE

This is to certify that this dissertation titled **"GROWTH EVALUATION AND TREATMENT OUTCOME OF UNILATERAL AND BILATERAL CLEFT LIP AND CLEFT PALATE PATIENTS - A RETROSPECTIVE STUDY"** is a bonafide record of work done by **Dr. P. Hariharan** under our guidance and to our satisfaction during his postgraduate study period **2013-2016.**

This Dissertation is submitted to **THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY,** in partial fulfillment for the award of the Degree of **MASTER OF DENTAL SURGERY– ORAL AND MAXILLOFACIAL SURGERY, BRANCH III.** It has not been submitted (partial or full) for the award of any other degree or diploma.

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Introduction

INTRODUCTION

The human face is the most admired part of the human body and is often considered as the mirror of the human mind. Any deformity of the human face causes significant functional deficit and enormous psychological impact for the involved patient.

Cleft deformity of the lip and palate is one of the frequently occurring congenital deformity. The etiology of cleft lip and palate includes various genetic and environmental factors. The incidence of cleft lip and palate in India is between 27000 and 30000 clefts per year.[26] The total number of operated clefts in India is between 7000 and 10000 clefts per year.[26] The occurrence of cleft lip and palate ensures that the affected child is subjected to social ridicule and neglect. This in turn, affects the psychological development of the child. Children born with cleft lip and palate exhibit a marked difficulty in speech and mastication. This further results in nutritional problems, thus affecting the general growth of the patient.

The growth of child is determined by the size of an infant at the end of the first year of life, which is partly determined by inherited genetic characteristics and to a greater extent by nutrition and subsequent rate at which child grows[26]. Nutritional status is found to have a profound effect on growth hormone secretion. The mechanism of the effects of emotional deprivation on

growth is not well documented but is linked to reduced growth hormone secretion and its associated growth failure.

Many scientific studies have found significant growth differences in cleft lip and palate patients when compared to non-cleft patients with published cephalometric standards. It has been well documented that the most commonly associated deviation from normal values is found in the antero-posterior dimension of the maxilla.[26] Other commonly noted deviations in the cleft group, include a mild similarity in growth pattern or magnitude in transverse maxillary length of the palate.

The unoperated unilateral cleft lip and palate patients (age range 13-47 years) present with large overjets, proclined upper incisors, eversion of major segment, mild contraction of lesser segment, buccal crossbites.[26]

The unoperated bilateral cleft lip and palate patients (age range 14 – 55 years) present with massive protrusion of the premaxilla with gross proclination of the upper incisors, smaller cranial base lengths, intrinsic growth deficiencies, shortened ramus height, reduced upper anterior mid facial height and upper posterior face height, prominent premaxilla, wide alar bases, laterally deviated premaxillary segment, short columella and rudimentary prolabium with no muscle attachment.[26]

The unoperated isolated cleft palate patients (age range 13-44 years) present with relatively normal clinical appearance but have been associated

with intrinsic growth deficiencies compared to patients with clefts of lip and palate. They present with normal upper and lower dental arch relationships along with bimaxillary retrusion, short maxillary length, small mandible and reduced upper anterior and posterior face heights.[26]

The various treatment procedures for cleft patients include primary cleft repair, cleft palate repair, pharyngoplasty, alveolar bone grafting, orthognathic surgery or distraction osteogenesis, rhinoplasty, secondary scar revision[32]. Although the surgical treatment for cleft patient drastically improves the facial aesthetics and function, there are evidences in literature supporting growth retardation in operated cleft lip and palate patients.

The precise etiology for deficient growth in cleft lip and palate is not known but substantial proportion of this is due to scarring by the primary surgical repair.

Primary cleft lip and palate both unilateral and bilateral results in the formation of scar tissue at the surgical site. This causes dynamic and static alterations that, in association with the cleft itself, have negative consequences on maxillary growth and development and thus on the whole maxillofacial complex of the child.

The bilateral cleft lip and palate exhibits a prominent maxilla initially, but the maxilla recedes over time, reaches a similar anteroposterior relationships to that of patients with unilateral cleft lip and palate by the late

teen years. The mandible also presents with retrusion, steep mandibular plane and increased gonial angle. Anterior lower facial height is found to be elongated along with a reduced with a posterior facial height.

Rui Manuel Rodrigues Pereira et al (2011)[36] observed that the restriction of maxillary growth does not depend on the genetic predisposition associated with the presence of the cleft but is rather a consequence of the primary surgical repair. Nevertheless, the ability of the surgeon, the width of the cleft and the surgical technique is found to have impact on the results and interfere with the growth and development of facial structure involved.

Yu-Fang Liao et al (2006)[41] observed that the timing of hard palate repair significantly affects the growth of the maxilla in patients with cleft lip and palate. Late hard palate repair (around 9 years) is found to have a smaller adverse effect than early hard palate repair (around 1.5 years) on the growth of the maxilla. This variation in the timing of palatal repair primarly affects the anteroposterior development of the maxillary dentoalveolus and is attributed to the development being undisturbed before closure of the hard palate.

Rohit Khanna et al (2015)[35] from their study reported that surgical intervention interferes with growth in facial region. They attribute this finding due to resultant scar tissue in lip and palate region, which is found to have producing a restraining effect on growth in the facial region, as there is an alteration in the functional matrices.

Friede et al (1985)[16] observed more favorable growth in patients treated with a vomer flap in bilateral cleft lip and palate patients.

Zbynek smahel et al (1999)[42] evaluated manipulation of nasal septum, primary repositioning of the nasal septum is found to have a favorable effect on nasal septum in unilateral cleft lip and palate patients.

Harith A Al Ani et al (2006)[17] evaluated the effect of fracture of pterygoid hamulus in cleft palate repair. They do not recommend routine fracturing of pterygoid hamulus in repair of narrow to moderate clefts. They further state that even in wide clefts, adequate release of flaps from the muscle can be done, to obtain a satisfactory surgical closure. Fracturing of the pterygoid hamulus is only justifiable to reduce the tension across the suture line.

The result of cleft surgery depends upon surgical operator skills and experience, severity of cleft and uniformity in cleft treatment protocol. There are no evidences of a single center, single operator, scientific studies in literature assessing growth and treatment outcome of unilateral and bilateral cleft lip and palate surgeries performed by a standard cleft treatment protocols, ie Modified Millards rotational advancement flap for primary cleft lip repair and Bardach two flap palatoplasty for primary palate repair.

The method employed in the study involves lateral cephalograph (McNAMARA'S analysis), Goslon Yardstick assessment of dental models

and real time soft tissue measurements between the cleft and non cleft sides. Patients who were operated for cleft lip and palate by the above mentioned standard cleft treatment protocols are recalled after 8 to 18 years and the above mentioned investigations are performed.

The results obtained from this study would provide a unbiased standard data regarding growth and treatment outcome of operated cleft lip and palate patients by the above mentioned standard cleft treatment protocols. The data thus obtained from this study will influence the selection of surgical procedure and it‘s timing for performing future cleft lip and palate surgeries.

Aims and Objectives

AIMS AND OBJECTIVES

The aim of the study is to compare the growth and treatment outcome of unilateral and bilateral cleft lip and palate patients operated by same surgeon employing the standard cleft treatment protocols which includes, primary lip repair using modified Millards rotational advancement flap and primary palate repair using Bardach two flap palatoplasty, by evaluating lateral cephalograph (McNAMARA'S analysis), Goslon Yardstick assessment of dental models and real time soft tissue measurements between the cleft and non-cleft sides.

Review of Literature

REVIEW OF LITERATURE

Nakamura et al (1972)[6] studied growth rate changes in mandibular length and high maxillary width in clefted and nonclefted groups and found to be similar in both arches.

Mapes et al (1974)[6] assessed growth rates of maxillary arch before and after palatal surgery and found delayed growth initially followed by an accelerated growth phase in the length of the maxillary arch.

Foster et al (1977)[6] studied growth rates of maxilla and mandible and found that most growth and configurational changes occurred between 6 and 8 years of age and 9 and 10 years of age respectively or before the pubertal growth spurt.

Hans Friede, Odont DR et al (1978)[16] studied growth capacity of the vomero-premaxillary suture was analysed as this growth site, sometimes exposed during cleft surgery, is usually unrecognized in the patients mid-facial development. Metallic implants were inserted on both sides of the suture in eight infants with unilateral cleft lip and palate at the time of the first surgery. The patients were followed radiographically to the age of 3 years. They concluded that surgery seriously impedes or stops growth in the vomeropalatine suture is likely to be an important factor in the etiology of the mid-facial retrusion that is sometimes seen in patients with unilateral cleft lip and palate.

Erik Dahl, DR. Odont et al (1979)[11] studied transverse maxillary growth radiographically by the metallic implant method in 5 Danish boys with combined cleft lip and palate. The study covered the age range of 5 to 20 years with individual observation periods of 9 to 12 years. Lip closure and palate closure had been performed at 2 months and 24 months of age respectively by conventional methods. Orthodontic treatment was carried out in all cases. The maxillary width was determined from posteroanterior cephalometric radiographs as the distance between metallic implants inserted at the lower aspect of the maxillary-zygomatic process on both sides. Other radiographic measurements were obtained for further estimate of the facial growth in width. The growth curves for maxillary width differed definitely from normal and indicated that the spontaneous transverse palatal growth was inhibited in these patients.

Michael Mars, Dennis A.Plint et al (1987)[28] evaluated a new system of assessing dental arch relationships by using the Goslon Yardstick in children with unilateral clefts of lip and palate. The results of their study demonstrate that the Goslon Yardstick is highly reliable and is capable of discriminating among the quality of results at different centres.

Rodger M. Dalston, Jeffrey L. Marsh et al (1988)[34] proposed a set of minimal standards for reporting the results of surgery on patients with cleft lip with or without cleft palate and isolated cleft palate. They have proposed certain set of standards which should be reviewed and updated periodically.

Bruce B. Horswell, Bruce A. Levant et al (1988)[6] performed a study to compare the growth rates of six dimensions in the facial skeleton between a noncleft group and a unilateral cleft lip and palate group. They concluded that in the clefted group there was a little similarity in growth pattern and magnitude in horizontal maxillary length of the palate. The vertical height of the nasomaxillary region differ as well, but not to the same degree as maxillary length – there may be "catch – up" mechanism in the posterior and anterior nasomaxillary regions.

Hans Enemark, Stig Bolund et al (1990)[15] studied 57 consecutive complete unilateral cleft lip and palate patients who were followed longitudinally from birth to 21 years of age. All patients were operated with the same primary surgical procedures. They concluded that 51 patients had acceptable occlusion following orthodontic treatment, secondary surgery for correction of nasal deformities was required for 52 patients. Growth analysis demonstrated deficiency in growth, however acceptable profiles were obtained in 50 out of 57 patients.

Mars, Houston et al (1996)[10] reported that the precise etiology of the deficient growth is not known, although it seems probable that a substantial proportion of this is due to the scarring produced by the primary surgical repair.

Michael Mars, William J.B Houston et al (1990)[30] performed a study to investigate the effects of surgery on facial growth and morphology in

Srilankan males with unilateral cleft lip and palate who were over 13 years of age at the time of study with cephalometry and dental study models. The results show that subjects who had no surgery had a potential for normal maxillary growth. Subjects who have had lip repair in early infancy show relatively normal maxillary growth, but maxillary hypoplasia is common when the palate has also been repaired early.

Gunvor Semb (1991)[14] performed a study of facial growth with bilateral cleft lip and palate using lateral and frontal cephalometric analysis of a mixed longitudinal survey of 90 individuals treated by the Oslo CLP Team. He concluded that the craniofacial form in this sample was generally similar to that reported for Caucasian subjects treated for this condition elsewhere.

Christopher T. Roberts, Gunvor Semb et al (1991)[9] examined the clinical research methodologies used for the evaluation of cleft lip and palate therapies. A survey done in the cleft palate journal between 1964 and 1988 revealed that most of them used retrospective methods (90%). They thus concluded that if the uncertainties associated with the choice of primary cleft surgery were to be resolved, the challenge of multicentre prospective clinical trials must be faced by the various disciplines involved in cleft palate clinical research.

Zbynek Smahel, Ziva Mullerova et al (1991)[42] performed this study to evaluate whether manipulation of the nasal septum, its release, and changing of its abnormal position in infancy has an impact on maxillary

growth and facial development in patients with unilateral cleft lip and palate. They concluded that primary repositioning of the nasal septum has a favourable effect on nasal development, and it neither deteriorates nor markedly improves maxillary growth in patients with unilateral cleft lip and palate.

Michael Mars, Catherine asher-McDade (1992)[27] studied a 149 dental casts of subjects with complete unilateral clefts of lip and palate from 6 European cleft palate centres were assessed by means of the Goslon Yardstick. They concluded that the yardstick proved capable of discriminating between the quality of the dental arch relationships between the six centres.

Noverraz AE, Kuijpers-Jagtman AM et al (1993)[31] performed a mixed longitudinal study, the dental arch relationships of 88 consecutive unilateral cleft lip and cleft palate patients were evaluated using the Goslon yardstick. Four stages of dental development were distinguished deciduous dentition, early mixed dentition, late mixed dentition and permanent dentition. Reproducibility of scoring with the Goslon yardstick was good for all stages of dental development. In 86% of the cases, the dental arch relationships of unilateral cleft lip and palate patients were treated was acceptable.

Dai Roberts-Harry, Gunvor Semb et al (1996)[10] performed a study in 10-year-old patients with complete unilateral clefts of the lip and palate in two centers Bristol, UK and Oslo, Norway had different treatment regimens. They concluded that significant differences in maxillary growth and soft tissue

profile were noted with a much more retruded mid-face in Bristol group compared with oslo group showed better results due to absence of presurgical orthopaedics.

Atack et al (1997)[29] reported that facial growth is not fully expressed until after the pubertal growth spurt. It is believed that a centre with very good or bad results when compared with average results will skew the validity of the 5-year index because few patients lie in extremes of very good or very bad results.

Fernando R.et al(1998)[26] found in his study that malnutrition is a well-recognised form of reversible growth hormone resistance, normalised with nutritional supplements in cleft lip and palate patients. He also found out a malnourished mother likely to give birth to a baby with low birth weight.

Alex A Kane, Lun-Jou Lo et al (2000)[1] performed a study to determine whether, during the course of performing a palatoplasty, fracture of pterygoid hamulus is beneficial, or neutral with respect to intra-operative and perioperative complications, hearing outcome, and speech out-come. This study found no statistically significant differences in any of the measured surgical, otolaryngological, or preliminary speech outcomes were found between the groups who did and did not receive hamulus fracture.

Alison C. Williams, David Bearn et al (2001)[2] performed a cross-sectional study to describe facial development and appearance, quality of bone grafts, oral health, and patient/parent satisfaction, clinical outcome for children

in 5 & 12 years born with unilateral cleft lip and palate in UK. Their study revealed that dental occlusion and facial growth were poor for 40%, bone grafting was found out to be unsatisfactory.

Bhateja, kharbanda et al (2001)[5] study evaluated the standards of cleft care, spectrum of problems and treatment need of operated unilateral cleft lip and palate patients visiting a referral hospital in Delhi. The results showed that no definite surgical protocol was being followed and majority of patients had poor outcome. The above mentioned findings suggests that the need for the development of team approach with well-defined treatment protocol for care of cleft lip and palate patients.

Chad A. Perlyn, Jeffrey N. Brownstein et al (2002)[8] performed a retrospective study in 41 consecutive patients to determine whether there is any correlation between intial maxillary arch dysmorphology patterns in complete bilateral cleft/palate and occlusal relationship in early mixed dentition. They concluded that in early mixed dentition three fourth of patients had favourable occlusion and one fourth of patients demonstrated unfavourable occlusion. Initial dysmorphology of maxillary arch in infants with complete bilateral cleft lip/palate cannot be used to predetermine molar occlusal relationships in the mixed dentition.

Michael Mars (2002)[26] studied the outcome of facial growth, morphology, and speech using a absolute comparative baseline in 1000 cleft Srilankan subjects on whom 820 operations have been performed compared

with 119 healthy adult Srilankan non-cleft subjects provided control data. They concluded that it should not be inferred that as unoperated cleft lip and palate subjects grow relatively normally, surgical regimens delaying palatal surgery are indicated.

Michael Mars, Puneet Batra et al (2006)[29] performed a retrospective study to assess the validity of the 5 years index by subjecting study models at the age of 5 years to both the 5 years index and the goslon yardstick and then relating these resuts to the goslon ratings at 10 years. They concluded that the use of Goslon yardstick at 5 years demonstated some inherent flaws in its use at that age, these drawbacks are fewer than those when the 5 years index is used at 5 years of age.

Gopinath V K, Wan Abdul Manan Wan Muda et al (2005)[13] performed a study to asses general health and growth parameters in children with Cleft lip and palate and in normal children and to investigate the feeding methods of cleft lip and palate infants and normal infants. They concluded that the cleft lip and palate patients demonstrate slower growth than in normal children. 40% of mothers with cleft lip/palate infants were successful in breast feeding compared to 90% of mothers with normal infants. Cleft lip/palate children were more susceptible to infection.

Pieter J.P.M, Nollet et al (2005)[33] performed a study to assess determinants for treatment outcome in unilateral cleft lip and palate, evaluated with the Goslon Yardstick, Meta-Analysis of 1236 patients. They concluded

that delayed palatal closure generally results in better dental arch relationships than early palatal closure.

Yu-Fang Liao, Michael Mars et al (2005)[40] performed a study to investigate whether timing of hard palate repair, before versus after pubertal peak velocity age, had a significant effect on facial growth in patients with unilateral cleft lip and palate. A total of 125 adult patients with nonsyndromic unilateral cleft lip and palate were recruited and their last cephalometric radiographs were used. They concluded that the timing of hard palate repair significantly affects the growth of the maxilla in patients with unilateral cleft lip and palate. Hard palate repair after pubertal peak velocity age has a smaller adverse effect on the forward growth of the maxilla. This timing affects the forward displacement of the basal maxilla and the anteroposterior development of the maxillary dentoalveolus.

Michael Mars, Puneet Batra et al (2006)[29] performed a study to assess the validity of the 5-year index by subjecting study models at the age of 5 years to both the 5-year and the Goslon Yardstick, and then relating these results to the Goslon Yardstick, and then relating these results to the Goslon ratings at 10 years. They concluded that the use of Goslon Yardstick at 5 years has demonstrated some inherent flaws in its use at that age, these drawbacks are fewer than those when the 5-year index is used at 5 years of age.

Yu-Fang Liao, Timothy J. Cole et al (2006)[41] performed a longitudinal study to investigate whether timing of hard palate repair had a

significant effect on facial growth in patients with unilateral cleft lip and palate. They concluded that timing of hard palate repair significantly affects the growth of maxilla, late palatal repair has a smaller adverse effect than early repair affects the anteroposterior development of maxilla.

Harith A Al Ani, Zakaria Y Arajy et al (2006)[17] demonstrated that the actual need for fracturing the pterygoid hamulus in palatoplasty. They concluded that fracturing of the pterygoid hamulus is not indicated in repair of narrow to moderate clefts. In wide clefts successful closure can be obtained without fracturing if adequate release of the flaps from the muscles is done, otherwise fracturing might be justifiable to reduce the tension across the suture line.

Wolfgang Zemann, RudolfmMossbock et al (2007)[36] performed a study to compare saggital growth of the facial skeleton of 6 year-old children treated in two cleft centres with different surgical protocols. They concluded that there was a similar saggital growth of the facial skeleton in both centres which were not been affected by the different surgical protocols and final evaluation should be delayed until the growth of facial skeleton is complete.

Catharina A.M. Bongaarts, Martin A. van't Hof et al (2008)[7] tested the reliability of some cephalometric measurements in unilateral cleft lip and palate patients to search any alternatives for point A, ANS, and PNS. They concluded the landmarks A, ANS and PNS are hard to trace and no better landmarks were found in the study.

Tindlund et al (2008)[7] studied 41 cleft cases at five different ages, 30 cephalograms were traced twice. They reported that measurement errors were generally small, except for variables reflecting not fully developed and erupting incisors, but no supporting numerical data were given.

Klaus Sinko, Emma Caacbay et al (2008)[20] performed a study to compare a Vienna unilateral cleft lip and palate patient sample with the Eurocleft samples using the Goslon score. 123 plaster casts of unilateral cleft lip and palate patients born between 1970 and 1997, with an average age of 9.2 years and all treated with same regimen, were rated according to Goslon score. They conclude that their regimen was found to be good for patients with unilateral cleft lip and palate patients in regard to maxillary growth.

Maria Costanza Meazzini, Greta Giussani et al (2008)[24] performed a study to compare the short and long term craniofacial growth of patients operated with the Milan protocol to those operated with the Oslo protocol. The Milian sample included 88 patients with unilateral cleft lip and palate at 5 years, 26 patients at 10 years, and 23 patients at the end of growth. The Oslo samples included 48 unilateral cleft lip and palate patients at 5 years, 29 patients at 10 years, and 23 patients at growth completion. Lateral cephalogram were used for comparison. There was no any significant cephalometric difference in the maxillary prominence at 5 years, a mild but significant difference at 10 years and again no difference at the end of growth.

Maria Costanza Meazzini, Vera Donati et al (2008)[25] performed a study to evaluate a simplified method to identify the causes of this growth impairment in cleft lip and palate patients. Congenitally missing laterals, inherent tissue hypoplasia seems to be a striking important factor. Timing of lip repair also had an influence.

IIZA L.Marques, Nackashi et al (2009)[18] performed longitudinal study of growth of children with unilateral cleft-lip and palate from birth to two years of age. At birth, children of both genders with unilateral cleft lip-palate presented with smaller body dimensions in relation to national centre for health statistics. Weight was found to be the most compromised for both genders and this study established that the growth curves for children with unilateral cleft lip/palate.

Arunkumar k.v, Viveka Vardhan Reddy et al (2010)[3] performed a study to establish cephalometric norms for the south Indian (Karnataka) population based on burstone analysis. They concluded that statistically significant differences were found between south Indian men and women when compared with Caucasians in certain key parameters. These differences should be taking into when analysing the cephalogram for orthognathic surgeries.

Rui Manuel Rodrigues Pereira Edna Maria Costa De Melo et al (2011)[36] performed a study to evaluate the craniofacial growth in patients with cleft lip and palate undergoing one- stage palate repair. They concluded that

the attack index is an important instrument for the preliminary assessment of the effects of primary surgeries on the maxillofacial growth of patients showing ease of use and good reproducibility. This attack index thus helped the author to compare the results between different treatment centers.

Jyosna Preetham Naduwinmani, Chandrashekar Hallollli et al (2011)[19] performed a study to evaluate the differences in the cephalometric norms between normal individuals and the cleft lip/palate individuals and also between unilateral and bilateral cleft patients. They concluded that these comparison between cleft and normal data revealed a multitude of vertical and horizontal soft and skeletal tissue abnormal relationships and suggests that these persons do not simply exhibit maxillary deficiency.

Ronald Hathaway John, DaskalogiannakisAna et al (2011)[35] performed a cohort retrospective study to compare maxillomandibular relationships for individuals with non-syndromic complete unilateral cleft lip and palate using the Goslon Yardstick for dental models. They concluded that the Goslon Yardstick proved capable of discriminating among the centres dental archrelationships.

Ashhan Uzel, Servet Dogan et al (2012)[4] performed study to investigate the importance of the clinical experience on the reliability of the GOSLON Yardstick. They concluded that the results of this study does not affect significantly the reliability of the GOSLON Yardstick but the raters should be trained before scoring.

Rohit Khanna, Tripti tikku et al (2012)[35] performed a cross-sectional retrospective cephalometric study which was designed to clarify whether the maxillary deficiency seen in surgically treated individuals with non-syndromic complete unilateral cleft lip and palate is due to the inherent growth potential or iatrogenicity. They concluded that surgical intervention does interfere with growth in the facial region. This could be attributed to the scar tissue in lip and palate region, which had a restraining effect on growth in the facial region. These altered functional matrices play a significant role in determining the growth of the facial structures.

Kristian Andersen, Sven Erik Norholt et al (2012)[21] performed a retrospective study to compare cleft lip and palate patients satisfaction with aesthetics and functional parameters after conventional advancement of the maxilla or by the use of distraction osteogenesis. They concluded that cleft lip and palate patients have more satisfied with surgical maxillary advancement and less satisfied with distraction osteogenesis.

Sumathi Felicita, Shyamala Chandrasekar et al (2014)[39] performed a study to measure the linear cephalometric dimensions of anterior and posterior segments of the craniofacial complex for sagittal plane. They concluded that a dimensional balance was found to exist between the maxilla and mandible both at the dentoalveolar and skeletal level with a ratio of 1:1.

Snigdha pattanaik, Sudhakar Pathur (2014)[38] performed a study to establish soft tissue facial profile norms for coastal Andhra population by

means of angular measurements and to evaluate the difference between male & female groups. They concluded that the males of coastal Andhra Pradesh had mild convex profile and prominent nose whereas females had mild convex profile due to recessive chin.

Sherif Bakri, Sara Rizell et al (2014)[37] performed a retrospective cohort study to compare vertical maxillofacial growth in patients born with unilateral cleft lip and palate who were treated using two different surgical protocols. 92 patients in Gothenburg study had undergone hard palate & soft palate surgical procedure in 9 month, 46 consecutive patients in Sweden hard palate surgery delayed to 8-10 years and soft palate repair in 7 month. They concluded that delayed hard palate closure does not affect anterior maxillary vertical growth.

Eyas abuhijleh, Halise aydemir et al (2014)[12] assessed three-dimensional craniofacial morphology in unilateral cleft lip and palate. These group had no distinctive mandibular asymmetry, the cranial base, maxilla, and mandible were affected on the sagittal plane during all growth periods. Horizontal asymmetries were more than vertical asymmetries.

Rohit Khanna, Tripti Tikku et al (2015)[35] performed this cross-sectional retrospective cephalometric study was designed to clarify whether the maxillary deficiency seen in surgically treated individuals with non-syndromic complete unilateral cleft lip and palate is due to inherent growth potential or iatrogenicity. They concluded that surgical intervention does

interfere with growth in the facial region. This could be attributed to the scar tissue in lip and palate region, which has a restraining effect on growth in the facial region. These altered functional matrices play a significant role in determining the growth of facial structures.

Materials and Methods

MATERIALS AND METHODS

This retrospective study was performed at Department of Oral and Maxillofacial Surgery, Ragas Dental College and Hospital, Uthandi, Chennai. Eleven (11) patients who were operated for cleft lip and palate by employing standard cleft lip treatment protocol were included in the study. All the participants were informed about the study. The ethical clearance was obtained from the institutional review board for conducting study. After the patients were recalled, a lateral cephalograph was obtained and McNamara's analysis were performed. A clinical impression of the dentition was made using alginate impression material (Algitex, Dental products of India, Mumbai.) A diagnostic model using type IV die stone (Zhermack company product of Carlo Orlandi) was obtained. The real time soft tissue clinical measurements of the nasomaxillary region were measured using a divider and assessed with ruler. Thus obtained values were compared between the cleft and non-cleft sides.

Inclusion criteria:

Surgical protocol:

1. Cleft lip and Cleft palate surgical cases operated by single surgeon.
2. Cleft lip operated at the age of 3 to 6 months using standard modified Millard's rotation advancement flap.
3. Cleft palate operated at the age of 12 to 18 months by Bardach two flap palatoplasty.

Exclusion criteria:

1. Craniofacial syndromic patients.
2. Patients who underwent treatment with naso alveolar moulding appliances.
3. Patients who underwent treatment with growth modification orthodontic appliance.
4. If primary repair of cleft lip or cleft palate were operated after 2 years of age.

ARMAMENTARIUM:

1. Lateral cephalogram
2. Dental study cast
3. Real time soft tissue measurements between cleft and non-cleft sides
4. Geometry box (inclusive of divider, ruler, metal scale)
5. The lateral cephalogram was standardized by obtaining cephalograph with following specifications.

Lateral Cephalograph standardizations

- Anode to midsaggital distance is precisely 152.5 cm (the imperial measurement of 5 feet).
- The midsaggital plane to film distance is 16 cm.
- The patients in pose with teeth lightly occluding in maximum intercuspation and Frankfort plane parallel to the ground.

Tracing supplies and Equipments

- A lateral cephalogram
- Acetate matte tracing paper (0.003 inches thick, 8×10 inches)
- A sharp 3H drawing pencil or a very fine tipped pen
- Geometry box
- Masking tape
- The cephalograph was placed on the view box facing towards the right and tracing was done using following methods.
- The following points were traced in lateral cephalograph and linear measurements were measured using ruler.
- Co (Condylion) – The most superoposterior point on the head of the condyle.
- Gn (Gnathion) – The lowest, most anterior, middle point on the symphysis of the mandible.
- A (Subspinale) – The deepest midline point on the maxilla between anterior nasal spine and the maxillary dental alveolus.
- Me (Bony Menton) – The most inferior point on the symphysis of the mandible in the mid saggital plane.

Methodology:

Skeletal growth assessment

McNamara's Analysis: Lateral cephalogram

Skeletal values derived from the Bolton standards (N=16) for each sex age
Standardized 8% enlargement (mm)

Gender	6yrs	9yrs	12yrs	14yrs	16yrs	18yrs
Female Mand.Length (Co-Gn)	97.7±3.4	106.1±3.4	113.1±3.6	118.9±5.0	120±3.4	121.6±4.5
Max.Length (Co-Point A)	79.8±2.2	85±2.3	89.6±2.4	92.1±2.7	92.7±2.3	93.6±3.2
Maxillo.mand Differential	17.9±8.1	21.1±2.7	23.5±3.0	26.8±4.1	27.3±3.0	28.0±3.2
Lower Ant. Facial Height	57.9±3.7	60±2.9	62.6±4.5	65.6±4.9	66.1±4.3	67.2±4.7
Male Mand.Length (Co-Gn)	99.3±3.6	107.7±3.8	114.4±4.4	120.6±4.3	126.8±4.7	131±4.6
Max.Length (Co-Point A)	81.7±3.4	87.7±4.1	92.1±4.1	95.2±3.2	98.6±4.4	100.9±3.9
Maxillo.mand Differential	17.5±2.2	20±2.6	22.3±3.1	25.4±3.5	27.9±3.3	30.1±3.9
Lower Ant. Facial Height	58.4±3.1	61±3.6	64.3±3.6	66.8±3.9	69.7±4.3	71.6±4.9

PATIENT NAME: AGE/SEX

Gender	**6yrs**	**7.5yrs**	**9yrs**	**10.5yrs**	**12yrs**	**14yrs**	**15yrs**	**16yrs**	**17yrs**	**18yrs**
Female Mand.Length (Co-Gn)										
Max.Length (Co-Point A)										
Maxillo.mand Differential										
Lower Ant. Facial Height										
Male Mand.Length (Co-Gn)										
Max.Length (Co-Point A)										
Maxillo.mand Differential										
Lower Ant. Facial Height										

Dental study cast

The following parameters were assessed using Goslon Yardstick index.

Frontal view Parameters

Parameters	Present	Absent
Open bite		
Cross bite		

Profile view parameters

Parameters	Present	Absent
Incisor Inclination		
Overjet		

Goslon Yardstick: (Great Ormond Street, London and Oslo) Michael Mars (2008) criteria

Group 1: Positive overjet with average inclined or retroclined incisors with no crossbite or open bite. Long-term outcome: **Excellent**.

Group 2: Positive overjet with average inclined or proclined incisors with unilateral crossbite or crossbite tendency with or without open-bite tendancy around cleft side. Long- term outcome: **Good**.

Group 3: Edge- to- edge bite with average inclined or proclined incisors or reverse overjet with retroclined incisors. Unilateral crossbite with

or without bilateral open-bite tendancy around cleft side. Long-term outcome: **Fair**.

Group 4: Reverse overjet with average inclined or proclined incisors. Unilateral crossbite with or without open- bite tendancy around cleft side. Long- term outcome: **poor**.

Group 5: Reverse overjet with proclined incisors, bilateral crossbite, and poor maxillary arch form and palatal vault anatomy. Long-term outcome: **very poor**.

Real time soft tissue measurements between cleft and non cleft sides were measured using divider and ruler.

SOFT TISSUE LANDMARKS

Fig.1: Height of the cleft side (A')

Fig.2: Height of the non cleft side (A)

Fig.3: Width of the cleft side (B')

Fig.4: Width of the non cleft side (B)

Fig.5: The height of the lower alar groove from the interpupilary line of cleft side (C')

Fig.6: The height of the lower alar groove from the interpupilary line of non-cleft side (C)

Fig.7: The height of the upper alar groove from the interpupilary line of cleft side (D')

Fig.8: The height of the upper alar groove from the interpupilary line of non-cleft side (D)

- Patient Name :
- Age/Sex :

Measurements

- A =
- B =
- A' =
- B' =
- C =
- D =
- C' =
- D' =
- Right cupid =
- Left cupid =
- Right chelion =
- Left chelion =
- A'/B' : A/B =
- D'/C' : D/C =

STATISTICAL TOOLS EMPLOYED

The statistical analysis was done using using paired 't' test for both cephalometic evaluation and real time soft tissue measurements.

CASE PROFORMA

Name: RegNo: Religion:

Age/Date of Birth: Gender: Language:

Address:

Occupation of father: Mother:

Tel: e-mail:

Dx

Cleft Details	Dx	Right	Patient's Side	Left			
	Simonart''s Bands	Y	I = Incomplete	Y			
	Lip	I C	C = Complete	I C	Vomer attached to Hard Palate	Y	N
	Alveolus	I C		I C	Submucous Cleft	Y	N
	Hard Palate		I C		No Cleft, but seen for VPI	Y	N
	Soft Palate		I C				
	Cleft Summary						
	Other congenital malformations / Syndrome						

H/o Cleft Surgery:

Type of Surgery	Date	Age

Family history of cleft

Does mother have a cleft	Y	N		
Does father have a cleft	Y	N		
Maternal family history of cleft	Y	N		
Paternal family history of cleft	Y	N		
Number of siblings without cleft	M		F	
Number of siblings with cleft	M		F	
Twins with cleft	Y	N		

Order of Birth:

Parents – Consanguinity

If Yes, exact relationship

Age of mother at parturition

Menarche age of mother

I trimester fever/ illness / medications / alcohol/ smoking/ surgeries under GA/ attempt at abortion/ General Anesthesia / irradiation.

Feeding difficulties

Past Medical History

Allergies

Other non-congenital Anomalies

Current Medication

Examination

Height (cm) **Weight (kg)**

Examination of Face:

Intra Oral Examination:

Dental Evaluation:

D -
M -
F -
MISC -

Study Casts:

Photographs

Radiographs and Evaluation

Paediatric Evaluation

ENT Evaluation

Speech Evaluation

Cleft Clinic Recommendation

Figures

Fig.9: Lateral cephalograph with McNamara analysis

Fig.10: Patient Frontal view

Fig.11: Models Frontal view

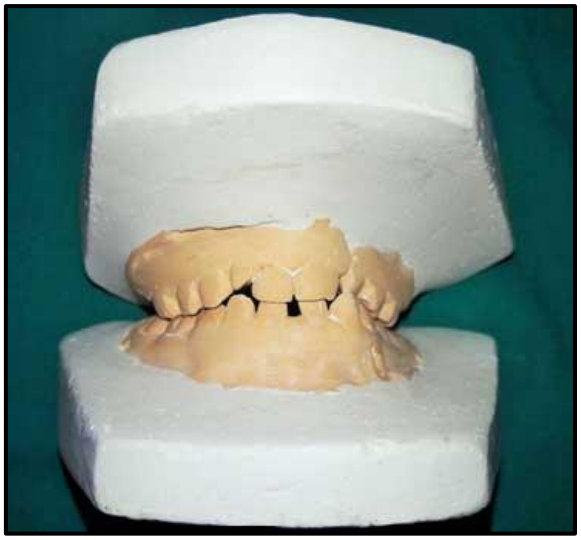
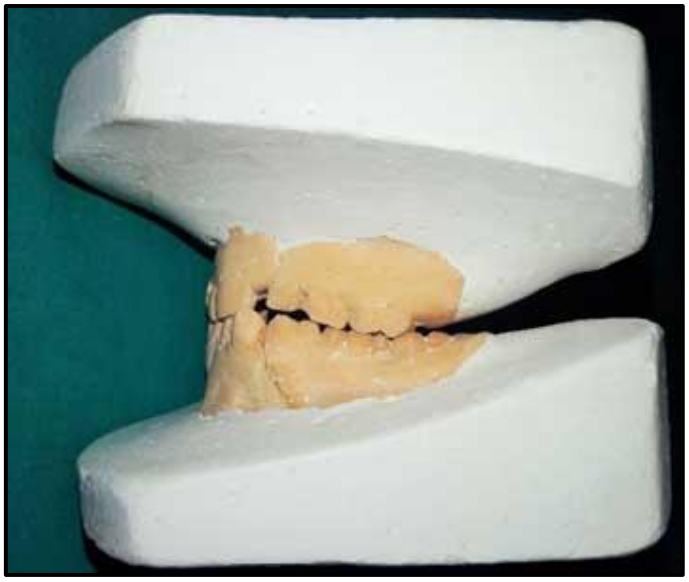


Fig.12: Models right lateral view

Fig.13: Models left lateral view



Results

RESULTS

The present retrospective clinical study was done to compare the growth and treatment outcome of unilateral and bilateral cleft lip and palate patients operated by same surgeon employing the standard cleft treatment protocols. A total of 11 patients who were eligible for the study according to inclusion criteria were recalled and assessed in the Out-Patient Department of Oral and Maxillofacial Surgery, Ragas Dental College and Hospital, Uthandi, Chennai.

A McNamara analysis using the standard lateral cephalograph was performed for all patients whose age ranges from 6 to 18 years. Thus obtained cephalometric values in operated cleft lip and palate cases were compared to the normal standard values.

A Goslon Index was performed on diagnostic models, obtained from operated cleft lip and palate patients.

The real time soft tissue clinical measurements of the naso-maxillary region were compared between operated cleft and non-cleft sides.

The following observations were made from the results obtained from the statistical analysis of the study.

1. Out of the 11 patients enrolled for this study, 4(36.4%) were males and 7(63.6%) were females (Table-4, Graph-4). The male to female ratio of

the study subjects was 0.6:1. The overall mean age of the patients who participated in the study was 13.2 years.

2. McNamara analysis using lateral cephalograph

On comparing the cephalometric values of the mandibular length, we observed a mean value of 110.54 with standard deviation of 9.19, the 'p' value for the above criteria was obtained as 0.002. Hence this radiographic parameter was found to be statistically significant.

On comparing the cephalometric values of the **maxillary length**, we observed a mean value of **82.63** with standard deviation of **5.85**, the **'p'** value for the above criteria was obtained as **0.342**. Hence this radiographic parameter was found to be **statistically insignificant**.

On comparing the cephalometric values of the maxillary-mandibular differential, we observed a mean value of 27.90 with standard deviation of 7.60, the 'p' value for the above criteria was obtained as 0.006. Hence this radiographic parameter was found to be statistically significant.

On comparing the cephalometric values of the lower anterior facial height, we observed a mean value of 69.95 with standard deviation of 7.37, the 'p' value for the above criteria was obtained as less than 0.001. Hence this radiographic parameter was found to be statistically significant.

3. A Goslon index was performed on all the samples using diagnostic models.

   A total of 5 samples (45.5%) were found to be under Group 1 category and the outcome is interpreted as Excellent and 3 samples (27.2%) were found to be in Group 2 category and the outcome is interpreted as Good and 2 samples (18.2%) were found in Group 5 category and the outcome is interpreted as Very Poor and 1 sample (9.1%) were found in Group 4 category and the outcome is interpreted as Poor (Table-3, Graph-4).

4. Real Time Soft Tissue Clinical Measurements.

   The real time soft tissue measurements of nasomaxillary region was assessed and the following results were obtained.

The inner alar base width of the non-cleft side (A) Fig.3 was found to have a mean value of 9.91 with standard deviation of 3.08 and inner alar base width of the cleft side (A') Fig.1 was found to have a mean value of 8.82 with standard deviation of 1.60 and the 'p' value for the above criteria was obtained as 0.19. Hence this soft tissue parameter was found to be statistically insignificant.

The height of the inner alar base of the non-cleft side (B) Fig.4 was found to have a mean value of 12.36 with standard deviation of 3.83 and the height of inner alar base of the cleft side (B') Fig.2 was found to have a mean value of 12.18 with standard deviation of 3.87 and the 'p' value for the above

criteria was obtained as 0.76. Hence this soft tissue parameter was found to be statistically insignificant.

The height of the lower alar groove from the interpupilary line of the non-cleft side **(C) Fig.8** was found to have a mean value of **38.73** with standard deviation of **6.66** and the height of the lower alar groove from the interpupilary line of the cleft side **(C') Fig.6** was found to have mean value of **40.82** with standard deviation of **6.38** and the **'p'** value for the above criteria was obtained as **0.004**. Hence this soft tissue parameter was found to be statistically **significant**.

The height of the upper alar groove from the interpupilary line of the non-cleft side (D) Fig.7 was found to have a mean value of 26.00 with standard deviation of 6.00 and the height of the upper alar groove from the interpupilary line of the cleft side (D') Fig.5 was found to have mean value of 27.36 with standard deviation of 4.46 and the 'p' value for the above criteria was obtained as 0.16. Hence this soft tissue parameter was found to be statistically insignificant.

Tables and Graphs

SOFT TISSUE LANDMARKS

Table 1: COMPARISON BETWEEN CLEFT SITE AND NORMAL SIDE

S.No	Variable	N	Mean	Std. Deviation	p value
1	A’	11	8.82	1.60	0.19
	A	11	9.91	3.08	
2	B’	11	12.18	3.87	0.76
	B	11	12.36	3.83	
3	C'	11	40.82	6.38	0.004
	C	11	38.73	6.66	
4	D'	11	27.36	4.46	0.16
	D	11	26.00	6.00	

***paired ‘t’ test**

Table 2: CEPHALOMETRIC LANDMARKS

S.No		N	Mean	Std. Deviation	p value
1	MAND.L	11	110.5455	9.19090	0.002
	MAND.NORMAL.L	11	116.4727	9.24901	
2	MAX.L	11	82.6364	5.85274	0.342
	MAX.NORMAL.L	11	91.4818	5.88503	
3	MAX.MAND DIFF	11	27.9091	7.60861	0.006
	MAX.MAND DIFF.NORMAL.L	11	24.9845	3.53687	
4	LOW ANT.FACIAL HEIGHT	11	69.9545	7.37040	<0.001
	LOW ANT.FACIAL HEIGHT.NORMAL.L	11	64.9045	4.01961	

***paired 't' test**

Table 3: GOSLON INDEX ASSESSMENT OF ALL THE SAMPLES

Goslon Index	Samples
Group 1 (Excellent)	45.50%
Group 2 (Good)	27.20%
Group 3 (Fair)	0.00%
Group 4 (Poor)	9.10%
Group 5 (Very Poor)	18.20%

Table 4: SAMPLE GENDER DISTRIBUTION

Gender	Samples
Male	**36%**
Female	**64%**

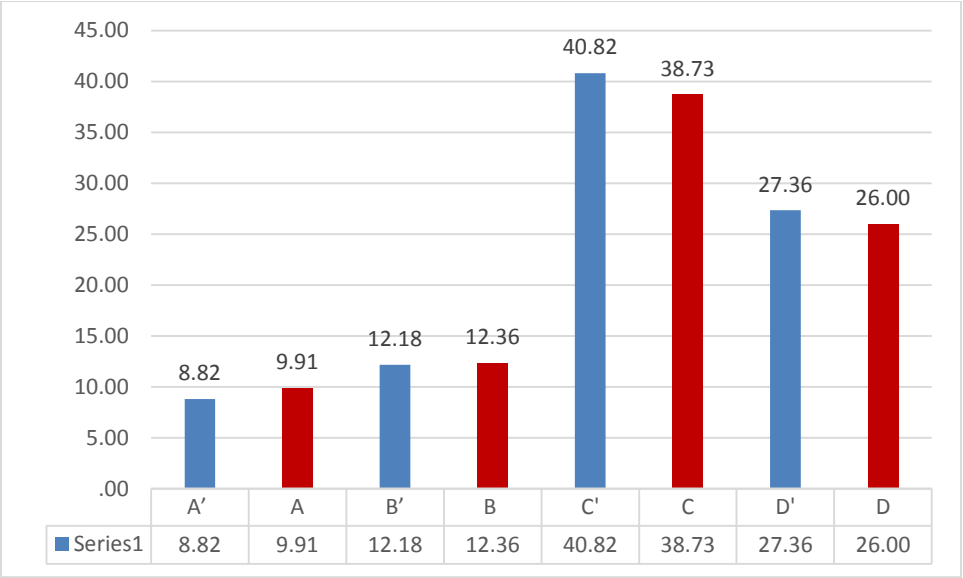
Table 5: SAMPLE CLEFT SIDE DISTRIBUTION

Cleft Side	Samples
Right	**18%**
Left	**55%**
Both	**27%**

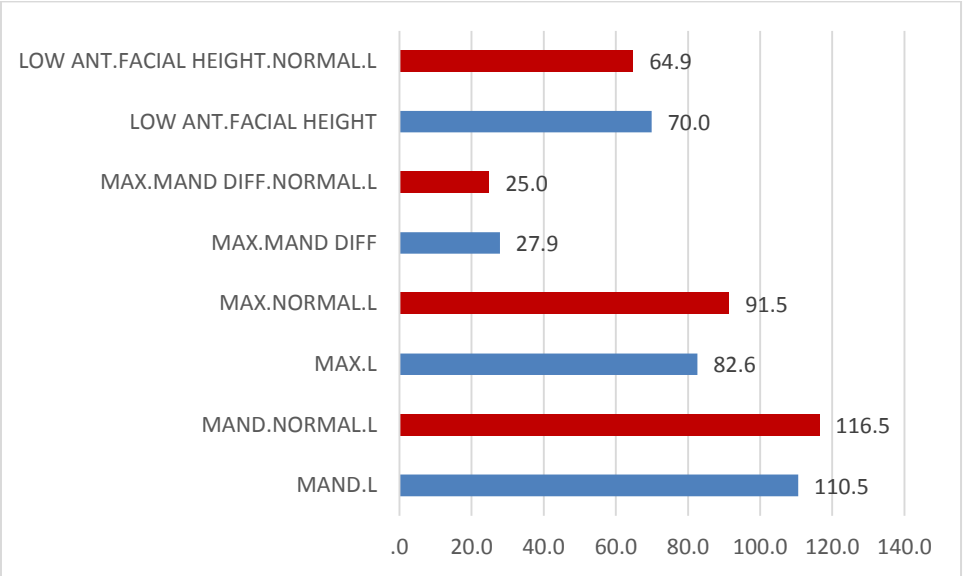
Table 6: SAMPLE CLEFT REGION DISTRIBUTION

Cleft Region	Samples
Unilateral	**73%**
Bilateral	**27%**

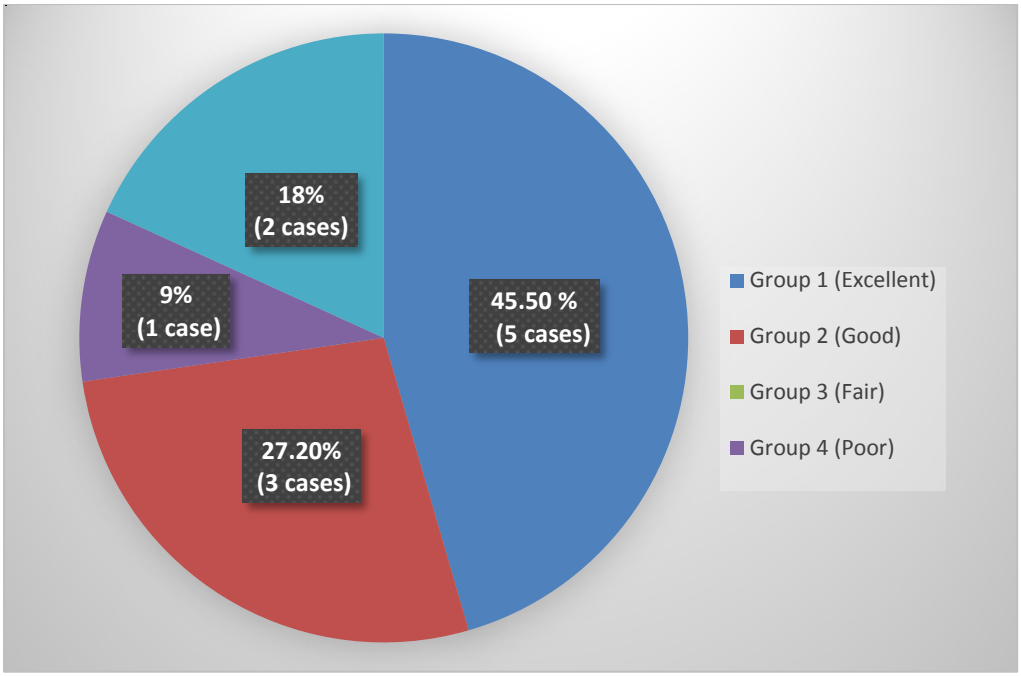
GRAPH 1: SOFT TISSUE LANDMARKS



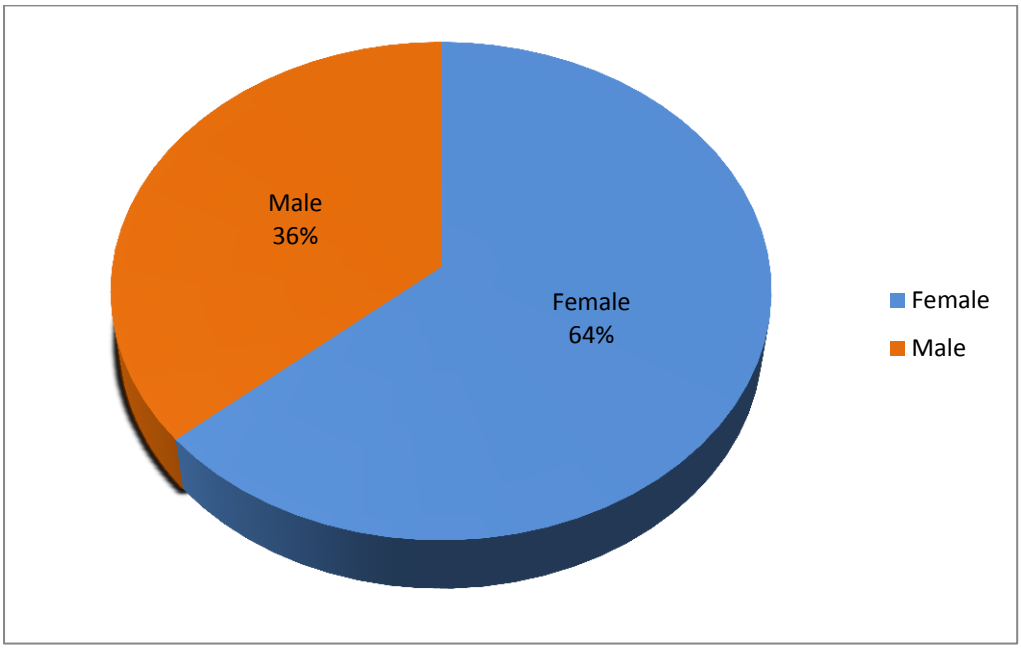
GRAPH 2: CEPHALOMETRIC LANDMARKS



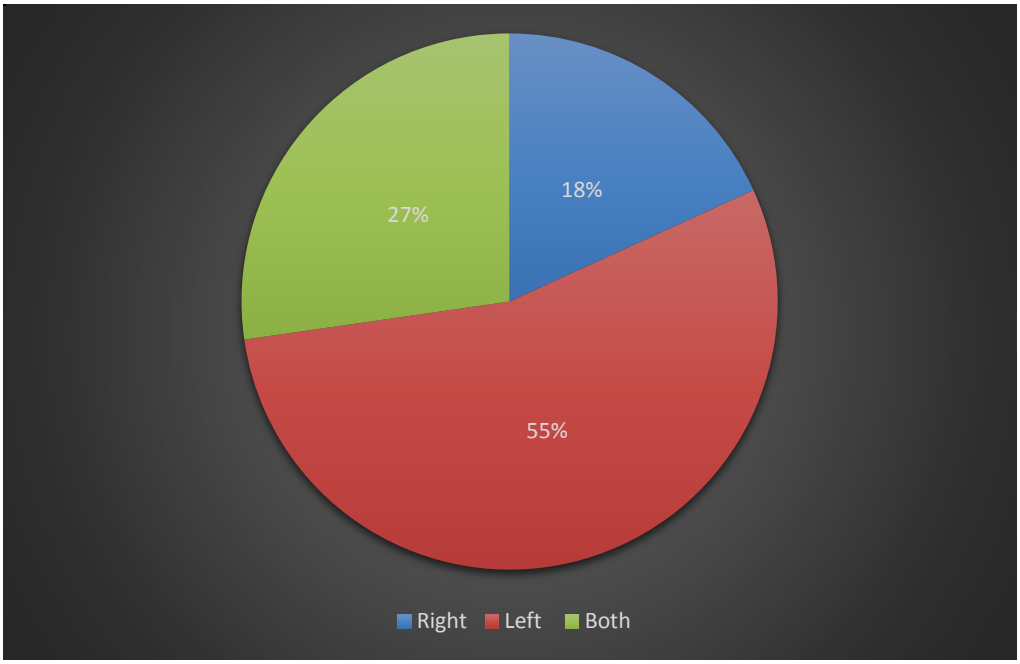
GRAPH 3: GOSLON INDEX ASSESSMENT OF ALL THE SAMPLES



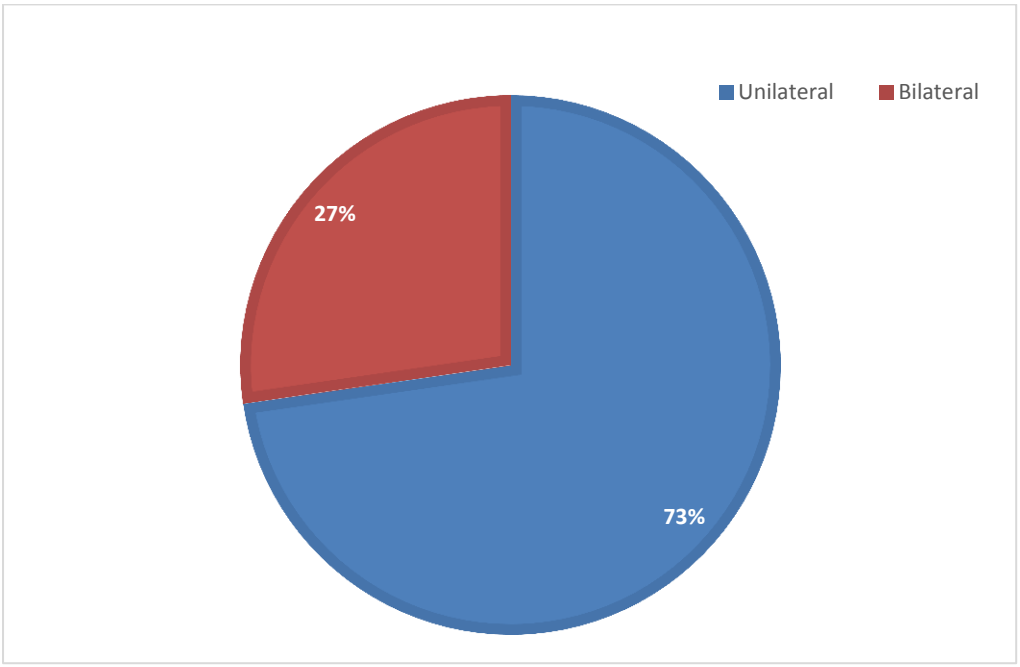
GRAPH 4: SAMPLE GENDER DISTRIBUTION



GRAPH 5: SAMPLE CLEFT SIDE DISTRIBUTION



GRAPH 6: SAMPLE CLEFT REGION DISTRIBUTION



Discussion

DISCUSSION

Cleft lip and palate is the most commonly occuring congenital anamoly of the face.[17] The etiology for cleft lip and cleft palate includes various genetic factors, teratogens and environmental factors. The incidence of cleft lip and palate in India is between 27000 and 30000 clefts per year.[26] Of these, only less than 50 percent of them make themselves available for the treatment. Cleft lip and palate care gets compromised in India because of poor socioeconomic status, low literacy, lack of awareness and non-availability of health care in these areas. Patients frequently reported with unoperated clefts, partially repaired clefts, clefts with severe collapse of maxilla due to repeated surgeries, problems of oro-nasal fistula, severe speech problems.

The clinical examination often reveals facial asymmetry and deviation of nasal septum to the opposite side of the cleft in all patients[42]. The upper lip was averted because of contraction of the scar of lip repair. Much frequently patients present with oro-nasal fistula, thus results in nasal regurgitation of oral fluids. Around the world, many treatment protocols are being followed with regard to timing of the initial and secondary surgeries, technique, treatment modifications, orthodontic intervention, speech considerations, orthognathic surgeries and surgeries to improve speech. The understanding of craniofacial growth of operated and unoperated cleft children along with treatment outcomes from various centres of world practising different

treatment protocols has considerably influenced the overall treatment approach to this problem.

A growth site is merely a location at which growth occurs. Eg: condylar cartilage, sutures. In contrary, Growth centre is a location at which independent (genetically) controlled growth occurs. Eg: Nasal septum, Synchondrosis, Epiphyseal plates of long bones. In addition all growth centres are also growth sites, but the reverse is not true.

It has been seen evidently, that operated cleft patients frequently present with fistulas of varying size and have been associated with problems of impaired craniofacial growth, poor dental arch relationship, severe malocclusion, poor esthetics, nutritional deficiencies, grossly impaired speech and hearing loss of varying degree.[5]

Clinical studies evaluating growth in operated cleft patients are frequently **multi-centered, multi-operator studies**. There is a **lack of scientific study** which evaluates the growth of cleft lip and palate patients who were operated by **same surgeon** employing **standard treatment protocols**. In India, it is not uncommon to find unoperated patients even during adulthood.

In India, we have not yet standardized the treatment protocols amongst various inter disciplinary centres. The present study evaluates the standard of cleft care, complexity of problem and treatment outcomes in cleft children in an Indian scenario. No definite surgical regime is being followed and many

patients were operated in one hospital for cleft lip surgery and subsequently cleft palate surgery has been performed in another hospital[5]. In majority of patients both lip surgery and palatal surgeries were delayed but in our study all the patients were operated for cleft lip and palate surgeries within 2 years of age. In our protocol primary surgical repair lip surgery was done between 3-6 months of age (modified Millard's rotation advancement flap), palate was done at 12-18 months of age (Bardach two flap palatoplasty), pharyngoplasty was done between 4-5 years of age, alveolar bone grafting was done 9-11 years of age, osteotomy and rhinoplasty was done after growth completion.

According to **Noverraz et al (1993)[31]** the Goslon Yardstick is useful for the assessment of dental arch relationship at all stages of dental development and is suitable for longitudinal research.

Mars and Plint et al (1987)[28] reported that there is a close correlation of Goslon grouping and cephalometric values for anteroposterior landmarks on the mandible and maxilla in relation to cranial base. In our study we performed both Goslon grouping and cephalometric evaluation along with real time soft issue evaluation.

Pieter J.P.M. Nollet (2005)[33] et al reported that Goslon Yardstick assessment includes the ranking of casts into one of five categories compared to a standard set of casts reflecting the different categories. The effect of cleft lip and palate surgeries on the inherent growth was evaluated by Goslon index

and the following results were obtained in this study, 45 percent of patients were placed in a favourable excellent group (Group-1), 27.2 percent of patients were placed in a favourable good group (Group-2), 9 percent of patient were placed in a unfavourable very poor group (Group-4) and 18 percent of patient was placed in a unfavourable very poor group (Group-5).

Mars et al (1992)[27] in their study have reported that Cephalographs can be suggested as a means of assessing treatment outcome in patients with cleft lip and palate, but have been found to have limited use, particularly in patients with abnormal anamolies. Some cephalometric landmarks may be difficult to identify in subjects with cleft lip and palate because of the distortion of maxillary skeletal structures. High image quality can reduce these problems, but there is often difficulty in identifying the form of the maxilla and therefore in determining its anteroposterior position. The results of the cephalometric analysis were disappointing, principally because of difficulty in identifying landmarks and in standardizing radiographic equipment and techniques in different centers. To overcome the above mentioned deficiencies in our study we have standardised the lateral cephalographic techniques and equipments.

Maria costanza et al (2008)[25] reported that maxillary growth in operated cleft lip and palate patients is often restricted three-dimensionally. The cause of this growth inhibition is due to congenital hypoplasia of both the

alveolar and the palatal soft and hard tissue due to the lack of migration of mesenchymal and neural crest cells.

Bjork and skieller et al (2014)[37] extensively studied the normal growth of maxillary complex, regarding vertical dimension. They state that the maxilla is relocated downward through appositional growth in the hard palate and the alveolar process. The bony surfaces of the maxilla are selectively resorptive or depository to maintain the general shape of the midface during growth.

Friede et al (2014)[37] reported that the normal mid facial growth also involves displacement of maxilla forward and downward in relation to the vomer. Through various studies of cleft lip and palate patients, the displacement has been documented to occur in the vomeropremaxillary suture and mainly during the first year of life.

Lambrecht et al (2014)[37] reported that the vertical dimension of the maxilla is close to normal in unoperated cleft patients, indicating that surgery is the factor mainly responsible for growth restriction.

Liao et al (2006)[41] reported that the effect of timing of hard palate repair on facial growth in patients with unilateral cleft lip and palate patients still remain controversial. It is unethical to withhold surgery to study the effect of timing of hard palate on facial growth, as speech often gets disturbed after delaying hard palate repair past the age of early speech development.

Bardach et al (2006)[41] reported that the facial growth outcome of operated patients depends on number of factors namely genetic inheritance, gender, age, ethnicity, and the cleft type are all well-known determinants of facial growth. Cases of favourable maxillary growth and dental occlusion after cleft palate repair have strongly suggested the benefit of delaying hard palate repair until adolescence. In our study, palatal surgical repair was performed between 12-18 months.

Ross and Shaw et al (2006)[41] reported that facial growth outcome may also be technique sensitive. There is an increasing belief that the **surgeon's skill** may have a **greater influence on facial growth outcome** than the timing or technique used for primary repair. Thus we are **eliminating the above mentioned bias, as all the cases have been performed by same surgeon**.

Mackay et al (2008)[41] suggested that the soft tissue profile outline may be a useful indicator. However, it is actually a two-dimensional representation of a three-dimensional structure, and there are inherent problems in achieving a standardized and accurate representation of soft tissues. In our study to overcome the above mentioned difficulty, we used real time soft tissue measurements.

The use of dental models, which is a minimally invasive investigation, would seem to offer great scope as an early outcome measure in subjects with

cleft lip and palate. In our study we used a study cast to perform Goslon index for the cleft lip and palate patients.

Pieter J.P.M. Nollet et al (2005)[33] found that the results obtained from the meta-analysis suggest that apart from the timing of palatal surgery, there were no background variables that delayed palatal closure. They further state that delayed palatal closure has better treatment outcome regarding dental arch relationships than early palatal closure. For many years there has been much controversy about the timing of palatal closure. Some investigators advocated early hard palate closure, while others suggested that delayed palatal closure would result in more favourable growth of the maxilla. The timing of independently performed soft palate closures varied from birth to 3 years of age. The timing of independently performed hard palate closure varied from birth to 13 years of age. A disadvantage of late closure of the hard palate could be a negative influence on speech. To prevent this disadvantage, in our study we performed the hard palate and soft palate closure within 2 years of age.

This study documents the status of cleft lip and palate care among unilateral and bilateral cleft lip and palate patients on the basis of scientific data , controls from the normal population, operated by same surgeon , standardised treatment protocols. Our **cephalometric growth evaluation** revealed that **maxillary length does not have any statistically significant difference in operated cleft lip and cleft palate cases**. This further indicates that the **growth of maxilla is not affected by our surgical protocol** which is

in **contrast to the similar studies**. A Goslon index was performed on all 11 samples using diagnostic models which that demonstates 5 samples were found to be in excellent treatment outcome group (Group-1), 3 samples were found to be in good treatment outcome group (group-2). The real time soft tissue measurements showed that (C') (Fig.6) the height of the lower alar groove from the interpupilary line of the cleft side showed significant changes compared to the non-cleft side (C) (Fig.8).

C' = The height of lower alar groove from the interpupilary line in the cleft side.

C = The height of the lower alar groove from the interpupilary line in the non-cleft side.

The **limitations** of our study includes

- Small sample size.
- Wide age distribution.
- Narrow age distribution of very young subjects.
- Mixture of subjects from different cleft types.
- Males and Females grouped together.

Summary and Conclusion

SUMMARY AND CONCLUSION

In this retrospective clinical study the growth of operated cleft lip and palate patients were assessed using standardized Lateral Cephalograph, Goslon Index using study models, Real time soft tissue clinical measurements of naso-maxillary region.

From the results obtained from our study, we conclude that the **growth of maxilla in operated cleft lip and palate patients** using standardized cleft treatment protocols (modified Millard's rotation advancement flap for cleft lip and Bardach two flap palatoplasty for cleft palate) does not show statistically significant reduction.

In addition, we would like to conclude the comparison between C (Fig.8) (the height of the lower alar groove from the interpupilary line of the non-cleft side) and C' (Fig.6) (the height of the lower alar groove from the interpupilary line of cleft side) shows a statistically significant difference, hence forth we would like to state from above mentioned results that C' (Fig.6) (the height of the lower alar groove from the interpupilary line of cleft side) is greater than C (Fig.8) (the height of the lower alar groove from the interpupilary line of the non-cleft side) .

We would also like to conclude that by employing Goslon Index using study models 45 percent of patients were placed in a favourable excellent treatment outcome group (Group 1) (Table 3, Graph 3).

Further clinical studies involving the large sample, assessment of greater clinical parameters should be done to obtain more confirmative results about the evaluation of growth, in operated cleft lip and palate patients.

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Annexure

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TO WHOM SO EVER IT MAY CONCERN

THE THESIS TOPIC **"GROWTH EVALUATION AND TREATMENT OUTCOME OF UNILATERAL AND BILATERAL CLEFT LIP AND CLEFT PALATE PATIENTS - A RETROSPECTIVE STUDY"** SUBMITTED BY **Dr. P. HARIHARAN** HAS BEEN APPROVED BY THE INSTITTUTIONAL REVIEW BOARD OF RAGAS DENTAL COLLEGE AND HOSPITAL ON 5th May 2014.

(Dr.S.RAMACHANDRAN, M.D.S)
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